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Presidential Documents

Title 3—

The President

Presidential Determination No. 2020–06 of June 5, 2020

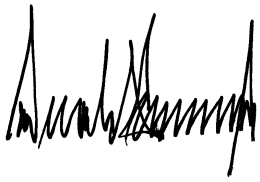
Presidential Determination Pursuant to Section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012

Memorandum for the Secretary of State[,] the Secretary of the Treasury[, and] the Secretary of Energy

By the authority vested in me as President by the Constitution and the laws of the United States, after carefully considering the reports submitted to the Congress by the Energy Information Administration, including the report submitted in April 2020, and other relevant factors, including global economic conditions, increased oil production by certain countries, the global level of spare petroleum production capacity, and the availability of strategic reserves, I determine, pursuant to section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012, Public Law 112–81, and consistent with prior determinations, that there is a sufficient supply of petroleum and petroleum products from countries other than Iran to permit a significant reduction in the volume of petroleum and petroleum products purchased from Iran by or through foreign financial institutions.

I will continue to monitor this situation closely.

The Secretary of State is authorized and directed to publish this determination in the *Federal Register*.



THE WHITE HOUSE,
Washington, June 5, 2020

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Rules and Regulations

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SMALL BUSINESS ADMINISTRATION

13 CFR Part 120

[Docket No. SBA–2020–0037]

RIN 3245–AH51

Business Loan Program Temporary Changes; Paycheck Protection Program—Revisions to the Third and Sixth Interim Final Rules

AGENCY: U.S. Small Business Administration.

ACTION: Interim final rule.

SUMMARY: On April 2, 2020, the U.S. Small Business Administration (SBA) posted on its website an interim final rule relating to the implementation of sections 1102 and 1106 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act or the Act) (published in the **Federal Register** on April 15, 2020). Section 1102 of the Act temporarily adds a new product, titled the ''Paycheck Protection Program,'' to SBA's 7(a) Loan Program. Subsequently, SBA and Treasury issued additional interim final rules implementing the Paycheck Protection Program. On June 5, 2020, the Paycheck Protection Program Flexibility Act of 2020 (Flexibility Act) was signed into law, amending the CARES Act. This interim final rule revises interim final rules posted on SBA's website on April 14, 2020 (published in the **Federal Register** on April 20, 2020) and April 28, 2020 (published in the **Federal Register** on May 4, 2020), by changing provisions to conform to the Flexibility Act. Several of these amendments are retroactive to the date of enactment of the CARES Act, as required by section 3(d) of the Flexibility Act.

DATES:

Effective dates: The provisions in this interim final rule related to loan forgiveness for PPP loans are effective March 27, 2020. The provision in this interim final rule relating to the maturity date of PPP loans is effective June 5, 2020. The remaining provisions in this interim final rule are effective June 16, 2020.

Comment date: Comments must be received on or before July 20, 2020.

ADDRESSES: You may submit comments, identified by number SBA–2020–0037, through the Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

SBA will post all comments on *www.regulations.gov.* If you wish to submit confidential business information (CBI) as defined in the User Notice at *www.regulations.gov,* please send an email to *ppp-ifr@sba.gov.* Highlight the information that you consider to be CBI and explain why you believe SBA should hold this information as confidential. SBA will review the information and make the final determination whether it will publish the information.

FOR FURTHER INFORMATION CONTACT: A Call Center Representative at 833–572–0502, or the local SBA Field Office; the list of offices can be found at *https://www.sba.gov/tools/local-assistance/districtoffices.*

SUPPLEMENTARY INFORMATION:

I. Background Information

On March 13, 2020, President Trump declared the ongoing Coronavirus Disease 2019 (COVID–19) pandemic of sufficient severity and magnitude to warrant an emergency declaration for all states, territories, and the District of Columbia. With the COVID–19 emergency, many small businesses nationwide are experiencing economic hardship as a direct result of the Federal, State, and local public health measures that are being taken to minimize the public's exposure to the virus. These measures, some of which are government-mandated, have been implemented nationwide and include the closures of restaurants, bars, and gyms. In addition, based on the advice of public health officials, other measures, such as keeping a safe distance from others or even stay-at-home orders, have been implemented, resulting in a dramatic decrease in economic activity as the public avoids malls, retail stores, and other businesses.

On March 27, 2020, the President signed the Coronavirus Aid, Relief, and Economic Security Act (the CARES Act or the Act) (Pub. L. 116–136) to provide emergency assistance and health care response for individuals, families, and businesses affected by the coronavirus pandemic. The Small Business Administration (SBA) received funding and authority through the Act to modify existing loan programs and establish a new loan program to assist small businesses nationwide adversely impacted by the COVID–19 emergency.

Section 1102 of the Act temporarily permits SBA to guarantee 100 percent of 7(a) loans under a new program titled the ''Paycheck Protection Program.'' Section 1106 of the Act provides for forgiveness of up to the full principal amount of qualifying loans guaranteed under the Paycheck Protection Program.

On April 24, 2020, the President signed the Paycheck Protection Program and Health Care Enhancement Act (Pub. L. 116–139), which provided additional funding and authority for the PPP. On June 5, 2020, the President signed the Paycheck Protection Program Flexibility Act of 2020 (Flexibility Act) (Pub. L. 116–142), which changes key provisions of the Paycheck Protection Program, including provisions relating to the maturity of PPP loans, the deferral of PPP loan payments, and the forgiveness of PPP loans. Section 3(d) of the Flexibility Act provides that the amendments relating to PPP loan forgiveness and extension of the deferral period for PPP loans shall be effective as if included in the CARES Act, which means that they are retroactive to March 27, 2020. Section 2 of the Flexibility Act provides that the amendment relating to the extension of the maturity date for PPP loans shall take effect on the date of enactment (June 5, 2020). Under the Flexibility Act, the extension of the maturity date for PPP loans is applicable to PPP loans made on or after that date, and lenders and borrowers may mutually agree to modify PPP loans made before such date to reflect the longer maturity.

II. Comments and Retroactive/Immediate Effective Date

This interim final rule is effective without advance notice and public comment because section 1114 of the CARES Act authorizes SBA to issue regulations to implement Title I of the Act without regard to notice requirements. In addition, SBA has determined that there is good cause for dispensing with advance public notice

and comment on the grounds that it would be contrary to the public interest. Specifically, advance public notice and comment would defeat the purpose of this interim final rule given that SBA's authority to guarantee PPP loans expires on June 30, 2020, and that many PPP borrowers can now apply for loan forgiveness following the end of their eight-week covered period. Providing borrowers and lenders with certainty on both loan requirements and loan forgiveness requirements following the enactment of the Flexibility Act will enhance the ability of lenders to make loans and process loan forgiveness applications, particularly in light of the fact that most of the Flexibility Act's provisions are retroactive to March 27, 2020. Specifically, small businesses that have yet to apply for and receive a PPP loan need to be informed of the terms of PPP loans as soon as possible, because the last day on which a lender can obtain an SBA loan number for a PPP loan is June 30, 2020. Borrowers who already have applied for and received a PPP loan need certainty regarding how loan proceeds must be used during the covered period, as amended by the Flexibility Act, so that they can maximize the amount of loan forgiveness. These same reasons provide good cause for SBA to dispense with the 30-day delayed effective date provided in the Administrative Procedure Act. Although this interim final rule is effective on or before date of filing, comments are solicited from interested members of the public on all aspects of the interim final rule, including section III below. These comments must be submitted on or before July 20, 2020. The SBA will consider these comments, comments received on the interim final rules amended by this interim final rule, which were posted on April 14 and April 28, 2020 (and published in the **Federal Register** on April 20, 2020 and May 4, 2020, respectively), and the need for making any revisions as a result of these comments.

III. Paycheck Protection Program—Revisions to Third and Sixth Interim Final Rules

Overview

The CARES Act was enacted to provide immediate assistance to individuals, families, and businesses affected by the COVID–19 emergency. Among the provisions contained in the CARES Act are provisions authorizing SBA to temporarily guarantee loans under a new 7(a) loan program titled the ''Paycheck Protection Program.'' Loans guaranteed under the Paycheck Protection Program (PPP) will be 100 percent guaranteed by SBA, and the full principal amount of the loans may qualify for loan forgiveness. The Flexibility Act amends the CARES Act, including its provisions relating to loan terms and loan forgiveness. The purpose of this interim final rule is to update the Interim Final Rule on Additional Eligibility Criteria and Requirements for Certain Pledges of Loans (Third Interim Final Rule), posted on SBA's website on April 14, 2020 and published in the **Federal Register** on April 20, 2020 (85 FR 21747), and the Interim Final Rule on Disbursements (Sixth Interim Final Rule), posted on SBA's website on April 28, 2020 and published in the **Federal Register** on May 4, 2020 (85 FR 26321), in light of the amendments under the Flexibility Act. The Third Interim Final Rule and the Sixth Interim Final Rule, each as amended by this interim final rule, should be interpreted consistent with the frequently asked questions (FAQs) regarding the PPP that are posted on SBA's website [1] and the other interim final rules issued regarding the PPP.[2]

1. Changes to the Third Interim Final Rule

a. Use of PPP Loan Proceeds

Under section 1102 of the CARES Act, certain provisions regarding the issuance and use of PPP loans are limited to the ''covered period.'' ''Covered period,'' as that term is used in section 1102 of the CARES Act, was originally defined as the period from February 15, 2020, to June 30, 2020. However, section 3(a) of the Flexibility Act extended the ''covered period'' as defined in section 1102 until December 31, 2020. Therefore, Part III.1.d.(iii.) of the Third Interim Final Rule (85 FR 21747, 21749) is revised by striking ''during the eight-week period following the first disbursement of the loan (the ''covered period'')'' and ''during the covered period''.

Section 2(a) of the Flexibility Act provides a minimum maturity of five years for all PPP loans made on or after the date of enactment of the Flexibility Act (June 5, 2020), and permits lenders and borrowers to extend the maturity date of earlier PPP loans by mutual agreement. Therefore, Part III.1.d.v. of the Third Interim Final Rule (85 FR 21747, 21749) is revised by striking ''PPP's maturity of two years'' and replacing it with ''PPP's maturity of two years for PPP loans made before June 5, 2020 unless the borrower and lender mutually agree to extend the maturity of such loans to five years, or PPP's maturity of five years for PPP loans made on or after June 5''.

Section 3(b) of the Flexibility Act amended the requirements regarding forgiveness of PPP loans to reduce, from 75 percent to 60 percent, the portion of PPP loan proceeds that must be used for payroll costs for the full amount of the PPP loan to be eligible for forgiveness. Consistent with this change, SBA's interim final rule posted on June 11, 2020, decreased from 75 percent to 60 percent the portion of loan proceeds that must be used for payroll costs. Therefore, Part III.1.e. of the Third Interim Final Rule (85 FR 21747, 21750) is revised to read as follows:

e. Are there any other restrictions on how I can use PPP loan proceeds?

Yes. At least 60 percent of the PPP loan proceeds shall be used for payroll costs. For purposes of determining the percentage of use of proceeds for payroll costs (but not for forgiveness purposes), the amount of any refinanced EIDL will be included. The rationale for this 60 percent floor is contained in the First PPP Interim Final Rule and SBA's interim final rule posted on June 11, 2020.

b. Loan Forgiveness

Under section 1106 of the CARES Act, certain provisions regarding the forgiveness of PPP loans are limited to the ''covered period.'' ''Covered period,'' as that term is used in section 1106 of the CARES Act, was originally defined as the eight-week period beginning on the date of the origination of a covered loan. However, section 3(b) of the Flexibility Act extended the length of the covered period as defined in section 1106 of the CARES Act from eight to 24 weeks, while allowing borrowers that received PPP loans before June 5, 2020 to elect to use the original eight-week covered period. As noted above, section 3(b) of the Flexibility Act also amended the requirements regarding forgiveness of PPP loans to reduce, from 75 percent to 60 percent, the amount of PPP loan proceeds that must be used for payroll costs for the full amount of the PPP loan to be eligible for forgiveness. Therefore, Part III.1.f. of the Third Interim Final Rule (85 FR 21747, 21750) is revised to read as follows:

f. What amounts shall be eligible for forgiveness?

The amount of loan forgiveness can be up to the full principal amount of the loan plus accrued interest. The actual amount of loan forgiveness will depend, in part, on the total amount spent over the 24-week period

[1] *See https://www.sba.gov/document/support--faq-lenders-borrowers.*

[2] *See https://www.sba.gov/funding-programs/loans/coronavirus-relief-options/paycheck-protection-program.*

beginning on the date your PPP loan is disbursed[3] (''covered period'') on:

i. Payroll costs including salary, wages, and tips, up to $100,000 of annualized pay per employee (for 24 weeks, a maximum of $46,154 per individual,[4] or for eight weeks, a maximum of $15,385 per individual), as well as covered benefits for employees (but not owners), including health care expenses, retirement contributions, and state taxes imposed on employee payroll paid by the employer (such as unemployment insurance premiums);

ii. owner compensation replacement, calculated based on 2019 net profit as described in Paragraph 1.b. above, with forgiveness of such amounts limited to eight weeks' worth (8/52) of 2019 net profit (up to $15,385) for an eight-week covered period or 2.5 months' worth (2.5/12) of 2019 net profit (up to $20,833) for a 24-week covered period, but excluding any qualified sick leave equivalent amount for which a credit is claimed under section 7002 of the Families First Coronavirus Response Act (FFCRA) (Pub. L. 116–127) or qualified family leave equivalent amount for which a credit is claimed under section 7004 of FFCRA;

iii. payments of interest on mortgage obligations on real or personal property incurred before February 15, 2020, to the extent they are deductible on Form 1040 Schedule C (business mortgage payments);

iv. rent payments on lease agreements in force before February 15, 2020, to the extent they are deductible on Form 1040 Schedule C (business rent payments); and

v. utility payments under service agreements dated before February 15, 2020 to the extent they are deductible on Form 1040 Schedule C (business utility payments).

The Administrator, in consultation with the Secretary, has determined that it is appropriate to limit the forgiveness of owner compensation replacement for individuals with self-employment income who file a Schedule C or F to either eight weeks' worth (8/52) of 2019 net profit (up to $15,385) for an eight-week covered period or 2.5 months' worth (2.5/12) of 2019 net profit (up to $20,833) for a 24-week covered period per owner in total across all businesses. This approach is consistent with the structure of the CARES Act and its overarching focus on keeping workers paid, and will prevent windfalls that Congress did not intend. Specifically, Congress determined that the maximum loan amount is generally based on 2.5 months of the borrower's average total monthly payroll costs during the one-year period preceding the loan. 15 U.S.C. 636(a)(36)(E). For example, a borrower with one other employee would receive a maximum loan amount equal to five months of payroll (2.5 months of payroll for the owner plus 2.5 months of payroll for the employee). If the owner laid off the employee and availed itself of the safe harbor in the Flexibility Act from reductions in loan forgiveness for a borrower that is unable to return to the same level of business activity the business was operating at before February 15, 2020, the owner could treat the entire amount of the PPP loan as payroll, with the entire loan being forgiven. This would not only result in a windfall for the owner, by providing the owner with five months of payroll instead of 2.5 months, but also defeat the purpose of the CARES Act of protecting the paycheck of the employee. For borrowers with no employees, this limitation will have no effect, because the maximum loan amount for such borrowers already includes only 2.5 months of their payroll. Finally, at least 60 percent of the amount forgiven must be attributable to payroll costs, for the reasons specified in the First PPP Interim Final Rule and SBA's interim final rule posted on June 11, 2020.

In addition, Part III.1.g. of the Third Interim Final Rule (85 FR 21747, 21750) is revised by striking ''eight-week''.

2. Changes to the Sixth Interim Final Rule

As described above, section 3(b) of the Flexibility Act extended the length of the covered period as defined in section 1106 of the CARES Act from eight to 24 weeks, while allowing borrowers that received PPP loans before June 5, 2020 to elect to use the original eight-week covered period. Therefore, Part III.1.a. of the Sixth Interim Final Rule (85 FR 26321, 26322–23) is revised by striking both references to ''eight-week covered period'' and replacing them with ''covered period''.

3. Additional Information

SBA may provide further guidance, if needed, through SBA notices which will be posted on SBA's website at *www.sba.gov.* Questions on the Paycheck Protection Program may be directed to the Lender Relations Specialist in the local SBA Field Office. The local SBA Field Office may be found at *https://www.sba.gov/tools/local-assistance/districtoffices.*

Compliance With Executive Orders 12866, 12988, 13132, 13563, and 13771, the Paperwork Reduction Act (44 U.S.C. Ch. 35), and the Regulatory Flexibility Act (5 U.S.C. 601–612)

Executive Orders 12866, 13563, and 13771

This interim final rule is economically significant for the purposes of Executive Orders 12866 and 13563, and is considered a major rule under the Congressional Review Act. SBA, however, is proceeding under the emergency provision at Executive Order 12866 Section 6(a)(3)(D) based on the need to move expeditiously to mitigate the current economic conditions arising from the COVID–19 emergency. This rule's designation under Executive Order 13771 will be informed by public comment.

This rule is necessary to implement Sections 1102 and 1106 of the CARES Act and the Flexibility Act in order to provide economic relief to small businesses nationwide adversely impacted under the COVID–19 Emergency Declaration. We anticipate that this rule will result in substantial benefits to small businesses, their employees, and the communities they serve. However, we lack data to estimate the effects of this rule.

Executive Order 12988

SBA has drafted this rule, to the extent practicable, in accordance with the standards set forth in section 3(a) and 3(b)(2) of Executive Order 12988, to minimize litigation, eliminate ambiguity, and reduce burden. The rule has no preemptive effect but does have a limited retroactive effect consistent with section 3(d) of the Flexibility Act.

Executive Order 13132

SBA has determined that this rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various layers of government. Therefore, SBA has determined that this rule has no federalism implications warranting preparation of a federalism assessment.

Paperwork Reduction Act, 44 U.S.C. Chapter 35

SBA has determined that this rule will not modify existing recordkeeping or reporting requirements under the Paperwork Reduction Act.

Regulatory Flexibility Act (RFA)

The Regulatory Flexibility Act (RFA) generally requires that when an agency issues a proposed rule, or a final rule

[3] If your PPP loan was made before June 5, 2020, you may elect to have your covered period be the eight-week period beginning on the date your PPP loan was disbursed. In addition, under section 3(b)(1) of the Paycheck Protection Program Flexibility Act of 2020 (Flexibility Act), the covered period of any borrower will end no later than December 31, 2020.

[4] Given the 2.5 multiplier in the calculation of maximum PPP loan amount in SBA Form 2483, this per-individual maximum would only be reached if the borrower had reduced its FTEs but was eligible for an exemption (safe harbor) from the resulting reduction in forgiveness.

pursuant to section 553(b) of the APA or another law, the agency must prepare a regulatory flexibility analysis that meets the requirements of the RFA and publish such analysis in the **Federal Register**. 5 U.S.C. 603, 604. Specifically, the RFA normally requires agencies to describe the impact of a rulemaking on small entities by providing a regulatory impact analysis. Such analysis must address the consideration of regulatory options that would lessen the economic effect of the rule on small entities. The RFA defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a nonprofit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. 5 U.S.C. 601(3)–(6). Except for such small government jurisdictions, neither State nor local governments are ''small entities.'' Similarly, for purposes of the RFA, individual persons are not small entities.

The requirement to conduct a regulatory impact analysis does not apply if the head of the agency ''certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' 5 U.S.C. 605(b). The agency must, however, publish the certification in the **Federal Register** at the time of publication of the rule, ''along with a statement providing the factual basis for such certification.'' If the agency head has not waived the requirements for a regulatory flexibility analysis in accordance with the RFA's waiver provision, and no other RFA exception applies, the agency must prepare the regulatory flexibility analysis and publish it in the **Federal Register** at the time of promulgation or, if the rule is promulgated in response to an emergency that makes timely compliance impracticable, within 180 days of publication of the final rule. 5 U.S.C. 604(a), 608(b).

Rules that are exempt from notice and comment are also exempt from the RFA requirements, including conducting a regulatory flexibility analysis, when among other things the agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. Small Business Administration's Office of Advocacy guide: *How to Comply with the Regulatory Flexibility Act, Ch.1. p.9.* Accordingly, SBA is not required to conduct a regulatory flexibility analysis.

Authority: 15 U.S.C. 636(a)(36); Paycheck Protection Program Flexibility Act of 2020, Pub. L. 116–142; Coronavirus Aid, Relief, and Economic Security Act, Pub. L. 116–136, Section 1114.

Jovita Carranza,

Administrator.

[FR Doc. 2020–13293 Filed 6–16–20; 4:15 pm]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2019–0683; Project Identifier AD–2020–00149–E; Amendment 39–21149; AD 2020–13–04]

RIN 2120–AA64

Airworthiness Directives; General Electric Company Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2017–09–06 for all General Electric Company (GE) GEnx-1B and GEnx-2B model turbofan engines. AD 2017–09–06 required updating electronic engine control (EEC) full authority digital electronic control (FADEC) software on GEnx-1B and GEnx-2B turbofan engines and replacing a certain fan hub frame assembly part installed on GEnx-2B turbofan engines. This AD requires updating EEC software on GEnx-1B and GEnx-2B engines and replacing a certain fan hub frame assembly part installed on GEnx-2B engines. This AD was prompted by the development of a design change by GE to remove the unsafe condition. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective July 24, 2020.

ADDRESSES: For service information identified in this final rule, contact General Electric Company, GE Aviation, Room 285, 1 Neumann Way, Cincinnati, OH 45215; phone: 513–552–3272; email: *geae.aoc@ge.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call 781–238–7759. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0683.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2019–0683; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7743; fax: (781) 238–7199; email: *Mehdi.Lamnyi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Discussion

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2017–09–06, Amendment 39–18868 (82 FR 21111, May 5, 2017), (''AD 2017–09–06''). AD 2017–09–06 applied to all GE GEnx-1B and GEnx-2B model turbofan engines. The NPRM published in the **Federal Register** on November 19, 2019 (84 FR 63820). The NPRM was prompted by the development of a design change by GE to remove the unsafe condition. The NPRM proposed to require updating EEC FADEC software on GEnx-1B and GEnx-2B model turbofan engines and replacing a certain fan hub frame assembly part installed on GEnx-2B model turbofan engines. The FAA is issuing this AD to address the unsafe condition on these products.

Comments

The FAA gave the public the opportunity to participate in developing this final rule. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Clarify Compliance Time

The Air Line Pilots Association, International (ALPA), commented that it is unclear why the compliance time to remove the affected fan hub stator assembly booster outlet guide vanes (BOGV) of ''before further flight,'' would occur after an independent engine shop visit. ALPA suggested either removal or clarification of the ''before further flight'' compliance time requirement.

This AD supersedes AD 2017–09–06 (82 FR 21111, May 5, 2017), which specified removal of certain fan hub stator assembly BOGV at the next engine shop visit after its effective date (June 9, 2017). This AD retains the requirement

to remove the fan hub stator assembly BOGV at the next engine shop visit after June 9, 2017, the effective date of the superseded AD, but adds the option of compliance ''or before further flight, whichever occurs later.'' This added compliance time option provides operators that have yet to comply with AD 2017–09–06 the option to comply with this AD, averting a situation wherein operators may be in violation of this AD upon its publication.

Request To Extend Compliance Time

American Airlines (American) requested that the compliance time be extended from 120 days to 180 days for removal of the affected EEC software. American noted that there is a concurrent requirement in Boeing Service Bulletin B787–73–0051, Issue 001, dated July 9, 2019, to update the software for the Loadable Diagnostic Information (LDI) on some configurations of B787 model airplanes. American indicated that the EEC software that supersedes version B195 will not properly function without the LDI update on those aircraft. Accomplishment of the LDI update requires an additional three work hours, bringing the total to four work hours, during which the Boeing Service Bulletin (SB) instructs that no other maintenance tasks be performed. American commented that extending the compliance time will allow operators to better accommodate for these requirements for the out of service time.

The FAA disagrees. Based on information received by the FAA, the EEC software, version B200 or later, will provide the Ice Crystals Icing (ICI) mitigation logic regardless of whether the LDI software is installed. The LDI update is not required to address the unsafe condition. The FAA did not change this AD.

Request To Add Terminating Action

American and Japan Airlines (JAL) commented that since this AD is replacing AD 2017–09–06, which includes a terminating action for paragraphs (g) and (i) of AD 2013–24–01 (78 FR 70851; November 27, 2013) (''AD 2013–24–01''), the referenced terminating action should also be included in this AD. American noted that updating the EEC software removes the unsafe icing condition identified in the AD.

The FAA agrees that updating the EEC FADEC software on the affected engines removes the unsafe condition. The FAA disagrees with adding a terminating action to this AD. Since the issuance of FAA AD 2017–09–06, the FAA has approved alternative methods of compliance (AMOCs) to paragraphs (g) and (h) of AD 2013–24–01 for Boeing model 747–8 airplanes, powered by GEnx-1B model engines, and for Boeing model 747–8 and 747–8F airplanes, powered by GEnx-2B model engines. These AMOCs replaced the need for the terminating action previously included in AD 2017–19–06.

Request To Clarify Compliance Language

American commented that previous ADs involving EEC FADEC software have required operators to ''remove [EEC FADEC] software, version B195 or earlier from the engine and from service.'' Previously published ADs also stated, ''. . . do not operate any GE GEnx-1B engine with [EEC FADEC] software version B180 [or B175, for earlier AD] or earlier installed. . . .'' Additionally, American indicated the SBs that replace the B195 software do not require removal of earlier software, just the installation of later software. American requested clarification that the proposed AD only forbids operation of software B195 or earlier, without specifying removal of old software. American noted that specifying removal of the software can cause confusion regarding whether deleting software from the File Server Module is also required.

The FAA agrees. This AD does not need to require removal of the previous version of software that is being updated. The FAA has revised the compliance language in paragraph (g)(1) of this AD to require installation of software that is eligible for installation. The FAA also added a definition to this AD, defining software that is eligible for installation.

Request To Clarify Applicability

JAL noted that paragraph (g)(1) of this AD requires the removal of EEC software, version B195 or earlier, from the engine and from service. JAL asked if ''the engine'' includes the spare engine or if it means the engine installed on the airplane. JAL noted that paragraph (e)(1) of AD 2017–09–06 says ''Thirty days after the effective date of this AD, do no operate any GEnx-1B engine with electronic engine control EEC full authority digital engine control (FADEC) software version B180 or earlier, installed.'' JAL commented that even if the EEC software of the spare engine is a version B180, or earlier, JAL could still install the EEC software, version B185, during engine installation and avoid operating the engine with EEC, software version B180 or earlier. JAL indicated that it believes the intent of this NPRM is to avoid operating the engine on aircraft with EEC software, version B195 or earlier. Therefore, JAL believes the installation of EEC software, version B195, on spare engines or spare EECs is acceptable. JAL requested that the FAA clarify the intent of this AD.

The FAA notes that ADs cannot be enforced until the product is operated. Per 14 CFR 39.7 ''Anyone who operates a product that does not meet the requirements of an applicable airworthiness directive is in violation of this section.'' The intent of this AD is to prevent operation of any affected engine installed on an aircraft with EEC software, version B195 or earlier. The requirements of this AD do not apply to spare engines and spare EECs. Therefore, no change to this AD is needed.

Request To Include Latest Service Information

GE Aviation requested that the FAA include a reference to the Revision 1 of GEnx-2B SB 72–00241 in the Related Service Information section of this AD. GE indicated the latest revision of this SB adds a repair process for the BOGV.

The FAA agrees with adding the SB reference to the Related Service Information section of this AD to include GEnx-2B SB 72–00241 R01, dated July 4, 2019. The FAA is also adding a definition of a part eligible for installation to this AD, which clarifies that the operator may replace the affected BOGV P/N B1316–00720, with a repaired BOGV P/N B1316–06008. The required actions section of this AD mandates removal of the affected BOGV P/N B1316–00720 and replacing it with a part eligible for installation.

Request To Change Definition of Engine Shop Visit

GE Aviation requested the FAA change the definition of an ''engine shop visit'' in paragraph (h) of this AD. GE Aviation stated that accomplishment of a top/bottom case removal procedure should be excluded from the definition to allow for an instance where maintenance is required in the high-pressure compressor module but further extensive flange separation is not required, thus resulting in ability to reduce engine maintenance time. Additionally, GE Aviation stated that this procedure is listed as a shop visit definition exception in GE Service Bulletin 72–0000.

The FAA disagrees. The FAA has not received documentation to support any determination regarding the impact on safety by allowing this exception to the definition of a shop visit.

Support for the AD

United Airlines and the Boeing Company commented that they support the proposed rule.

Conclusion

The FAA reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting this final rule with the changes described previously and minor editorial changes. The FAA determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

The FAA also determined that these changes will not increase the economic burden on any operator or increase the scope of this final rule.

Related Service Information

The FAA reviewed GE GEnx-1B Service Bulletin (SB) 73–0082 R00, dated July 9, 2019, and GE GEnx-2B SB 73–0077 R00, dated October 29, 2018. The service information describes procedures for installation of new EEC software on GEnx-1B and GEnx-2B model turbofan engines. The FAA also reviewed GE GEnx-2B SB 72–0241 R01, dated July 4, 2019. The service information describes removal and installation procedures for the fan hub stator assembly BOGV.

Costs of Compliance

The FAA estimates that this AD affects 110 engines installed on airplanes of U.S. registry. The FAA estimates that 15 engines will require replacement of the fan hub stator assembly BOGV.

The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Install EEC software	1 work-hour × $85 per hour = $85	$0	$85	$9,350
Replace fan hub stator assembly BOGV	60 work-hours × $85 per hours = $5,100	387,800	392,900	5,893,500

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

This AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive 2017–09–06, Amendment 39–18868 (82 FR 21111, May 5, 2017); and

■ b. Adding the following new airworthiness directive (AD):

2020–13–04 General Electric Company: Amendment 39–21149; Docket No. FAA–2019–0683; Project Identifier AD–2020–00149–E.

(a) Effective Date

This AD is effective July 24, 2020.

(b) Affected ADs

This AD replaces AD 2017–09–06, Amendment 39–18868 (82 FR 21111, May 5, 2017).

(c) Applicability

This AD applies to all General Electric Company (GE) GEnx-1B and GEnx-2B model turbofan engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7600, Engine Controls.

(e) Unsafe Condition

This AD was prompted by reports of GEnx-1B and GEnx-2B model turbofan engines experiencing power loss in ice crystal icing conditions. The FAA is issuing this AD to prevent engine failure. The unsafe condition, if not addressed, could result in loss of thrust control and damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) Within 120 days after the effective date of this AD, install electronic engine control (EEC) software that is eligible for installation.

(2) At the next engine shop visit after June 9, 2017 (the effective date of AD 2017–09–06), or before further flight, whichever occurs later, remove from service all GE GEnx-2B67, -2B67B, and -2B67/P fan hub stator assembly booster outlet guide vanes (BOGV), part number (P/N) B1316–00720, and replace with a part eligible for installation.

(h) Definition

(1) For the purpose of this AD, an ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine case flanges, except for the following which do not constitute an engine shop visit:

(i) Separation of engine flanges solely for the purposes of transportation without subsequent maintenance does not constitute an engine shop visit.

(ii) Separation of engine flanges solely for the purpose of replacing the fan or propulsor without subsequent maintenance does not constitute an engine shop visit.

(2) For the purpose of this AD, EEC software that is eligible for installation is:

(i) For GE GEnx-1B model turbofan engines, EEC software that is version B200 or later.

(ii) For GEnx-2B model turbofan engines, EEC software that is version C090 or later.

(3) For the purpose of this AD, a part eligible for installation is a fan hub stator assembly BOGV which:

(i) Is not P/N B1316–00720; or,

(ii) Was previously a P/N B1316–00720, but has been repaired and modified into P/N B1316–07637.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

For more information about this AD, contact Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7743; fax: (781) 238–7199; email: *Mehdi.Lamnyi@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued on June 12, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–13126 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0085; Airspace Docket No. 20–ASO–2]

RIN 2120–AA66

Amendment of Class D Airspace; Jacksonville NAS, FL, and Amendment of Class D and Class E Airspace; Mayport, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule, correction.

SUMMARY: This action corrects a final rule published in the **Federal Register** on June 2, 2020 amending Class D and E airspace for Jacksonville NAS and Mayport, FL. The FAA inserted an effective date of July 16, 2020. The correct date is August 13, 2020.

DATES: Effective 0901 UTC, August 13, 2020. The Director of the Federal Register approves this incorporation by reference action under Title 1 Code of Federal Regulations part 51, subject to the annual revision of FAA Order 7400.11 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: John Fornito, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Ave., College Park, GA 30337; telephone (404) 305–6364.

SUPPLEMENTARY INFORMATION:

History

The FAA published a final rule in the **Federal Register** (85 FR 33536, June 2, 2020) for Doc. No. FAA–2020–0085, amending airspace at Jacksonville NAS, FL and Mayport, FL. Subsequent to publication, the FAA found that the effective date of this action was incorrect. This action corrects the error.

Class D and Class E airspace designations are published in Paragraphs 5000 and 6004, respectively, of FAA Order 7400.11D, dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR part 71.1. The Class D and E airspace designations listed in this document will be published subsequently in the Order.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Correction to Final Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) part 71 by correcting the effective date as follows:

The effective date listed under the DATES header is changed to August 13, 2020.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' paragraph 5–6.5.a. This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, effective September 15, 2019, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ASO FL D Jacksonville NAS, FL [Amended]

Jacksonville NAS (Towers Field), FL

(Lat. 30°14′01″ N, long. 81°40′34″ W)
Jacksonville TACAN
(Lat. 30°14′05″ N, long. 81°40′30″ W)
Herlong Recreational Airport, FL
(Lat. 30°16′40″ N, long. 81°48′21″ W)

That airspace extending upward from the surface of the Earth, to and including 2,600 feet MSL, within a 5.3-mile radius of Jacksonville NAS (Towers Field) and within 1 mile north and 2.5 miles south of the Jacksonville TACAN 270 radial, extending from the 5.3-mile radius to 6.5 miles west of the TACAN; excluding that airspace within a 1.8-mile radius of the Herlong Recreational Airport.

ASO FL D Mayport, FL [Amended]

Mayport NS (ADM David L McDonald Field), FL
(Lat. 30°23′29″ N, long. 81°25′28″ W)
Jax Executive Airport at Craig
(Lat. 30°20′11″ N, long. 81°30′52″ W)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.2-mile radius of Mayport NS (ADM David L McDonald Field), excluding the portion southwest of a line connecting the two points of intersection with a 4.2-mile radius circle centered on Jacksonville Executive Airport at Craig. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Paragraph 6004 Class E Airspace Designated as an Extension to Class D or E Surface Area.

* * * * *

ASO FL E4 Mayport, FL [Amended]

Mayport NS (ADM David L McDonald Field), FL
(Lat. 30°23′29″ N, long. 81°25′28″ W)
Mayport (Navy) TACAN
(Lat. 30°23′19″ N, long. 81°25′23″ W)

That airspace extending upward from the surface within 3.2-miles each side of the Mayport (Navy) TACAN 035° radial extending from the 4.2-mile radius of Mayport NS (ADM David L McDonald Field) to 5 miles northeast of the TACAN. This Class E airspace is effective during the dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

Issued in College Park, Georgia, on June 12, 2020.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2020–13134 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

28 CFR Part 85

[Docket No. OAG 168; AG Order No. 4693–2020]

Civil Monetary Penalties Inflation Adjustment

AGENCY: Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice is adjusting for inflation the civil monetary penalties assessed or enforced by components of the Department, in accordance with the provisions of the Bipartisan Budget Act of 2015, for penalties assessed after June 19, 2020 with respect to violations occurring after November 2, 2015.

DATES: This rule is effective June 19, 2020.

FOR FURTHER INFORMATION CONTACT: Robert Hinchman, Senior Counsel, Office of Legal Policy, U.S. Department of Justice, Room 4252 RFK Building, 950 Pennsylvania Avenue NW, Washington, DC 20530, telephone (202) 514–8059 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Statutory Process for Implementing Annual Inflation Adjustments

Section 701 of the Bipartisan Budget Act of 2015, Public Law 114–74 (Nov. 2, 2015) (''BBA''), 28 U.S.C. 2461 note, substantially revised the prior provisions of the Federal Civil Monetary Penalties Inflation Adjustment Act of 1990, Public Law 101–410 (the ''Inflation Adjustment Act''), and substituted a different statutory formula for calculating inflation adjustments on an annual basis.

In accordance with the provisions of the BBA, on June 30, 2016 (81 FR 42491), the Department of Justice published an interim rule (''June 2016 interim rule'') to adjust for inflation the civil monetary penalties assessed or enforced by components of the Department after August 1, 2016, with respect to violations occurring after November 2, 2015, the date of enactment of the BBA. Readers may refer to the **SUPPLEMENTARY INFORMATION** (also known as the preamble) of the Department's June 2016 interim rule for additional background information regarding the statutory authority for adjustments of civil monetary penalty amounts to take account of inflation and the Department's past implementation of inflation adjustments. The June 2016 interim rule was finalized without change by the publication of a final rule on April 5, 2019 (84 FR 13520).

After the initial adjustments in 2016, the BBA also provides for agencies to adjust their civil penalties on January 15 of each year to account for inflation during the preceding year, rounded to the nearest dollar. Accordingly, on February 3, 2017 (82 FR 9131), and on January 29, 2018 (83 FR 3944), the Department published final rules pursuant to the BBA to make annual inflation adjustments in the civil monetary penalties assessed or enforced by components of the Department after those dates, with respect to violations occurring after November 2, 2015. The Department did not publish such a rule in 2019, thereby leaving in place the civil monetary penalties as adjusted by the 2018 final rule.

II. Inflation Adjustments Made by This Rule

As required, the Department is publishing this final rule to adjust for 2020 the civil penalties that were most recently adjusted as of January 29, 2018. Under the statutory formula, the adjustments made by this rule are based on the Bureau of Labor Statistics' Consumer Price Index for October 2019. The OMB Memorandum for the Heads of Executive Departments and Agencies M–20–05 (Dec 16, 2019), *https://www.whitehouse.gov/wp-content/uploads/2019/12/M-20-05.pdf* (last visited January 10, 2020), instructs that the applicable inflation factor is 1.01764. For the previous year, the OMB Memorandum for the Heads of Executive Departments and Agencies M–19–04 (Dec. 14, 2018), *https://www.whitehouse.gov/wp-content/uploads/2017/11/m_19_04.pdf* (last visited November 21, 2019), instructs that the applicable inflation factor was 1.02522.

Because the Department did not publish civil penalty amounts adjusted for inflation in 2019, this rule adjusts the civil penalty amounts in 28 CFR 85.5 by first applying the 2018 inflation factor and then applying the 2019 inflation factor mechanically to each of the civil penalty amounts listed (rounded to the nearest dollar).

Example

- In 2016, the Program Fraud Civil Remedies Act penalty was increased to $10,781 in accordance with the adjustment requirements of the BBA.
- For 2017, where the applicable inflation factor was 1.01636, the existing penalty of $10,781 was multiplied by 1.01636 and revised to $10,957 (rounded to the nearest dollar).
- For 2018, where the applicable inflation factor is 1.02041, the existing penalty of $10,957 was multiplied by

1.02041 and revised to $11,181 (rounded to the nearest dollar).

• For this final rule in 2020, where the applicable inflation factor in 2018 was 1.02522 and the current applicable inflation factor is 1.01764, the existing penalty of $11,181 is multiplied by 1.02522 and 1.01764 and revised to $11,665 (rounded to the nearest dollar).

This rule adjusts for inflation civil monetary penalties within the jurisdiction of the Department of Justice for purposes of the Inflation Adjustment Act, as amended. Other agencies are responsible for the inflation adjustments of certain other civil monetary penalties that the Department's litigating components bring suit to collect. The reader should consult the regulations of those other agencies for inflation adjustments to those penalties.

III. Effective Date of Adjusted Civil Penalty Amounts

Under this rule, the adjusted civil penalty amounts are applicable only to civil penalties assessed after June 19, 2020, with respect to violations occurring after November 2, 2015, the date of enactment of the BBA.

The penalty amounts set forth in the existing table in 28 CFR 85.5 are applicable to civil penalties assessed after August 1, 2016, and on or before the effective date of this rule, with respect to violations occurring after November 2, 2015. Civil penalties for violations occurring on or before November 2, 2015, and assessments made on or before August 1, 2016, will continue to be subject to the civil monetary penalty amounts set forth in the Department's regulations in 28 CFR parts 20, 22, 36, 68, 71, 76, and 85 as such regulations were in effect prior to August 1, 2016 (or as set forth by statute if the amount had not yet been adjusted by regulation prior to August 1, 2016).

This rule also contains inflation adjustments for two penalties which were enacted by the SUPPORT for Patients and Communities Act, Public Law 115–271 (Oct. 24, 2018), subsequent to publication of the Department's 2018 civil monetary penalty inflation adjustment rule.

IV. Statutory and Regulatory Analyses

A. Administrative Procedure Act

The BBA provides that, for each annual adjustment made after the initial adjustments of civil penalties in 2016, the head of an agency shall adjust the civil monetary penalties each year notwithstanding 5 U.S.C. 553. Accordingly, this rule is being issued as a final rule without prior notice and public comment, and without a delayed effective date.

B. Regulatory Flexibility Act

Only those entities that are determined to have violated Federal law and regulations would be affected by the increase in the civil penalty amounts made by this rule. A Regulatory Flexibility Act analysis is not required for this rule because publication of a notice of proposed rulemaking was not required. *See* 5 U.S.C. 603(a).

C. Executive Orders 12866 and 13563—Regulatory Review

This final rule has been drafted in accordance with Executive Order 12866, ''Regulatory Planning and Review,'' section 1(b), The Principles of Regulation, and in accordance with Executive Order 13563, ''Improving Regulation and Regulatory Review,'' section 1, General Principles of Regulation. Executive Orders 12866 and 13563 direct agencies, in certain circumstances, to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).

The Department of Justice has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' section 3(f), and, accordingly, this rule has not been reviewed by the Office of Management and Budget. This final rule implements the BBA by making an across-the-board adjustment of the civil penalty amounts in 28 CFR 85.5 to account for inflation since the adoption of the Department's final rule published on January 29, 2018.

D. Executive Order 13132—Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

E. Executive Order 12988—Civil Justice Reform

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988.

F. Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

G. Congressional Review Act

This rule is not a major rule as defined by the Congressional Review Act, 5 U.S.C. 804. It will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.

List of Subjects in 28 CFR Part 85

Administrative practice and procedure, Penalties.

Accordingly, for the reasons set forth in the preamble, chapter I of Title 28 of the Code of Federal Regulations is amended as follows:

PART 85—CIVIL MONETARY PENALTIES INFLATION ADJUSTMENT

■ 1. The authority citation for part 85 continues to read as follows:

Authority: 5 U.S.C. 301, 28 U.S.C. 503; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 104–134, 110 Stat. 1321; Pub. L. 114–74, section 701, 28 U.S.C. 2461 note.

■ 2. Revise § 85.5 to read as follows:

§ 85.5 Adjustments to penalties for violations occurring after November 2, 2015.

For civil penalties assessed after June 19, 2020, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are adjusted as set forth in the seventh column of the following table. For civil penalties assessed after January 29, 2018, and on or before June 19, 2020, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are those set forth in the sixth column of table 1 to this section. For civil penalties assessed after February 3, 2017, and on or before

January 29, 2018, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are those set forth in the fifth column of table 1 to this section. For civil penalties assessed after August 1, 2016, and on or before February 3, 2017, whose associated violations occurred after November 2, 2015, the civil monetary penalties provided by law within the jurisdiction of the Department are those set forth in the fourth column of table 1 to this section. All figures set forth in this table are maximum penalties, unless otherwise indicated.

TABLE 1 TO § 85.5

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 8/1/16 ($)	DOJ penalty assessed after 2/3/17 ($)	DOJ penalty assessed after 1/29/2018 ($) [1]	DOJ penalty assessed after June 19, 2020 ($) [2]
ATF						
18 U.S.C. 922(t)(5)	Brady Law—Nat'l Instant Criminal Check System; Transfer of firearm without checking NICS.		8,162	8,296	8,465	8,831.
18 U.S.C. 924(p)	Child Safety Lock Act; Secure gun storage or safety device, violation.		2,985	3,034	3,096	3,230.
Civil Division						
12 U.S.C. 1833a(b)(1)	Financial Institutions Reform, Recovery, and Enforcement Act (FIRREA) Violation.	28 CFR 85.3(a)(6)	1,893,610	1,924,589	1,963,870	2,048,915.
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing) (per day).	28 CFR 85.3(a)(7)	1,893,610	1,924,589	1,963,870	2,048,915.
12 U.S.C. 1833a(b)(2)	FIRREA Violation (continuing).	28 CFR 85.3(a)(7)	9,468,050	9,622,947	9,819,351	10,244,577.
22 U.S.C. 2399b(a)(3)(A)	Foreign Assistance Act; Fraudulent Claim for Assistance (per act).	28 CFR 85.3(a)(8)	5,500	5,590	5,704	5,951.
31 U.S.C. 3729(a)	False Claims Act; [3] Violations.	28 CFR 85.3(a)(9)	Min 10,781, Max 21,563.	Min 10,957, Max 21,916.	Min 11,181, Max 22,363.	Min 11,665, Max 23,331.
31 U.S.C. 3802(a)(1)	Program Fraud Civil Remedies Act; Violations Involving False Claim (per claim).	28 CFR 71.3(a)	10,781	10,957	11,181	11,665.
31 U.S.C. 3802(a)(2)	Program Fraud Civil Remedies Act; Violation Involving False Statement (per statement).	28 CFR 71.3(f)	10,781	10,957	11,181	11,665.
40 U.S.C. 123(a)(1)(A)	Federal Property and Administrative Services Act; Violation Involving Surplus Government Property (per act).	28 CFR 85.3(a)(12)	5,500	5,590	5,704	5,951.
41 U.S.C. 8706(a)(1)(B)	Anti-Kickback Act; Violation Involving Kickbacks [4] (per occurrence).	28 CFR 85.3(a)(13)	21,563	21,916	22,363	23,331.
18 U.S.C. 2723(b)	Driver's Privacy Protection Act of 1994; Prohibition on Release and Use of Certain Personal Information from State Motor Vehicle Records—Substantial Non-compliance (per day).		7,954	8,084	8,249	8,606.
18 U.S.C. 216(b)	Ethics Reform Act of 1989; Penalties for Conflict of Interest Crimes [5] (per violation).	28 CFR 85.3(c)	94,681	96,230	98,194	102,446.

TABLE 1 TO § 85.5—Continued

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 8/1/16 ($)	DOJ penalty assessed after 2/3/17 ($)	DOJ penalty assessed after 1/29/2018 ($) [1]	DOJ penalty assessed after June 19, 2020 ($) [2]
41 U.S.C. 2105(b)(1)	Office of Federal Procurement Policy Act; [6] Violation by an individual (per violation).		98,935	100,554	102,606	107,050.
41 U.S.C. 2105(b)(2)	Office of Federal Procurement Policy Act; [6] Violation by an organization (per violation).		989,345	1,005,531	1,026,054	1,070,487.
42 U.S.C. 5157(d)	Disaster Relief Act of 1974; [7] Violation (per violation).		12,500	12,705	12,964	13,525.
Civil Rights Division (excluding immigration-related penalties)						
18 U.S.C. 248(c)(2)(B)(i)	Freedom of Access to Clinic Entrances Act of 1994 (''FACE Act''); Nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(1)(i)	15,909	16,169	16,499	17,161.
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(1)(ii)	23,863	24,253	24,748	25,820.
18 U.S.C. 248(c)(2)(B)(i)	FACE Act; Violation other than a nonviolent physical obstruction, first violation.	28 CFR 85.3(b)(2)(i)	23,863	24,253	24,748	25,820.
18 U.S.C. 248(c)(2)(B)(ii)	FACE Act; Violation other than a nonviolent physical obstruction, subsequent violation.	28 CFR 85.3(b)(2)(ii)	39,772	40,423	41,248	43,034.
42 U.S.C. 3614(d)(1)(C)(i)	Fair Housing Act of 1968; first violation.	28 CFR 85.3(b)(3)(i)	98,935	100,554	102,606	107,050.
42 U.S.C. 3614(d)(1)(C)(ii)	Fair Housing Act of 1968; subsequent violation.	28 CFR 85.3(b)(3)(ii)	197,869	201,106	205,211	214,097.
42 U.S.C. 12188(b)(2)(C)(i).	Americans With Disabilities Act; Public accommodations for individuals with disabilities, first violation.	28 CFR 36.504(a)(3)(i).	89,078	90,535	92,383	96,384.
42 U.S.C. 12188(b)(2)(C)(ii).	Americans With Disabilities Act; Public accommodations for individuals with disabilities, subsequent violation.	28 CFR 36.504(a)(3)(ii).	178,156	181,071	184,767	192,768.
50 U.S.C. 4041(b)(3)	Servicemembers Civil Relief Act of 2003; first violation.	28 CFR 85.3(b)(4)(i)	59,810	60,788	62,029	64,715.
50 U.S.C. 4041(b)(3)	Servicemembers Civil Relief Act of 2003; subsequent violation.	28 CFR 85.3(b)(4)(ii)	119,620	121,577	124,058	129,431.
Criminal Division						
18 U.S.C. 983(h)(1)	Civil Asset Forfeiture Reform Act of 2000; Penalty for Frivolous Assertion of Claim.		Min 342, Max 6,834	Min 348, Max 6,946	Min 355, Max 7,088	Min 370, Max 7,395.
18 U.S.C. 1956(b)	Money Laundering Control Act of 1986; Violation [8].		21,563	21,916	22,363	23,331.

TABLE 1 TO § 85.5—Continued

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 8/1/16 ($)	DOJ penalty assessed after 2/3/17 ($)	DOJ penalty assessed after 1/29/2018 ($) [1]	DOJ penalty assessed after June 19, 2020 ($) [2]
			DEA			
21 U.S.C. 844a(a)	Anti-Drug Abuse Act of 1988; Possession of small amounts of controlled substances (per violation).	28 CFR 76.3(a)	19,787	20,111	20,521	21,410.
21 U.S.C. 961(1)	Controlled Substance Import Export Act; Drug abuse, import or export.	28 CFR 85.3(d)	68,750	69,875	71,301	74,388.
21 U.S.C. 842(c)(1)(A)	Controlled Substances Act (''CSA''); Violations of 842(a)—other than (5), (10), (16), and (17) —Prohibited acts re: controlled substances (per violation).		62,500	63,523	64,820	67,627.
21 U.S.C. 842(c)(1)(B)(i)	CSA; Violations of 842(a)(5), (10), and (17)—Prohibited acts re: controlled substances.		14,502	14,739	15,040	15,691.
21 U.S.C. 842(c)(1)(B)(ii)	SUPPORT for Patients and Communities Act; Violations of 842(b)(ii)—Failures re: opioids.				100,000 (Statutory amount of new penalty enacted 10/24/18) [11].	101,764.
21 U.S.C. 842(c)(1)(C)	CSA; Violation of 825(e) by importer, exporter, manufacturer, or distributor—False labeling of anabolic steroids (per violation).		500,855	509,049	519,439	541,933.
21 U.S.C. 842(c)(1)(D)	CSA; Violation of 825(e) at the retail level—False labeling of anabolic steroids (per violation).		1,002	1,018	1,039	1,084.
21 U.S.C. 842(c)(2)(C)	CSA; Violation of 842(a)(11) by a business—Distribution of laboratory supply with reckless disregard [9].		375,613	381,758	389,550	406,419.
21 U.S.C. 842(c)(2)(D)	SUPPORT for Patients and Communities Act; Violations of 842(a)(5), (10), and (17) by a registered manufacture or distributor of opioids. Failures re: opioids.				500,000 (Statutory amount of new penalty enacted 10/24/18) [11].	508,820.
21 U.S.C. 856(d)	Illicit Drug Anti-Proliferation Act of 2003; Maintaining drug-involved premises [10].		321,403	326,661	333,328	374,763.

TABLE 1 TO § 85.5—Continued

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 8/1/16 ($)	DOJ penalty assessed after 2/3/17 ($)	DOJ penalty assessed after 1/29/2018 ($) [1]	DOJ penalty assessed after June 19, 2020 ($) [2]
Immigration-Related Penalties						
8 U.S.C. 1324a(e)(4)(A)(i)	Immigration Reform and Control Act of 1986 ("IRCA"); Unlawful employment of aliens, first order (per unauthorized alien).	28 CFR 68.52(c)(1)(i).	Min 539, Max 4,313	Min 548, Max 4,384	Min 559, Max 4,473	Min 583, Max 4,667.
8 U.S.C. 1324a(e)(4)(A)(ii)	IRCA; Unlawful employment of aliens, second order (per such alien).	28 CFR 68.52(c)(1)(ii).	Min 4,313, Max 10,781.	Min 4,384, Max 10,957.	Min 4,473, Max 11,181.	Min 4,667, Max 11,665.
8 U.S.C. 1324a(e)(4)(A)(iii)	IRCA; Unlawful employment of aliens, subsequent order (per such alien).	28 CFR 68.52(c)(1)(iii).	Min 6,469, Max 21,563.	Min 6,575, Max 21,916.	Min 6,709, Max 22,363.	Min 6,999, Max 23,331.
8 U.S.C. 1324a(e)(5)	IRCA; Paperwork violation (per relevant individual).	28 CFR 68.52(c)(5)	Min 216, Max 2,156	Min 220, Max 2,191	Min 224, Max 2,236	Min 234, Max 2,332.
8 U.S.C. 1324a, (note)	IRCA; Violation relating to participating employer's failure to notify of final nonconfirmation of employee's employment eligibility (per relevant individual).	28 CFR 68.52(c)(6)	Min 751, Max 1,502	Min 763, Max 1,527	Min 779, Max 1,558	Min 813, Max 1,625.
8 U.S.C. 1324a(g)(2)	IRCA; Violation/prohibition of indemnity bonds (per violation).	28 CFR 68.52(c)(7)	2,156	2,191	2,236	2,332.
8 U.S.C. 1324b(g)(2)(B)(iv)(I).	IRCA; Unfair immigration-related employment practices, first order (per individual discriminated against).	28 CFR 68.52(d)(1)(viii).	Min 445, Max 3,563	Min 452, Max 3,621	Min 461, Max 3,695	Min 481, Max 3,855.
8 U.S.C. 1324b(g)(2)(B)(iv)(II).	IRCA; Unfair immigration-related employment practices, second order (per individual discriminated against).	28 CFR 68.52(d)(1)(ix).	Min 3,563, Max 8,908.	Min 3,621, Max 9,054.	Min 3,695, Max 9,239.	Min 3,855, Max 9,639.
8 U.S.C. 1324b(g)(2)(B)(iv)(III).	IRCA; Unfair immigration-related employment practices, subsequent order (per individual discriminated against).	28 CFR 68.52(d)(1)(x).	Min 5,345, Max 17,816.	Min 5,432, Max 18,107.	Min 5,543, Max 18,477.	Min 5,783, Max 19,277.
8 U.S.C. 1324b(g)(2)(B)(iv)(IV).	IRCA; Unfair immigration-related employment practices, unfair documentary practices (per individual discriminated against).	28 CFR 68.52(d)(1)(xii).	Min 178, Max 1,782	Min 181, Max 1,811	Min 185, Max 1,848	Min 193, Max 1,928.
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(i).	Min 445, Max 3,563	Min 452, Max 3,621	Min 461, Max 3,695	Min 481, Max 3,855.
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(1)–(4) (per document).	28 CFR 68.52(e)(1)(iii).	Min 3,563, Max 8,908.	Min 3,621, Max 9,054.	Min 3,695, Max 9,239.	Min 3,855, Max 9,639.

TABLE 1 TO § 85.5—Continued

U.S.C. citation	Name/description	CFR citation	DOJ penalty assessed after 8/1/16 ($)	DOJ penalty assessed after 2/3/17 ($)	DOJ penalty assessed after 1/29/2018 ($) [1]	DOJ penalty assessed after June 19, 2020 ($) [2]
8 U.S.C. 1324c(d)(3)(A)	IRCA; Document fraud, first order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(ii).	Min 376, Max 3,005	Min 382, Max 3,054	Min 390, Max 3,116	Min 407, Max 3,251.
8 U.S.C. 1324c(d)(3)(B)	IRCA; Document fraud, subsequent order—for violations described in U.S.C. 1324c(a)(5)–(6) (per document).	28 CFR 68.52(e)(1)(iv).	Min 3,005, Max 7,512.	Min 3,054, Max 7,635.	Min 3,116, Max 7,791.	Min 3,251, Max 8,128.
FBI						
49 U.S.C. 30505(a)	National Motor Vehicle Title Identification System; Violation (per violation).		1,591	1,617	1,650	1,722.
Office of Justice Programs						
34 U.S.C. 10231(d)	Confidentiality of information; State and Local Criminal History Record Information Systems—Right to Privacy Violation.	28 CFR 20.25	27,500	27,950	28,520	29,755.

[1] The figures set forth in this column represent the penalty as last adjusted by Department of Justice regulation on January 29, 2018.

[2] All figures set forth in this table are maximum penalties, unless otherwise indicated.

[3] Section 3729(a)(1) of Title 31 provides that any person who violates this section is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C. 3729(a)(1) (2015). Section 3729(a)(2) permits the court to reduce the damages under certain circumstances to not less than 2 times the amount of damages which the Government sustains because of the act of that person. *Id.* section 3729(a)(2). The adjustment made by this regulation is only applicable to the specific statutory penalty amounts stated in subsection (a)(1), which is only one component of the civil penalty imposed under section 3729(a)(1).

[4] Section 8706(a)(1) of Title 41 provides that the Federal Government in a civil action may recover from a person that knowingly engages in conduct prohibited by section 8702 of Title 44 a civil penalty equal to twice the amount of each kickback involved in the violation and not more than $10,000 for each occurrence of prohibited conduct. 41 U.S.C. 8706(a)(1) (2015). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (a)(1)(B), which is only one component of the civil penalty imposed under section 8706.

[5] Section 216(b) of Title 18 provides that the civil penalty should be no more than $50,000 for each violation or the amount of compensation which the person received or offered for the prohibited conduct, whichever amount is greater. 18 U.S.C. 216(b) (2015). Therefore, the adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b), which is only one aspect of the possible civil penalty imposed under section 216(b).

[6] Section 2105(b) of Title 41 provides that the Attorney General may bring a civil action in an appropriate district court of the United States against a person that engages in conduct that violates section 2102, 2103, or 2104 of Title 41. 41 U.S.C. 2105(b) (2015). Section 2105(b) further provides that on proof of that conduct by a preponderance of the evidence, an individual is liable to the Federal Government for a civil penalty of not more than $50,000 for each violation plus twice the amount of compensation that the individual received or offered for the prohibited conduct, and an organization is liable to the Federal Government for a civil penalty of not more than $500,000 for each violation plus twice the amount of compensation that the organization received or offered for the prohibited conduct. *Id.* section 2105(b). The adjustments made by this regulation are only applicable to the specific statutory penalty amounts stated in subsections (b)(1) and (b)(2), which are each only one component of the civil penalties imposed under sections 2105(b)(1) and (b)(2).

[7] The Attorney General has authority to bring a civil action when a person has violated or is about to violate a provision under this statute. 42 U.S.C. 5157(b) (2015). The Federal Emergency Management Agency has promulgated regulations regarding this statute and has adjusted the penalty in its regulation. 44 CFR 206.14(d) (2015). The Department of Health and Human Services (HHS) has also promulgated a regulation regarding the penalty under this statute. 42 CFR 38.8 (2015).

[8] Section 1956(b)(1) of Title 18 provides that whoever conducts or attempts to conduct a transaction described in subsection (a)(1) or (a)(3), or section 1957, or a transportation, transmission, or transfer described in subsection (a)(2), is liable to the United States for a civil penalty of not more than the greater of the value of the property, funds, or monetary instruments involved in the transaction; or $10,000. 18 U.S.C. 1956(b)(1) (2015). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (b)(1)(B), which is only one aspect of the possible civil penalty imposed under section 1956(b).

[9] Section 842(c)(2)(C) of Title 21 provides that in addition to the penalties set forth elsewhere in the subchapter or subchapter II of the chapter, any business that violates paragraph (11) of subsection (a) of the section shall, with respect to the first such violation, be subject to a civil penalty of not more than $250,000, but shall not be subject to criminal penalties under the section, and shall, for any succeeding violation, be subject to a civil fine of not more than $250,000 or double the last previously imposed penalty, whichever is greater. 21 U.S.C. 842(c)(2)(C) (2015). The adjustment made by this regulation regarding the penalty for a succeeding violation is only applicable to the specific statutory penalty amount stated in subsection (c)(2)(C), which is only one aspect of the possible civil penalty for a succeeding violation imposed under section 842(c)(2)(C).

[10] Section 856(d)(1) of Title 21 provides that any person who violates subsection (a) of the section shall be subject to a civil penalty of not more than the greater of $250,000; or 2 times the gross receipts, either known or estimated, that were derived from each violation that is attributable to the person. 21 U.S.C. 856(d)(1) (2015). The adjustment made by this regulation is only applicable to the specific statutory penalty amount stated in subsection (d)(1)(A), which is only one aspect of the possible civil penalty imposed under section 856(d)(1).

[11] The SUPPORT for Patients and Communities Act, Public Law 115–271, was enacted October 24, 2018.

Dated: May 13, 2020.

William P. Barr,

Attorney General.

[FR Doc. 2020–10905 Filed 6–18–20; 8:45 am]

BILLING CODE 4410–19–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2020–0039]

RIN 1625–AA00

Safety Zone; Illinois River, Miles 10 to 187, Grafton, IL to Peoria, IL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the Illinois River from mile marker (MM) 10 to MM 187 between Grafton, IL and Peoria, IL. This action is necessary to provide for the safety of persons, vessels, and the marine environment on these navigable waters as a result of increasing flood conditions on the river that threaten to overtop levees. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative.

DATES: This rule is effective without actual notice from June 19, 2020 through June 20, 2020. For the purposes of enforcement, actual notice will be used from May 21, 2020 through June 19, 2020.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2020–0039 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notice of enforcement, call or email Chief Warrant Officer 4 Eric Kvistad, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2575, email *Eric.A.Kvistad@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. Actual notice is impracticable because of the unpredictable martime environmental conditions. Delaying this safety zone would be contrary to waterway users best interest because of the amount of danger and risk associated with high water. It is impracticable because we must establish this safety zone immediately and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing this rule. The NPRM process would delay the establishment of the safety zone and compromise public safety.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to public interest because immediate action is necessary to respond to the potential safety hazards associated with floodwaters threatening to overtop levees along the river.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP has determined that potential hazards associated with flood waters threaten to overtop levees along the river due to reports that vessel traffic in the affected area is causing water to overtop levees resulting in increased damage to the levees and flooding impacts to local communities and residential areas. This rule is necessary to ensure the safety of persons, vessels, and the marine environment on these navigable waters due to the flood impacts to USACE levees.

IV. Discussion of the Rule

The COTP has determined that the sudden increase in flood waters approaching the tops of levees along the Illinois River poses a hazard to the safety of persons, vessels, the marine environment, and the structural stability of the levees as a result of floodwaters overtopping the levees. This rule establishes a temporary safety zone from May 21, 2020 until June 20, 2020, or until cancelled by the COTP, whichever occurs first. The safety zone will cover all navigable waters of the Illinois River from MM 10 to MM 187, unless reduced in scope by the COTP as flood conditions warrant.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size of the safety zone as flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs), as appropriate.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has

not been reviewed by the Office of Management and Budget (OMB), and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771.

This regulatory action determination is based on the emergency nature of the action. Moreover, the Coast Guard will issue a BNM via VHF–FM marine channel 16 about the zone, and the rule allows vessels to seek permission to enter the zone on a case-by-case basis to minimize the impacts of this rule.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone prohibiting entry on a one hundred eighty one mile stretch of the Illinois River that is experiencing significant flooding that is impacting levees. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 01. Because this regulation is for a temporary safety zone established to deal with an emergency, and which is longer than one week in duration, a Record of Environmental Consideration is not required at this time, but will be made available in the Docket after the issuance of this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0171 to read as follows:

§ 165.T08–0171 Safety Zone; Illinois River, Miles 0–187, Grafton, IL to Peoria, IL.

(a) *Location.* The following area is a safety zone: All navigable waters of the Illinois River from mile marker (MM) 10 to MM 187, unless reduced in scope by the Captain of the Port Sector Upper Mississippi River (COTP) as flood conditions warrant.

(b) *Effective period.* This rule is effective without actual notice from June 19, 2020 until June 20, 2020, or until cancelled by the COTP, whichever occurs first. For the purposes of enforcement, actual notice will be provided from 5 p.m. on May 21, 2020 until June 19, 2020.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into this safety zone described in paragraph (a) of this section is prohibited unless authorized by the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units

under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size of the safety zone as flood conditions improve, through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Marine Safety Information Bulletins (MSIBs) as appropriate.

Dated: May 28, 2020.

R.M. Scott,

Commander, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2020–12227 Filed 6–18–20; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2019–0048; and EPA–HQ–OPP–2019–0327; FRL–10009–36]

Formic Acid and Sodium Formate; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of formic acid when used as an inert ingredient limited to 25% in pesticide formulations applied to growing crops pre- and post-harvest (adjuvant, pH buffering agent, or pH adjuster) and applied in/on animals (pH adjuster). In addition, this rule establishes an exemption from the requirement of a tolerance for residues of sodium formate when used as an inert ingredient (adjuvant, pH buffering agent) in pesticide formulations applied to growing crops pre- and post-harvest. The Monsanto Company and the Spring Trading Company on behalf of Stoller Enterprises, Inc., submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of these exemptions. This regulation eliminates the need to establish a maximum permissible level for residues of formic acid and sodium formate when used in accordance with the terms of these exemptions.

DATES: This regulation is effective June 19, 2020. Objections and requests for hearings must be received on or before August 18, 2020, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for this action, identified by docket identification (ID) number EPA–HQ–OPP–2019–0048 and EPA–HQ–OPP–2019–0327 are available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID numbers EPA–HQ–OPP–2019–0048 and/or EPA–HQ–OPP–2019–0327 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 18, 2020. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID numbers EPA–HQ–OPP–2019–0048 and/or EPA–HQ–OPP–2019–0327, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.* Additional instructions on commenting or visiting the docket, along with more

information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of May 13, 2019 (84 FR 20843) (FRL–9991–91), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11136) by Monsanto Company (1300 I Street, NW, Suite 450 East, Washington, DC 20005). The petition requested that 40 CFR be amended by establishing exemptions from the requirement of a tolerance for residues of formic acid (CAS Reg No. 64–18–6) and sodium formate (CAS Reg No. 141–53–7) when used as inert ingredients (adjuvants, pH buffering agents) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910. In addition, in the **Federal Register** of August 2, 2019 (84 FR 37818) (FRL–9996–78), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11264) by the Spring Trading Company (203 Dogwood Trail, Magnolia, TX 77354) on behalf of Stoller Enterprises, Inc. (9090 Katy Freeway, Suite 400, Houston, TX 77024). The petition requested that 40 CFR be amended by establishing exemptions from the requirement of a tolerance for residues of formic acid (CAS Reg No. 64–18–6) when used as an inert ingredient (pH adjuster) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910 and applied in/on animals under 40 CFR 180.930. The documents referenced summaries of petitions prepared by Monsanto Company, LLC (docket EPA–HQ–OPP–2019–0048) and Spring Trading Company on behalf of Stoller Enterprises, Inc. (docket EPA–HQ–OPP–2019–0327). The documents are available in the aforementioned dockets, *http://www.regulations.gov.* No substantive, relevant comments were received on the notices of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for formic acid and sodium formate including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with formic acid and sodium formate follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by formic acid and sodium formate as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in the document Formic Acid and Sodium Formate; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations at page 7 in docket ID number EPA–HQ–OPP–2019–0048 and Formic Acid; Human Health Risk Assessment and Ecological Effects Assessment to Support Proposed Exemption from the Requirement of a Tolerance When Used as an Inert Ingredient in Pesticide Formulations at page 7 in docket ID number EPA–HQ–OPP–2019–0327.

Formic acid and sodium formate exist in an equilibrium in aqueous solutions and the toxicological profiles of formic acid and its salts are expected to be similar. Therefore, data on dissociative salts, such as sodium formate and potassium diformate are used to bridge data gaps for formic acid.

Formic acid and sodium formate are of low acute toxicity via oral, dermal and inhalation routes of exposure. They are not dermal or eye irritants in rabbits. They are not dermal sensitizers in the guinea pig.

Repeated dose oral toxicity studies, developmental, and 2-generation reproduction toxicity studies show that formic acid and sodium formate are not toxic at doses less than 1,000 mg/kg/day, the limit dose, in rats, mice and rabbits. Portal of entry effects are observed in toxicity studies via the inhalation route of exposure. Systemic

effects are seen at a high dose in chronic oral toxicity and carcinogenicity studies in rats and mice. However, no cancers or tumors were observed; therefore, formic acid and sodium formate are not expected to be carcinogenic. Formic acid and sodium formate are not considered mutagenic based on negative results in the bacterial reverse mutation assay, mammalian cell gene mutation assay, mammalian cell cytogenetics assays.

Neurotoxicity and immunotoxicity studies are not available for review. However, evidence of neurotoxicity and immunotoxicity is not observed in the submitted studies.

B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/ safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm.*

An acute toxicity endpoint was not identified for formic acid and sodium formate; therefore, an acute dietary assessment was not performed. The 52-, 80- and 104-week chronic/ carcinogenicity toxicity studies in rats and mice are considered co-critical studies and are selected for the chronic dietary exposure scenario. The NOAELs are 400 mg/kg/day (142 mg/kg/day formic acid), and the lowest observed adverse effect levels (LOAELs) are 2,000 mg/kg/day (708 mg/kg/day formic acid) based on decreased reduced bodyweight gain and body weight. This represents the lowest NOAEL in the database in the most sensitive species. The developmental toxicity study in rats was selected for short-term incidental oral and dermal exposure scenarios. The NOAEL is 945 mg/kg/day, the highest dose tested. The LOAEL is not established. The 90-day oral toxicity in rats is selected for intermediate-term incidental oral and dermal exposure scenarios. The NOAEL is 3,000 mg/kg/day, the highest dose tested. The LOAEL is not established. The 2-week toxicity study via inhalation is selected for short-term inhalation exposure scenarios. The NOAEC is 31 ppm (18.36 mg/kg/day). The LOAEC is 64 ppm (36.72 mg/kg/day) based on squamous metaplasia, necrosis, and inflammation in the upper respiratory tract. The 90-day toxicity study via inhalation in mice is selected for intermediate- and long-term inhalation exposure scenarios. The NOAEC is 32 ppm. The LOAEC is 64 based on degeneration of olfactory epithelia. The Food Quality Protection Act (FQPA) safety factor of 10x is applied to the inhalation exposure scenario only to account for the extrapolation from subchronic to chronic inhalation exposure scenarios. The standard inter- and intra-species uncertainty factors of 10x are applied. The default factor of 100% is applied for dermal and inhalation absorption rates.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to formic acid and sodium formate, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from formic acid and sodium formate in food as follows:

No adverse effects attributable to a single exposure of endpoint was identified for formic acid and sodium formate; therefore, an acute dietary exposure assessment was not conducted.

In conducting the chronic dietary exposure assessment using the Dietary Exposure Evaluation Model DEEM–FCIDTM, Version 3.16, EPA used food consumption information from the U.S. Department of Agriculture's (USDA's) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, no residue data were submitted for formic acid and sodium formate. In the absence of specific residue data, EPA has developed an approach which uses surrogate information to derive upper bound exposure estimates for the subject inert ingredient. Upper bound exposure estimates are based on the highest tolerance for a given commodity from a list of high use insecticides, herbicides, and fungicides. A complete description of the general approach taken to assess inert ingredient risks in the absence of residue data is contained in the memorandum entitled ''Alkyl Amines Polyalkoxylates (Cluster 4): Acute and Chronic Aggregate (Food and Drinking Water) Dietary Exposure and Risk Assessments for the Inerts,'' (D361707, S. Piper, 2/25/09) and can be found at *http://www.regulations.gov* in docket ID number EPA–HQ–OPP–2008–0738.

In the dietary exposure assessment, the Agency assumed that the residue level of the inert ingredient would be no higher than the highest tolerance for a given commodity. Implicit in this assumption is that there would be similar rates of degradation (if any) between the active and inert ingredient and that the concentration of inert ingredient in the scenarios leading to these highest levels of tolerances would be no higher than the concentration of any active ingredient.

The Agency believes the assumptions used to estimate dietary exposures lead to an extremely conservative assessment of dietary risk due to a series of compounded conservatisms. First, assuming that the level of residue for an inert ingredient is equal to the level of residue for the active ingredient will overstate exposure. The concentrations of active ingredient in agricultural products are generally at least 50 percent of the product; however, formic acid is assessed at 25%. Further, pesticide products rarely have a single inert ingredient; rather there is generally a combination of different inert ingredients used which additionally reduces the concentration of any single inert ingredient in the pesticide product in relation to that of the active ingredient.

Second, the conservatism of this methodology is compounded by EPA's decision to assume that, for each commodity, the active ingredient which will serve as a guide to the potential level of inert ingredient residues is the active ingredient with the highest tolerance level. This assumption overstates residue values because it would be highly unlikely, given the high number of inert ingredients, that a single inert ingredient or class of ingredients would be present at the level of the active ingredient in the highest tolerance for every commodity. Finally, a third compounding conservatism is EPA's assumption that all foods contain the inert ingredient at

the highest tolerance level. In other words, EPA assumed 100 percent of all foods are treated with the inert ingredient at the rate and manner necessary to produce the highest residue legally possible for an active ingredient. In summary, EPA chose a very conservative method for estimating what level of inert residue could be on food, then used this methodology to choose the highest possible residue that could be found on food and assumed that all food contained this residue. No consideration was given to potential degradation between harvest and consumption even though monitoring data shows that tolerance level residues are typically one to two orders of magnitude higher than actual residues in food when distributed in commerce.

Accordingly, although sufficient information to quantify actual residue levels in food is not available, the compounding of these conservative assumptions will lead to a significant exaggeration of actual exposures. EPA does not believe that this approach underestimates exposure in the absence of residue data.

In the dietary assessment, EPA also considered exposures due the use of formic acid as a miticide, as a direct and indirect food additive and its natural occurrence in some foods; and sodium formate as an indirect food substance. Based on information on the typical concentrations of and use patterns as a miticide, direct and indirect food additive, the Agency believes that exposures to formic acid and sodium formate that might result from these uses would be markedly less than the conservatively-estimated exposures resulting from pesticide use and would not meaningfully contribute to aggregate exposures.

2. *Dietary exposure from drinking water.* For the purpose of the screening level dietary risk assessment to support this request for an exemption from the requirement of a tolerance for formic acid and sodium formate, a conservative drinking water concentration value of 100 ppb based on screening level modeling was used to assess the contribution to drinking water for the chronic dietary risk assessments for parent compound. These values were directly entered into the dietary exposure model.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Formic acid and sodium formate may be used as an inert ingredient in pesticide products that are registered for specific uses that may result in residential exposure. A conservative residential exposure and risk assessments were completed for pesticide products containing formic acid and sodium formate as inert ingredients. The Agency assessed pesticide products containing formic acid and sodium formate using exposure scenarios used by OPP's Antimicrobials Division to represent conservative residential handler exposure. Further details of this residential exposure and risk analysis can be found at *http://www.regulations.gov* in the memorandum entitled: ''JITF Inert Ingredients. Residential and Occupational Exposure Assessment Algorithms and Assumptions Appendix for the Human Health Risk Assessments to Support Proposed Exemption from the Requirement of a Tolerance When Used as Inert Ingredients in Pesticide Formulations,'' (D364751, 5/7/09, Lloyd/LaMay in docket ID number EPA–HQ–OPP–2008–0710).

Formic acid and sodium formate may be also be used in laundry detergents, rust remover, household cleaners, personal care products, and cosmetics. The Agency does not have sufficient data to quantitatively assess exposures to formic acid and sodium formate that might result from these uses. However, based on the typical concentrations of and use patterns of formic acid and sodium formate, the Agency believes that exposures that might result from these uses would be markedly less than the conservatively estimated exposures resulting from pesticide use and would not meaningfully contribute to aggregate exposures.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found formic acid and sodium formate to share a common mechanism of toxicity with any other substances, and formic acid and sodium formate do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that formic acid and sodium formate do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative.*

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10x) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The Agency has concluded that there is reliable data to determine that infants and children will be safe if the FQPA SF of 10x is reduced to 1x for the assessment of all exposure scenarios except for the long-term inhalation exposure scenario for the following reasons. The toxicity database for formic acid and sodium formate contains subchronic, developmental, reproduction, chronic/carcinogenicity and mutagenicity studies. There is no indication of immunotoxicity or neurotoxicity in the available studies; therefore, there is no need to require an immunotoxicity or neurotoxicity study. No fetal susceptibility is observed in developmental toxicity studies in the rat and rabbit or the 2-generation reproduction toxicity study. Neither maternal, offspring nor reproduction toxicity is observed in any of the studies. The FQPA 10x safety factor is retained for the long-term inhalation exposure scenario to account for the extrapolation from the use of a subchronic inhalation toxicity study to chronic inhalation exposure scenarios. Therefore, based on the adequacy of the toxicity database, the conservative nature of the exposure assessment and the lack of concern for prenatal and postnatal sensitivity, the Agency has concluded that there is reliable data to determine that infants and children will

be safe if the FQPA SF of 10x is reduced to 1x all exposure scenarios, except for long-term inhalation exposure scenarios in which the 10x is retained.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, formic acid and sodium formate are not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to formic acid and sodium formate from food and water will utilize 25% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Formic acid and sodium formate are currently used as inert ingredients in pesticide products that are registered for uses that could result in short-term residential exposures; however, the Agency has determined that it is not appropriate to aggregate chronic exposure through food and water with short-term residential exposures to formic acid and sodium formate. The mode of action of the toxicological effect must be the same across routes of exposure in order to aggregate the exposures; in this case, the toxic effects differ by route and duration. Therefore, to produce an aggregate risk estimate in situations in which it is not appropriate to aggregate exposures due to differing toxicological effects, risk measures are calculated separately for each route and duration for a given toxic effect for each hypothetical ''individual.''

Short-term aggregated residential pesticidal dermal exposures can occur and result in an MOE of 1,184 for adults. Adult residential dermal exposure combines high-end handler dermal exposure from indoor aerosol spray/trigger pump and post-application dermal exposure to treated lawns. EPA has concluded the short-term aggregated residential pesticide dermal exposure results in an MOE of 1,184 for children. Children's residential exposure includes total exposures associated with contact with treated surfaces (dermal and hand-to-mouth exposures). Short-term aggregated residential pesticidal inhalation exposures result in an MOE of 3,500 for adults. Adult residential inhalation exposure is based on high-end handler inhalation exposure from indoor aerosol spray/trigger pump. Post-application inhalation exposure is considered negligible. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

For reasons stated above, intermediate-term aggregated residential aggregated risks were calculated for each route of exposure. Intermediate-term pesticidal dermal exposures result in MOEs of 23,000 for adults. Adult residential dermal exposure is based on post-application exposure to treated lawns. Short-term aggregated residential pesticidal inhalation exposures result in an MOE of 3,500 for adults. Adult residential inhalation exposure is based on high-end handler inhalation exposure from indoor aerosol spray/trigger pump. Post-application inhalation exposure is considered negligible. As the level of concern is for MOEs that are lower than 100, these MOEs are not of concern.

5. *Long-term risks.* Long-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Long-term residential pesticidal uses of formic acid and sodium formate are not expected. However, long-term residential exposure is possible due to their use in household products, personal care products, and cosmetics. The Agency does not have sufficient data to quantitatively assess exposures to formic acid and sodium formate that might result from these uses. In the absence of actual residential exposure data resulting from such uses, the Agency considered information on the typical concentrations of and use patterns of household cleaning products, personal care products, and cosmetics containing formic acid and sodium formate. The available data indicate that exposures to formic acid and sodium formate that might result from these uses would be markedly less than the conservatively estimated exposures resulting from pesticide use. Therefore, the Agency believes that any contribution to aggregate exposure is negligible.

6. *Aggregate cancer risk for U.S. population.* Based on the lack of tumors in the carcinogenicity studies in rats and mice and the lack of mutagenicity, formic acid and sodium formate are not expected to be carcinogenic. Therefore, formic acid and sodium formate are not expected to pose a cancer risk to humans.

7. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to formic acid and sodium formate residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is not establishing a numerical tolerance for residues of formic acid and sodium formate in or on any food commodities. EPA is establishing limitations on the amount of formic acid and sodium formate that may be used in pesticide formulations applied pre- and post-harvest. These limitations will be enforced through the pesticide registration process under the Federal Insecticide, Fungicide, and Rodenticide Act (''FIFRA''), 7 U.S.C. 136 *et seq.* EPA will not register any pesticide formulation for food use that exceeds 25% of formic acid and sodium formate in the final pesticide formulation.

B. Revisions to Petitioned-for Tolerances

In concentrations above 25% of the formulation, formic acid has miticidal activity. Therefore, EPA is limiting the use of formic acid in pesticide formulations to 25% by weight to ensure that it is functioning as an adjuvant and pH buffering agent and not acting as a pesticide active ingredient.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of formic acid (CAS Reg No. 64–18–6), when used as an inert ingredient (adjuvant, pH buffering agent, or pH adjuster) limited to 25% in pesticide formulations applied to growing crops and raw

agricultural commodities after harvest under 40 CFR 180.910 and when used as an inert ingredient (pH adjuster) applied in/on animals under 40 CFR 180.930. In addition, an exemption from the requirement of a tolerance is established for residues of sodium formate (CAS Reg No. 141–53–7) when used as an inert ingredient (adjuvant, pH buffering agent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest (under 40 CFR 180.910).

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to petitions submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled ''Reducing Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 29, 2020.

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, add alphabetically the inert ingredients ''Formic Acid (CAS Reg. No. 64–18–6)''; and ''Sodium Formate (CAS Reg No. 141–53–7)'' to table 1 to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * *	*	* *
Formic Acid (CAS Reg. No. 64–18–6)	25%	adjuvant, pH buffering agent, pH adjuster.
* * * * *	*	* *
Sodium Formate (CAS Reg. No. 141–53–7)		adjuvant, pH buffering agent.
* * * * *	*	* *

■ 3. In § 180.930, add alphabetically the inert ingredient ''Formic Acid (CAS Reg. No. 64–18–6)'' to the table to read as follows:

§ 180.930 Inert ingredients applied to animals; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
Formic Acid (CAS Reg. No. 64–18–6)	25%	pH adjuster.
* * * * * * *		

[FR Doc. 2020–13030 Filed 6–18–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2020–0005; Internal Agency Docket No. FEMA–8633]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *https://www.fema.gov/national-flood-insurance-program-community-status-book.*

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Adrienne L. Sheldon, PE, CFM, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 400 C Street SW, Washington, DC 20472, (202) 674–1087.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. FEMA has determined that the community suspension(s) included in this rule is a non-discretionary action and therefore the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) does not apply.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for Part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.;* Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and location	Community no.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in SFHAs
Region IV				
North Carolina:				
Alliance, Town of, Pamlico County	370404	November 9, 1977, Emerg; August 5, 1985, Reg; June 19, 2020, Susp	June 19, 2020	June 19, 2020.
Bath, Town of, Beaufort County	370288	N/A, Emerg; April 8, 1987, Reg; June 19, 2020, Susp	do *	Do.
Bayboro, Town of, Pamlico County	370183	May 17, 1973, Emerg; December 4, 1985, Reg; June 19, 2020, Susp	do	Do.
Bridgeton, Town of, Craven County	370436	October 19, 1973, Emerg; May 4, 1987, Reg; June 19, 2020, Susp	do	Do.
Carteret County, Unincorporated Areas	370043	November 19, 1971, Emerg; May 15, 1980, Reg; June 19, 2020, Susp	do	Do.
Chocowinity, Town of, Beaufort County	370289	N/A, Emerg; June 30, 1997, Reg; June 19, 2020, Susp	do	Do.
Craven County, Unincorporated Areas	370072	October 19, 1973, Emerg; May 4, 1987, Reg; June 19, 2020, Susp	do	Do.
Currituck County, Unincorporated Areas	370078	March 4, 1974, Emerg; November 1, 1984, Reg; June 19, 2020, Susp	do	Do.
Emerald Isle, Town of, Carteret County	370047	June 29, 1973, Emerg; April 1, 1977, Reg; June 19, 2020, Susp	do	Do.
Greenville, City of, Pitt County	370191	January 15, 1974, Emerg; July 3, 1978, Reg; June 19, 2020, Susp	do	Do.
Grimesland, Town of, Pitt County	370535	November 14, 2000, Emerg; January 2, 2004, Reg; June 19, 2020, Susp	do	Do.
Havelock, City of, Craven County	370265	June 20, 1975, Emerg; May 4, 1987, Reg; June 19, 2020, Susp	do	Do.
Hyde County, Unincorporated Areas	370133	February 8, 1974, Emerg; February 4, 1987, Reg; June 19, 2020, Susp	do	Do.
Kill Devil Hills, Town of, Dare County	375353	February 4, 1972, Emerg; May 4, 1973, Reg; June 19, 2020, Susp	do	Do.
Mesic, Town of, Pamlico County	370426	N/A, Emerg; September 4, 1985, Reg; June 19, 2020, Susp	do	Do.
Minnesott Beach, Town of, Pamlico County.	370418	N/A, Emerg; September 23, 1985, Reg; June 19, 2020, Susp	do	Do.
Nags Head, Town of, Dare County	375356	December 17, 1971, Emerg; November 10, 1972, Reg; June 19, 2020, Susp	do	Do.
New Bern, City of, Craven County	370074	December 11, 1973, Emerg; June 1, 1978, Reg; June 19, 2020, Susp	do	Do.
North Topsail Beach, Town of, Onslow County.	370466	N/A, Emerg; June 15, 1990, Reg; June 19, 2020, Susp	do	Do.
Oriental, Town of, Pamlico County	370279	May 17, 1973, Emerg; December 4, 1985, Reg; June 19, 2020, Susp	do	Do.
Pamlico County, Unincorporated Areas	370181	May 17, 1973, Emerg; September 4, 1985, Reg; June 19, 2020, Susp	do	Do.
River Bend, Town of, Craven County	370432	August 5, 1981, Emerg; August 19, 1986, Reg; June 19, 2020, Susp	do	Do.
Southern Shores, Town of, Dare County.	370430	April 8, 1971, Emerg; May 13, 1972, Reg; June 19, 2020, Susp	do	Do.
Stonewall, Town of, Pamlico County	370437	May 17, 1973, Emerg; December 4, 1985, Reg; June 19, 2020, Susp	do	Do.
Swansboro, Town of, Onslow County	370179	April 11, 1975, Emerg; October 18, 1983, Reg; June 19, 2020, Susp	do	Do.
Washington, City of, Beaufort County	370017	October 6, 1972, Emerg; February 2, 1977, Reg; June 19, 2020, Susp	do	Do.
Washington County, Unincorporated Areas.	370247	January 24, 1975, Emerg; August 19, 1985, Reg; June 19, 2020, Susp	do	Do.
Region V				
Michigan:				
Bedford, Township of, Monroe County	260142	October 8, 1975, Emerg; November 4, 1981, Reg; June 19, 2020, Susp	do	Do.

State and location	Community no.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in SFHAs
Berlin, Charter Township of, Monroe County.	260143	March 9, 1973, Emerg; November 3, 1982, Reg; June 19, 2020, Susp	.....do	Do.
Erie, Township of, Monroe County	260145	January 26, 1973, Emerg; September 1, 1978, Reg; June 19, 2020, Susp	.....do	Do.
Estral Beach, Village of, Monroe County.	260261	March 30, 1973, Emerg; November 2, 1983, Reg; June 19, 2020, Susp	.....do	Do.
Frenchtown, Charter Township of, Monroe County.	260146	January 19, 1973, Emerg; January 19, 1978, Reg; June 19, 2020, Susp	.....do	Do.
LaSalle, Township of, Monroe County ..	260148	February 9, 1973, Emerg; August 15, 1977, Reg; June 19, 2020, Susp	.....do	Do.
Luna Pier, City of, Monroe County	260150	January 26, 1973, Emerg; June 1, 1982, Reg; June 19, 2020, Susp	.....do	Do.
Monroe, Charter Township of, Monroe County.	260154	February 2, 1973, Emerg; April 3, 1978, Reg; June 19, 2020, Susp	.....do	Do.
Region VI				
Texas: Denton County, Unincorporated Areas	480774	July 22, 1975, Emerg; May 4, 1987, Reg; June 19, 2020, Susp	.....do	Do.
Region VII				
Iowa:				
Charles City, City of, Floyd County	190128	March 3, 1972, Emerg; February 2, 1977, Reg; June 19, 2020, Susp	.....do	Do.
Floyd, City of, Floyd County	190382	November 10, 1999, Emerg; February 20, 2008, Reg; June 19, 2020, Susp	.....do	Do.
Floyd County, Unincorporated Areas	190127	September 18, 1996, Emerg; December 1, 1997, Reg; June 19, 2020, Susp	.....do	Do.
Leland, City of, Winnebago County	190529	October 2, 1975, Emerg; January 2, 1981, Reg; June 19, 2020, Susp	.....do	Do.
Nora Springs, City of, Floyd County	190384	April 25, 1980, Emerg; September 1, 1987, Reg; June 19, 2020, Susp	.....do	Do.
Rockford, City of, Floyd County	190129	July 28, 1975, Emerg; September 1, 1987, Reg; June 19, 2020, Susp	.....do	Do.
Rudd, City of, Floyd County	190385	February 29, 2000, Emerg; February 20, 2008, Reg; June 19, 2020, Susp	.....do	Do.
Scarville, City of, Winnebago County	190531	April 14, 2010, Emerg; May 1, 2011, Reg; June 19, 2020, Susp	.....do	Do.
Thompson, City of, Winnebago County	190666	July 8, 2010, Emerg; May 1, 2011, Reg; June 19, 2020, Susp	.....do	Do.
Winnebago County, Unincorporated Areas.	190915	October 15, 2010, Emerg; N/A, Reg; June 19, 2020, Susp	.....do	Do.
Region VIII				
Utah:				
Alpine, City of, Utah County	490228	May 27, 1975, Emerg; February 11, 1976, Reg; June 19, 2020, Susp	.....do	Do.
American Fork, City of, Utah County	490152	April 23, 1974, Emerg; November 25, 1980, Reg; June 19, 2020, Susp	.....do	Do.
Bluffdale, City of, Salt Lake and Utah Counties.	490247	April 7, 1986, Emerg; September 30, 1987, Reg; June 19, 2020, Susp	.....do	Do.
Genola, Town of, Utah County	490154	June 6, 1983, Emerg; January 30, 1984, Reg; June 19, 2020, Susp	.....do	Do.
Lehi, City of, Utah County	490209	October 18, 1974, Emerg; September 14, 1979, Reg; June 19, 2020, Susp	.....do	Do.
Orem, City of, Utah County	490216	March 10, 1975, Emerg; September 24, 1984, Reg; June 19, 2020, Susp	.....do	Do.
Payson, City of, Utah County	490157	December 26, 1974, Emerg; November 15, 1978, Reg; June 19, 2020, Susp	.....do	Do.
Salem, City of, Utah County	490160	January 20, 1975, Emerg; July 16, 1979, Reg; June 19, 2020, Susp	.....do	Do.
Saratoga Springs, City of, Utah County	490250	N/A, Emerg; May 10, 1999, Reg; June 19, 2020, Susp	.....do	Do.
Spanish Fork, City of, Utah County	490241	May 4, 1983, Emerg; February 19, 1986, Reg; June 19, 2020, Susp	.....do	Do.
Springville, City of, Utah County	490163	July 25, 1974, Emerg; September 29, 1978, Reg; June 19, 2020, Susp	.....do	Do.
Utah County, Unincorporated Areas	495517	November 12, 1971, Emerg; October 15, 1982, Reg; June 19, 2020, Susp	.....do	Do.
Region X				
Idaho:				

State and location	Community no.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain federal assistance no longer available in SFHAs
Ada County, Unincorporated Areas	160001	May 8, 1975, Emerg; December 18, 1984, Reg; June 19, 2020, Susp	.....do	Do.
Garden City, City of, Ada County	160004	January 12, 1979, Emerg; May 15, 1980, Reg; June 19, 2020, Susp	.....do	Do.
Meridian, City of, Ada County	160180	N/A, Emerg; March 20, 1992, Reg; June 19, 2020, Susp	.....do	Do.
Washington: Bothell, City of, Snohomish County.	530075	June 20, 1975, Emerg; June 1, 1982, Reg; June 19, 2020, Susp	.....do	Do.
Brier, City of, Snohomish County	530276	February 23, 1976, Emerg; September 24, 1984, Reg; June 19, 2020, Susp	.....do	Do.
Bucoda, Town of, Thurston County	530189	February 10, 1975, Emerg; September 2, 1981, Reg; June 19, 2020, Susp	.....do	Do.
Darrington, Town of, Snohomish County.	530233	September 1, 1976, Emerg; August 19, 1985, Reg; June 19, 2020, Susp	.....do	Do.
Edmonds, City of, Snohomish County	530163	April 30, 1974, Emerg; August 8, 1978, Reg; June 19, 2020, Susp	.....do	Do.
Everett, City of, Snohomish County	530164	December 17, 1973, Emerg; April 3, 1978, Reg; June 19, 2020, Susp	.....do	Do.
Gold Bar, City of, Snohomish County	530285	December 17, 1976, Emerg; December 1, 1983, Reg; June 19, 2020, Susp	.....do	Do.
Index, Town of, Snohomish County	530166	August 27, 1975, Emerg; December 1, 1983, Reg; June 19, 2020, Susp	.....do	Do.
Lake Stevens, City of, Snohomish County.	530291	December 29, 1976, Emerg; April 17, 1989, Reg; June 19, 2020, Susp	.....do	Do.
Lynnwood, City of, Snohomish County	530167	May 9, 1975, Emerg; June 5, 1985, Reg; June 19, 2020, Susp	.....do	Do.
Marysville, City of, Snohomish County	530168	October 16, 1974, Emerg; February 15, 1984, Reg; June 19, 2020, Susp	.....do	Do.
Mill Creek, City of, Snohomish County	530330	N/A, Emerg; July 9, 1997, Reg; June 19, 2020, Susp	.....do	Do.
Monroe, City of, Snohomish County	530169	August 14, 1974, Emerg; December 1, 1983, Reg; June 19, 2020, Susp	.....do	Do.
Mountlake Terrace, City of, Snohomish County.	530170	March 18, 1975, Emerg; August 19, 1985, Reg; June 19, 2020, Susp	.....do	Do.
Mukilteo, City of, Snohomish County	530235	February 3, 1977, Emerg; February 19, 1986, Reg; June 19, 2020, Susp	.....do	Do.
Snohomish County, Unincorporated Areas.	535534	November 27, 1970, Emerg; March 15, 1984, Reg; June 19, 2020, Susp	.....do	Do.
Stanwood, City of, Snohomish County	530172	March 6, 1975, Emerg; November 16, 1983, Reg; June 19, 2020, Susp	.....do	Do.
Sultan, City of, Snohomish County	530173	May 16, 1975, Emerg; September 30, 1983, Reg; June 19, 2020, Susp	.....do	Do.
Tenino, City of, Thurston County	530302	February 18, 1975, Emerg; June 4, 1980, Reg; June 19, 2020, Susp	.....do	Do.
Thurston County, Unincorporated Areas	530188	September 13, 1974, Emerg; December 1, 1982, Reg; June 19, 2020, Susp	.....do	Do.

* -do- = Ditto.
Code for reading third column: Emerg. —Emergency; Reg. —Regular; Susp. —Suspension.

Katherine B. Fox,

Assistant Administrator for Mitigation, Federal Insurance and Mitigation Administration—FEMA Resilience, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2020–12661 Filed 6–18–20; 8:45 am]

BILLING CODE 9110–12–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 17–310; FCC 19–78; FRS 16838]

Promoting Telehealth in Rural America

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of effective date.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that the Office of Management and Budget (OMB) has approved, for a period of three years, an information collection associated with the rules for the Telecommunications Program and the Healthcare Connect Fund Program contained in the Commission's *Promoting Telehealth in Rural America Report and Order,* FCC 19–78, which stated that the Commission would publish a document in the **Federal Register** announcing the effective date of the new information collection requirements.

DATES: The amendments to 47 CFR 54.622(d) and (e)(2), (4), and (5), 54.623(a)(2) through (4), 54.624,

54.626(b), 54.627(b), and 54.631(d), published at 84 FR 54952, October 11, 2019, are effective June 19, 2020.

FOR FURTHER INFORMATION CONTACT: Bryan Boyle, Telecommunications Access Policy Division, Wireline Competition Bureau at (202) 418–7400 or TTY: (202) 418–0484 or via email: *Bryan.Boyle@fcc.gov.* For additional information concerning the Paperwork Reduction Act information collection requirements, contact Nicole Ongele at (202) 418–2991 or via email: *Nicole.Ongele@fcc.gov.*

SUPPLEMENTARY INFORMATION: The Commission submitted new information collection requirements for review and approval by OMB, as required by the Paperwork Reduction Act of 1995, on April 7, 2020, which were approved by the OMB on May 22, 2020. The information collection requirements are contained in the Commission's

Promoting Telehealth in Rural America Report and Order, FCC 19–78, published at 84 FR 54952, October 11, 2019. The OMB Control Number is 3060–0804. The Commission publishes this document as an announcement of the effective date of the rules published on October 11, 2019. If you have any comments on the burden estimates listed herein, or how the Commission can improve the collection and reduce any burdens caused thereby, the Commission will accept your comments via email at *PRA@fcc.gov.* Please include the OMB Control Number, 3060–0804, in your correspondence. Due to the COVID–19 pandemic, the Commission's headquarters will be closed to the general public and will only be accepting electronic submissions until further notice.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received OMB approval on May 22, 2020 for the information collection requirements contained in 47 CFR 54.622(d) and (e)(2), (4), and (5), 54.623(a)(2) through (4), 54.624, 54.626(b), 54.627(b), and 54.631(d) published at 84 FR 54952, October 11, 2019. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number.

No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a current, valid OMB Control Number. The OMB Control Number is 3060–0804.

The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104–13, October 1, 1995, and 44 U.S.C. 3507.

The total annual reporting burdens and costs for the respondents are as follows:

OMB Control Number: 3060–0804.

OMB Approval Date: May 22, 2020.

OMB Expiration Date: May 31, 2023.

Title: Universal Service—Rural Health Care Program.

Form Nos.: FCC Forms 460, 461, 462, 463, 465, 466, and 467.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit; Not-for-profit institutions; Federal Government; and State, Local, or Tribal governments.

Number of Respondents and Responses: 10,494 unique respondents; 93,687 responses.

Estimated Time per Response: 0.30–17 hours.

Frequency of Response: On occasion, one-time, annual, quarterly, and monthly reporting requirements.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in sections 1–4, 201–205, 214, 254, 303(r), and 403 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154, 201–205, 214, 254, 303(r), and 403, unless otherwise noted.

Total Annual Burden: 382,741 hours.

Total Annual Cost: No Cost.

Privacy Impact Assessment: No Impact(s).

Nature and Extent of Confidentiality: There is no assurance of confidentiality provided to respondents concerning this information collection. Information submitted on FCC Forms for the RHC Program is subject to public inspection and is used by USAC to update and expand the RHC Program dataset as part of its Open Data Platform. However, respondents may request materials or information submitted to the Commission or to USAC be withheld from public inspection under 47 CFR 0.459 of the Commission's rules.

Needs and Uses: This collection is utilized for the RHC support mechanism of the Commission's universal service fund (USF). The Commission and the Universal Service Administrative Company (USAC) will use the information collected to determine if entities are eligible for funding pursuant to the RHC universal service support mechanism, to determine whether entities are complying with the Commission's rules, and to prevent waste, fraud, and abuse. This information also allows the Commission to evaluate the extent to which the RHC Program is meeting the statutory objectives specified in section 254(h) of the 1996 Act, and the Commission's performance goals for the RHC Program.

To aid in collecting this information, the public will use the Commission's forms to provide the necessary information and certifications. This revision modifies the existing information collection requirements applicable to both the Healthcare Connect Fund and Telecommunications (Telecom) Programs as a result of the *2019 Promoting Telehealth Report and Order.* The revisions, where applicable, are intended to make the RHC Program information requests consistent between the programs, to the extent possible, and help to ensure and verify that RHC Program participants are not engaging in fraudulent conduct or otherwise violating the Commission's rules.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2020–12844 Filed 6–18–20; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 200616–0161]

RIN 0648–BJ89

Revised Management Measures for the 2020 Guided Sport Pacific Halibut Fisheries in International Pacific Halibut Commission Regulatory Areas 2A, 2C, and 3A

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This action revises the 2020 regulations for guided Pacific halibut sport fishing in International Pacific Halibut Commission (IPHC) Regulatory Areas 2A, 2C, and 3A. The revised regulations supersede the vessel application deadline previously published in Section 15 Paragraph 9, and guided halibut sport fishing

management measures previously published in Section 29 of the 2020 annual management measures. No other regulations of the 2020 Pacific halibut management measures are changed by this action. The Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration (NOAA), on behalf of the International Pacific Halibut Commission (IPHC), publishes regulations governing the Pacific halibut fishery that have been recommended by the IPHC and accepted by the Secretary of State. The revisions in this action are intended to enhance the conservation of Pacific halibut and further the goals and objectives of the Pacific Fishery Management Council (PFMC) and North Pacific Fishery Management Council (NPFMC).

DATES: The revisions to IPHC's annual management measures are valid May 28, 2020. These revisions, and all other management measures previously published and not revised, are effective until superseded.

ADDRESSES: Additional requests for information regarding this action may be obtained by contacting the International Pacific Halibut Commission, 2320 W Commodore Way, Suite 300, Seattle, WA 98199–1287; or Sustainable Fisheries Division, NMFS Alaska Region, P.O. Box 21668, Juneau, AK 99802; or Sustainable Fisheries Division, NMFS West Coast Region, 7600 Sand Point Way NE, Seattle, WA 98115. This final rule also is accessible via the internet at the Federal eRulemaking portal at *http://www.regulations.gov,* identified by docket number NOAA–NMFS–2020–0833.

FOR FURTHER INFORMATION CONTACT: For waters off Alaska, Kurt Iverson, 907–586–7210; or, for waters off the U.S. West Coast, Kathryn Blair, 503–231–6858.

SUPPLEMENTARY INFORMATION:

Background

The IPHC has recommended regulations that would govern the Pacific halibut fishery in 2020, pursuant to the Convention between Canada and the United States for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979).

As provided by the Northern Pacific Halibut Act of 1982 (Halibut Act) at 16 U.S.C. 773b, the Secretary of State, with the concurrence of the Secretary of Commerce, may accept or reject, on behalf of the United States, regulations recommended by the IPHC in accordance with the Convention (Halibut Act, Sections 773–773k). The Secretary of State, with the concurrence of the Secretary of Commerce, accepted the 2020 IPHC regulations as provided by the Halibut Act.

The Halibut Act provides the Secretary of Commerce with the authority and general responsibility to carry out the requirements of the Convention and the Halibut Act. The Regional Fishery Management Councils may develop, and the Secretary of Commerce may implement, regulations governing harvesting privileges among U.S. fishermen in U.S. waters that are in addition to, and not in conflict with, approved IPHC regulations. The NPFMC has exercised this authority in developing halibut management programs for three fisheries that harvest halibut in Alaska: The subsistence, sport, and commercial fisheries. The PFMC has exercised this authority by developing a catch sharing plan governing the allocation of halibut and management of sport fisheries on the U.S. West Coast.

Subsistence and sport halibut fishery regulations for Alaska are codified at 50 CFR part 300. Commercial halibut fisheries off Alaska are subject to the Individual Fishing Quota (IFQ) Program and Community Development Quota (CDQ) Program (50 CFR part 679) regulations, and the area-specific catch sharing plans (CSPs) for Areas 2C, 3A, and Areas 4C, 4D, and 4E.

The NPFMC recommended and NMFS implemented through rulemaking a CSP for guided sport (charter) and commercial IFQ halibut fisheries in IPHC Regulatory Area 2C and Area 3A (Areas 2C and 3A) on January 13, 2014 (78 FR 75844; December 12, 2013). The Area 2C and 3A CSP regulations are codified at 50 CFR 300.65. The CSP defines an annual process for allocating halibut between the commercial and charter fisheries so that each sector's allocation varies in proportion to halibut abundance, specifies a public process for setting annual management measures, and authorizes limited annual leases of commercial IFQ for use in the charter fishery as guided angler fish (GAF).

The IPHC held its annual meeting in Anchorage, Alaska, February 3–7, 2020, and recommended a number of changes to the previous IPHC regulations (84 FR 9243; March 14, 2019). The Secretary of State accepted the 2020 annual management measures. Pursuant to regulations at 50 CFR 300.62, the 2020 IPHC annual management measures were published in the **Federal Register** (85 FR 14586; March 13, 2020) to provide notice of their immediate regulatory effectiveness and to inform persons subject to the regulations of their restrictions and requirements. Because NMFS publishes the regulations applicable to the entire Convention area, these regulations include some provisions relating to and affecting Canadian fishing and fisheries. NMFS may implement more restrictive regulations for the fishery for halibut or components of it in waters of the United States; therefore, anglers are advised to check the current Federal and IPHC regulations prior to fishing.

On May 20, 2020, the IPHC held an intersessional meeting to address stakeholder proposals, including a proposal from U.S. Commissioners regarding the Area 2A sablefish fishery, and a recommendation by the North Pacific Fishery Management Council (NPFMC) to revise guided sport (charter) halibut management measures for Areas 2C and 3A. The proposed revisions for Areas 2C and 3A were prompted by an unexpected decline in charter fishing effort for the 2020 season. The NPFMC and IPHC reviewed the best available information on the status of charter fishing effort supported by an analysis from the State of Alaska Department of Fish and Game (ADF&G) on the likely charter effort in Areas 2C and 3A and the relative effectiveness of various charter halibut management measures to maintain charter harvests within their allocations. The proposal for the incidental catch in the Area 2A sablefish fishery was for an extension to the application deadline.

The IPHC adopted revisions to Section 15, *Licensing Vessels for IPHC Regulatory Area 2A,* and Section 29, *Recreational (Sport) Fishing for Pacific Halibut—IPHC Regulatory Areas 2C, 3A, 3B, 4A, 4B, 4C, 4D, 4E,* of the charter fishing management measures. In a similar process as described above, the Secretaries of State and Commerce accepted the revised IPHC regulations. The revised Section 15 and Section 29 management measures published herein supersede the 2020 Section 15 and Section 29 regulations previously published in the **Federal Register** (85 FR 14586; March 13, 2020). The IPHC did not recommend any other changes to the 2020 Pacific halibut management measures. The revised management measures, and all other management measures previously published and not revised, are effective until superseded.

Revised Application Deadline for Incidental Catch in the Sablefish Fishery in Area 2A

At the May 20, 2020 IPHC intersessional meeting, the Commissioners adopted a regulatory proposal amending the deadline for when a vessel operating in the incidental catch fishery during the sablefish fishery in IPHC Regulatory Area 2A must have submitted its ''Application for Vessel License for the Pacific Halibut Fishery'' form. The regulatory change modified the deadline for submission from March 15 to May 29, 2020. This one-time modification was in response to potential negative impacts that current events may have had on a licensee's ability to submit an application and does not set a precedent for future years.

Fishery participants were informed of this regulatory change via IPHC media release, NMFS' contact list for sablefish tier permit holders, a bulletin posted to the NMFS website, as well as other directed outreach to potentially affected public.

Revised Management Measures for Charter Vessel Fishing in Area 2C

The two primary management measures previously established for 2020 in Area 2C were a daily bag limit of one halibut per charter angler, and size limits prohibiting retention of halibut that are greater than 40 inches (101.6 cm) or less than 80 inches (203.2 cm). The effect of these regulations is to limit both the number and pounds of retained halibut.

At the May 20, 2020 intersessional meeting, the IPHC recommended the continuation of a one-fish daily bag limit with a revision to the size limits. Specifically, the new regulations prohibit a person on board a charter vessel referred to in 50 CFR 300.65 and fishing in Area 2C from taking or possessing any halibut, with head on, that is greater than 45 inches (114.3 cm) and less than 80 inches (203.2 cm), as measured in a straight line, passing over the pectoral fin from the tip of the lower jaw with mouth closed, to the extreme end of the middle of the tail.

The analysis prepared by ADF&G indicates that, under the revised size limits, total harvests in Area 2C are expected to be less than the Area 2C charter halibut allocation. Under the current and expected charter fishing conditions in Area 2C, charter fishing effort has declined, and is expected to decline further later in the fishing season relative to previous years. The total amount of decline in fishing effort throughout the year is difficult to predict. Therefore, the revised charter management measures are conservative and intended to provide additional harvest opportunity while maintaining total charter harvests within the current allocation. The analysis prepared by ADF&G indicates that if charter fishing removals in Area 2C decline by approximately 12 percent or more compared the removals originally projected in December of 2019 for the 2020 season, the revised management measures are projected to maintain charter halibut harvests within the current allocation.

Revised Management Measures for Charter Vessel Fishing in Area 3A

For 2020, the IPHC previously recommended the following management measures for Area 3A: (1) A two-fish bag limit with a 26-inch (66.0 cm) size limit on one of the halibut; (2) a one-trip per day limit for charter vessels and for charter halibut permits for the entire season; (3) an annual limit of four fish, with a reporting requirement; and, (4) prohibition on halibut retention by charter vessel anglers on all Tuesdays and all Wednesdays (85 FR 14586; March 13, 2020).

At the May 20, 2020 intersessional meeting, the IPHC recommended retaining the one-trip per day limits for halibut charter vessels and for charter halibut permits. The IPHC also recommended revising the management measures as follows:

Size Limit for Halibut Retained on a Charter Vessel in Area 3A

The revised 2020 charter halibut fishery regulations in Area 3A will include a two-fish daily bag limit in which one of the retained halibut may be of any size and one of the retained halibut must be 32 inches (81.3 cm) or less, as measured in a straight line, passing over the pectoral fin from the tip of the lower jaw to the extreme end of the middle of the tail.

Retention of Halibut Allowed on All Days of the Week in Area 3A

The 2020 Area 3A charter fishing regulations are revised to allow retention of halibut by charter vessel anglers during any day of the week.

Withdraw the Annual Limit on Halibut Retained by Charter Vessels Anglers in Area 3A

The 2020 Area 3A charter fishing regulations are revised to withdraw the annual limit of four retained halibut for anglers on charter vessels. The revised regulations do not impose an annual limit on retained halibut for anglers on charter vessel fishing trips in Area 3A during the 2020 calendar year.

To enforce the previous annual limit, each charter vessel angler was required to record the date and location of each halibut harvested within a calendar year on the back of their fishing license or on a nontransferable Sport Harvest Record Card obtained from the Alaska Department of Fish and Game. The revised regulations withdraw this reporting requirement for Area 3A charter vessel fishing trips. All other reporting requirements remain in effect.

The analysis prepared by ADF&G indicates that, under the revised size limits, total harvests in Area 3A are expected to be less than the Area 3A charter halibut allocation. Under the current and expected charter fishing conditions in Area 3A, charter fishing effort has declined, and is expected to decline further later in the fishing season relative to previous years. The total amount of decline in fishing effort throughout the year is difficult to predict. Therefore, the revised charter management measures are conservative and intended to provide additional harvest opportunity while maintaining total charter harvests within the current allocation. The analysis prepared by ADF&G indicates that if charter fishing removals in Area 3A decline by approximately 38 percent or more compared the removals originally projected in December of 2019 for the 2020 season, the revised management measures are projected to maintain charter halibut harvests within the current allocation.

Revised Halibut Management Measures

The following revised management measures apply to Section 15 Paragraph 9 and Section 29 of the 2020 IPHC regulations. They are recommended by the IPHC and have been accepted by the Secretary of State, with the concurrence of the Secretary of Commerce. These management measures supersede Section 15 Paragraph 9 and Section 29 regulations of the Commission previously published. The IPHC did not recommend any other changes to the 2020 Pacific halibut management measures. All other 2020 management measures adopted by the IPHC and previously published in the **Federal Register** (85 FR 14586; March 13, 2020) remain unchanged and are effective until superseded.

15. Licensing Vessels for IPHC Regulatory Area 2A

(9) A vessel operating in the incidental catch fishery during the sablefish fishery in IPHC Regulatory Area 2A must have submitted its

''Application for Vessel License for the Pacific Halibut Fishery'' form no later than 2359 local time on 29 May, or the next weekday in May if 29 May is a Saturday or Sunday.

29. Recreational (Sport) Fishing for Pacific Halibut—IPHC Regulatory Areas 2C, 3A, 3B, 4A, 4B, 4C, 4D, 4E

(1) In Convention waters in and off Alaska.[1] [2]

(a) The recreational (sport) fishing season is from 1 February to 31 December.

(b) The daily bag limit is two Pacific halibut of any size per day per person unless a more restrictive bag limit applies in Commission regulations or Federal regulations at 50 CFR 300.65.

(c) No person may possess more than two daily bag limits.

(d) No person shall possess on board a vessel, including charter vessels and pleasure craft used for fishing, Pacific halibut that have been filleted, mutilated, or otherwise disfigured in any manner, except that each Pacific halibut may be cut into no more than 2 ventral pieces, 2 dorsal pieces, and 2 cheek pieces, with a patch of skin on each piece, naturally attached.

(e) Pacific halibut in excess of the possession limit in paragraph (1)(c) of this section may be possessed on a vessel that does not contain recreational (sport) fishing gear, fishing rods, hand lines, or gaffs.

(f) Pacific halibut harvested on a charter vessel fishing trip in IPHC Regulatory Areas 2C or 3A must be retained on board the charter vessel on which the Pacific halibut was caught until the end of the charter vessel fishing trip as defined at 50 CFR 300.61.

(g) Guided angler fish (GAF), as described at 50 CFR 300.65, may be used to allow a charter vessel angler to harvest additional Pacific halibut up to the limits in place for unguided anglers, and are exempt from the requirements in paragraphs (2) and (3) of this section.

(2) For guided recreational (sport) fishing (as referred to in 50 CFR 300.65) in IPHC Regulatory Area 2C:

(a) No person on board a charter vessel (as referred to in 50 CFR 300.65) shall catch and retain more than one Pacific halibut per calendar day.

(b) No person on board a charter vessel (as referred to in 50 CFR 300.65) shall catch and retain any Pacific halibut that with head on is greater than 45 inches (114.3 cm) and less than 80 inches (203.2 cm) as measured in a straight line, passing over the pectoral fin from the tip of the lower jaw with mouth closed, to the extreme end of the middle of the tail.

(3) For guided recreational (sport) fishing (as referred to in 50 CFR 300.65) in IPHC Regulatory Area 3A:

(a) No person on board a charter vessel (as referred to in 50 CFR 300.65) shall catch and retain more than two Pacific halibut per calendar day.

(b) At least one of the retained Pacific halibut must have a head-on length of no more than 32 inches (81.3 cm) as measured in a straight line, passing over the pectoral fin from the tip of the lower jaw with mouth closed, to the extreme end of the middle of the tail. If a person recreational (sport) fishing on a charter vessel in IPHC Regulatory Area 3A retains only one Pacific halibut in a calendar day, that Pacific halibut may be of any length.

(c) A ''charter halibut permit'' (as referred to in 50 CFR 300.67) may only be used for one charter vessel fishing trip in which Pacific halibut are caught and retained per calendar day. A charter vessel fishing trip is defined at 50 CFR 300.61 as the time period between the first deployment of fishing gear into the water by a charter vessel angler (as defined at 50 CFR 300.61) and the offloading of one or more charter vessel anglers or any Pacific halibut from that vessel. For purposes of this trip limit, a charter vessel fishing trip ends at 2359 (Alaska local time) on the same calendar day that the fishing trip began, or when any anglers or Pacific halibut are offloaded, whichever comes first.

(d) A charter vessel on which one or more anglers catch and retain Pacific halibut may only make one charter vessel fishing trip per calendar day. A charter vessel fishing trip is defined at 50 CFR 300.61 as the time period between the first deployment of fishing gear into the water by a charter vessel angler (as defined at 50 CFR 300.61) and the offloading of one or more charter vessel anglers or any Pacific halibut from that vessel. For purposes of this trip limit, a charter vessel fishing trip ends at 2359 (Alaska local time) on the same calendar day that the fishing trip began, or when any anglers or Pacific halibut are offloaded, whichever comes first.

Classification

IPHC Regulations

These IPHC revised management measures are a product of an agreement between the United States and Canada and are published in the **Federal Register** to provide notice of their effectiveness and content. Pursuant to section 4 of the Northern Pacific Halibut Act of 1982, 16 U.S.C. 773b, the Secretary of State, with the concurrence of the Secretary of Commerce, may ''accept or reject'' but not modify these recommendations of the IPHC. The notice-and-comment and delay-in-effectiveness date provisions of the Administrative Procedure Act (APA), 5 U.S.C. 553(b) and (d), are inapplicable to IPHC management measures because this regulation involves a foreign affairs function of the United States, 5 U.S.C. 553(a)(1). As stated above, the Secretary of State has no discretion to modify the recommendations of the IPHC. The additional time necessary to comply with the notice-and-comment and delay-in-effectiveness requirements of the APA would disrupt coordinated international conservation and management of the halibut fishery pursuant to the Convention. Furthermore, no other law requires prior notice and public comment for this rule. Because prior notice and an opportunity for public comment are not required to be provided for these portions of this rule by 5 U.S.C. 553, or any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable. Accordingly, no Regulatory Flexibility Analysis is required for this portion of the rule and none has been prepared. This final rule has been determined to be not significant for the purposes of Executive Order 12866. Because this is not a significant rule, the provisions of Executive Order 13771 are inapplicable.

Authority: 16 U.S.C. 773 *et seq.*

Dated: June 16, 2020.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

[FR Doc. 2020–13287 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–22–P

[1] NOAA Fisheries could implement more restrictive regulations for the recreational (sport) fishery or components of it, therefore, anglers are advised to check the current Federal or State regulations prior to fishing.

[2] Charter vessels are prohibited from harvesting Pacific halibut in IPHC Regulatory Areas 2C and 3A during one charter vessel fishing trip under regulations promulgated by NOAA Fisheries at 50 CFR 300.66.

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 200615–0159]

RIN 0648–BJ83

Fisheries Off West Coast States; Emergency Action To Temporarily Remove Seasonal Processing Limitations for Pacific Whiting Motherships and Catcher-Processors

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; emergency action; request for comments.

SUMMARY: This emergency rule temporarily allows at-sea Pacific whiting processing platforms to operate as both a mothership and a catcher-processor during the 2020 Pacific whiting fishery. This action is necessary to ensure catcher vessels in the mothership cooperative sector are able to fully harvest sector allocations. Emergency measures under this rule will allow catcher-processors to operate as motherships later in the year, and replace mothership processing platforms that have chosen not to operate in the cooperative in response to high economic uncertainty in 2020.

DATES: Effective June 19, 2020, until December 16, 2020. Comments must be submitted by July 19, 2020.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2020–0088 by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2020-0088,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Barry Thom, c/o Colin Sayre, Sustainable Fisheries Division, West Coast Region, NMFS, 7600 Sand Point Way NE, Seattle, WA 98115–0070.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic Access

This emergency rule is accessible via the internet at the Office of the Federal Register website at *https://www.federalregister.gov.* Background information and documents are available at the NMFS West Coast Region website at: *http://www.westcoast.fisheries.noaa.gov/fisheries/groundfish/index.html* and at the Pacific Fishery Management Council's website at *http://www.pcouncil.org/groundfish/fishery-management-plan/groundfish-amendments-in-development/.*

FOR FURTHER INFORMATION CONTACT: Colin Sayre, phone: 206–526–4656, or email: *colin.sayre@noaa.gov.*

SUPPLEMENTARY INFORMATION: On March 31, 2020, a company holding one of the mothership (MS) permits in the at-sea Pacific whiting fishery announced that because of new, unforeseen health, safety, and economic risks, it would not commit a processing platform to the MS sector for the 2020 Pacific whiting season, and would instead operate all of its eligible processing platforms in the Pacific whiting catcher-processor (C/P) sector. The Pacific Coast Groundfish Fishery Management Plan (FMP) prohibits processing platforms in the at-sea Pacific whiting fishery from operating as both an MS and C/P during the same calendar year. Some processing platforms are capable of both harvesting and processing catch at-sea, while others are built solely to process catch delivered by other vessels. Because of this, some processing platforms are able to switch between the C/P and MS sectors, while other platforms are not. To help ensure market stability in the separate sectors, the current rule does not allow processing platforms to switch between the MS and C/P sectors in a single calendar year. Therefore, the decision to operate processing platforms as a C/P in response to the new and unforeseen risks would prevent them from operating as a MS for the remainder of the 2020 fishing year. Without additional rulemaking action to allow these processing platforms to switch to the MS sector, three catcher vessels would lose their MS because the processing platform would be required to commit to operating as a C/P for the remainder of the 2020 fishing year. Losing the MS processing platform would prevent these catcher vessels from harvesting their 2020 Pacific whiting allocations, leaving unharvested about 25 percent of the MS sector Pacific whiting allocation, worth an estimated $5 million. The remaining processing companies participating in the MS cooperative do not possess the capacity to receive deliveries from the displaced catcher vessels for the 2020 Pacific whiting season.

On April 8, 2020, industry members from the MS cooperative submitted a letter to the Pacific Fishery Management Council (Council) requesting action to address this issue. On April 10, 2020, the Council voted to request that NMFS initiate an emergency action to temporarily allow any eligible MS and C/P to operate as both types of processing platform during the 2020 Pacific whiting season, instead of opting at the beginning of the fishing season to operate as one or the other for the year. This emergency action would allow at-sea Pacific whiting processing platforms to switch operations for 180 days after publication.

Justification for Emergency Action

Section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) authorizes the Secretary of Commerce to implement emergency regulations to address fishery emergencies. NMFS policy guidelines for the use of emergency rules define criteria for determining whether an emergency exists under section 305(c) of the Magnuson-Stevens Act (62 FR 44451; August 21, 1997). These criteria limit emergency management actions to ''recent unforeseen events or recently discovered circumstances'' that present serious management problems in the fishery when the benefits of an emergency action outweigh the benefits of the normal rulemaking process.

Maintaining the prohibition on processing platforms operating as both a C/P and MS in the same calendar year would have serious economic impacts within the 2020 Pacific whiting season by limiting catcher vessel operations without providing the benefit of long-term competitive stability between the MS and C/P sectors. The prohibition on processing platforms operating as both an MS and C/P would place both sectors at an economic disadvantage by limiting the operational flexibility of the at-sea sectors to respond to recent unforeseen circumstances. This emergency action would allow a processing platform to operate as both an MS or a C/P in the same year, depending on the processing needs of the at-sea Pacific whiting sectors. Under these emergency

measures, temporarily lifting the restriction on MS and C/P operations would increase the likelihood that MS catcher vessels have markets to deliver catch to throughout the 2020 fishing year. The operational flexibility provided in this emergency action would prevent significant direct economic loss to at-sea whiting fishery participants and fishing communities. These measures will allow at least three catcher vessels impacted by unforeseen circumstances to harvest MS sector Pacific whiting allocations and provide catch revenue to the respective vessel crews. In the event that additional processing platforms cannot commit to taking deliveries from catcher vessels for the remainder of the 2020 Pacific whiting season (due to changes in business plans or because a processing platform is rendered inoperable, for example) this emergency rule may provide additional harvesting and processing opportunities for at-sea Pacific whiting fishery participants.

In light of this information, NMFS finds that an emergency exists, and regulations are necessary to address the emergency.

Emergency Measures

This emergency action removes restrictions prohibiting an at-sea Pacific whiting processing platform from operating as an MS or C/P in the same calendar year, effective June 19, 2020. This action temporarily (for 180 days) allows a processing platform to operate as both an MS and C/P in the same calendar year, but not on the same trip. Owners of processing platforms intended to be switched between C/P and MS operations during the 2020 Pacific whiting season must follow this procedure:

(1) *Submit a request to register for both processing permits.* The vessel may be registered under both an MS permit and a C/P endorsed permit simultaneously for the duration of the emergency rule. The owner of a processing platform currently registered under a C/P endorsed permit may also operate as an MS by submitting a request to NMFS Permits to register the processing platform under a valid MS permit per regulations in 50 CFR 660.25(b). The owner of a processing platform currently registered under an MS permit may also operate as a C/P by submitting a request to NMFS Permits to register the processing platform under a valid C/P endorsed permit per regulations in 50 CFR 660.25(b).

(2) *Submit a notification of a material change to coop agreement within 7 days.* To operate in the MS fishery (*i.e.,* receive deliveries of catch from MS catcher vessels and process 2020 MS sector allocations at-sea) the vessel must be included in the MS coop agreement. To operate in the C/P fishery (*i.e.,* catch and process 2020 C/P sector allocations at-sea) the vessel must be included in the C/P coop agreement. Including a new vessel in either the MS or C/P coop agreement constitutes a material change to the coop agreement. Within 7 calendar days of the new processing platform operating for the first time in either the 2020 MS coop fishery or the 2020 C/P coop fishery, the respective coop manager must notify NMFS in writing of such change to the coop agreement as required in regulations at 50 CFR 660.150 (d)(1)(iii)(B)(*4*) and 50 CFR 660.160(d)(1)(iii)(B)(*4*).

(3) *Submit a revised coop agreement within 30 days of material change to the coop agreement.* Within 30 days of a new vessel participating in a coop fishery, the MS or C/P coop manager must submit a revised coop agreement to NMFS that lists all vessels and/or processing platforms operating in the respective coop and includes the new processing platform, along with a letter describing the change to the coop agreement, as required in regulations at 50 CFR 660.150(d)(1)(iii)(B)(*4*) and 50 CFR 660.160(d)(1)(iii)(B)(*4*).

(4) *Change vessel declaration before each fishing trip.* For each trip, the vessel must update its vessel monitoring system (VMS) declaration to reflect its activity for that trip prior to departure as specified in existing groundfish regulations at 50 CFR 660.13(d)(4)(iv)(A). The declaration is binding for the duration of the trip and may not be changed until completion of the trip. A processing platform must submit one of the following declarations: (a) Limited entry midwater trawl, Pacific whiting catcher/processor sector; or (b) Limited entry midwater trawl, Pacific whiting mothership sector (mothership).

Renewal of Emergency Regulations

The Magnuson-Stevens Act limits NMFS's emergency action authority to an initial period of 180 days, with a potential extension up to an additional 186 days, if warranted. The public has an opportunity to comment on the initial emergency action (see **ADDRESSES**). After considering public comments on this emergency rule, NMFS may renew the emergency regulation in December 2020 to provide at-sea Pacific whiting vessels the flexibility to switch between operating as an MS or C/P through December 31, 2020.

Classification

The NMFS Assistant Administrator has determined that this emergency rule is consistent with the Pacific Coast Groundfish FMP, section 305(c) and other provisions of the Magnuson-Stevens Act, the Administrative Procedure Act (APA), and other applicable law. Pursuant to 5 U.S.C. 553(b)(B), the Assistant Administrator for Fisheries finds good cause to waive prior notice and opportunity for public comment because it would be impracticable and contrary to the public interest. This emergency action was recommended by the Council following a letter and comments from members of the public representing the at-sea whiting industry during the March 2020 Council meeting. Providing prior notice through proposed rulemaking and public comment period in the normal rulemaking process would be counter to public interest by delaying implementation of emergency measures intended to provide relief for a time sensitive management problem. The at-sea industry develops extensive plans each year for the Pacific whiting season, and implementing this action as soon as possible maximizes the time available for the at-sea industry to adjust business plans for the year. For the reasons outlined above, NMFS finds it impracticable and contrary to the public interest to provide prior notice and opportunity to comment on these emergency measures.

Additionally, this rule is exempt from the 30-day delayed effectiveness provision of the APA under 5 U.S.C. 553(d)(1) because it relieves a restriction that would place mothership dependent catcher-vessels at an economic disadvantage in the 2020 Pacific whiting fishery. Waiving the 30-day delayed effectiveness for this rule is necessary to allow the at-sea sectors sufficient time to plan operations and maximize flexibility provided by this action. Maintaining the prohibition on vessels operating as both an MS and C/P in the same calendar year would present immediate serious economic impacts without contributing to the economic goals of the Catch Share Program, at-sea Mothership cooperative or Catch-Processor cooperative. Because this rule alleviates a restriction that would otherwise have serious and unnecessary economic harm on non-groundfish trawl vessels, it is not subject to the 30-day delayed effectiveness provision of the APA.

This final rule has been determined to be not significant for the purposes of Executive Order 12866.

This final rule is not an Executive Order 13771 regulatory action because it is not significant under Executive Order 12866.

The Regulatory Flexibility Act does not apply to this emergency rule because the rule is issued without prior notice and opportunity for public comment.

Recordkeeping and Reporting Requirements

This emergency action includes record keeping and reporting requirements previously approved by the Office of Management and Budget (OMB) under OMB Control Number 0648–0573: Expanded Vessel Monitoring System Requirement for the Pacific Groundfish Fishery. For each trip, prior to leaving port a Pacific whiting processing platform must declare whether it will be operating in the MS sector or the C/P sector for that trip. However, this action does not change existing recordkeeping and reporting requirements. Vessels in fisheries off West Coast states must declare through VMS the gear type and sector in which they will participate, including the limited entry midwater trawl and Pacific whiting MS and C/P sectors, as specified in existing groundfish regulations at 50 CFR 660.13(d)(4)(iv)(A). The number of declaration reports the vessel operator is required to submit to NMFS would not change under this action. Therefore, no entity would be subject new reporting requirements under this emergency action.

List of Subjects in 50 CFR Part 660

Fisheries, Fishing, and Indian fisheries.

Dated: June 16, 2020.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 660 is amended as follows:

PART 660—FISHERIES OFF WEST COAST STATES

■ 1. The authority citation for part 660 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.,* 16 U.S.C. 773 *et seq.,* and 16 U.S.C 7001 *et seq.*

■ 2. In § 660.25, add paragraph (b)(4)(vii)(D) to read as follows:

§ 660.25 Permits.

* * * * *

(b) * * *

(4) * * *

(vii) * * *

(D) *Emergency rule creating season flexibility on at-sea processing restrictions.* Effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, vessels may be registered to both a limited entry MS permit and limited entry trawl permit with a C/P endorsement during the same calendar year. Vessels registered to both an MS permit and a C/P endorsed permit may operate in both the at-sea MS sector and C/P sector during the same calendar year, but not on the same trip. Prior to leaving port, a vessel registered under both an MS permit and a C/P endorsed permit must declare through VMS the sector in which it will participate for the duration of the trip, as specified at § 660.13(d)(4)(iv)(A).

* * * * *

■ 3. In § 660.112, add paragraphs (d)(3)(i) and (ii) and (e)(3)(i) and (ii) to read as follows:

§ 660.112 Trawl fishery—prohibitions.

* * * * *

(d) * * *

(3) * * *

(i) Effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, a vessel that was used to fish in the C/P fishery may be used to receive and process catch as mothership in the same calendar year, but not on the same fishing trip.

(ii) [Reserved]

* * * * *

(e) * * *

(3) * * *

(i) Effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, catcher-processor vessels and motherships are exempt from this prohibition.

(ii) [Reserved]

* * * * *

■ 4. In § 660.150, add paragraphs (b)(1)(i)(D), (b)(2)(ii)(B)(*1*) and (*2*), (f)(1)(iii), and (f)(2)(i)(A) and (B) to read as follows:

§ 660.150 Mothership (MS) Coop Program.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(D) Under emergency measures effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, a vessel may operate as both a mothership and a C/P during the 2020 Pacific whiting primary season, but not on the same fishing trip.

* * * * *

(2) * * *

(ii) * * *

(B) * * *

(*1*) Under emergency measures effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, a vessel may operate as both a mothership and C/P during the 2020 Pacific whiting primary season, but not on the same fishing trip. A vessel registered in the same calendar year to operate under both a limited entry MS permit and limited entry permit with a C/P endorsement must declare prior to leaving port the sector in which it will participate for the duration of the trip, as per declaration requirements specified at § 660.13(d)(4)(iv)(A).

(*2*) [Reserved]

* * * * *

(f) * * *

(1) * * *

(iii) Emergency rule creating seasonal flexibility on at-sea processor restrictions. Effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, vessels may operate as both a mothership and a C/P during the 2020 Pacific whiting primary season, but not on the same fishing trip.

(2) * * *

(i) * * *

(A) Emergency rule creating seasonal flexibility on at-sea processing restrictions. Effective June 19, 2020, until December 16, 2020, a vessel registered to an MS permit is exempt from this declaration and may also operate as a catcher-processor during the 2020 Pacific whiting primary season, even if the permit owner previously declared to operate solely as a mothership.

(B) [Reserved]

* * * * *

■ 5. In § 660.160, add paragraphs (b)(1)(i)(D), (b)(1)(ii)(A)(*1*) and (*2*), (e)(1)(iii)(A) and (B), and (e)(2)(i)(A) and (B) to read as follows:

§ 660.160 Catcher/processor (C/P) Coop Program.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(D) Effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, a vessel may operate as both a mothership and a C/P during the 2020 Pacific whiting primary fishing season, but not on the same fishing trip.

* * * * *

(ii) * * *

(A) * * *

(*1*) Under emergency measures effective June 19, 2020, until December 16, 2020, a vessel may operate as both a mothership and C/P during the 2020 Pacific whiting primary season, but not on the same fishing trip. A vessel registered in the same calendar year to operate under both a limited entry MS permit and limited entry permit with a C/P endorsement must declare prior to leaving port the sector in which it will participate for the duration of the trip, as per declaration requirements specified at § 660.13(d)(4)(iv)(A).

(*2*) [Reserved]

* * * * *

(e) * * *

(1) * * *

(iii) * * *

(A) Emergency rule creating seasonal flexibility on at-sea processor restrictions. Effective June 19, 2020, until December 16, 2020, notwithstanding any other section of these regulations, vessels may operate as both a mothership and a C/P during the 2020 Pacific whiting primary season, but not on the same fishing trip.

(B) [Reserved]

* * * * *

(2) * * *

(i) * * *

(A) Emergency rule creating seasonal flexibility on at-sea processing restrictions. Effective June 19, 2020, until December 16, 2020, a vessel registered to a C/P endorsed permit is exempt from this declaration and may also operate as a mothership during the 2020 Pacific whiting primary season, even if the permit owner previously declared to operate solely as a C/P.

(B) [Reserved]

* * * * *

[FR Doc. 2020–13288 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 85, No. 119
Friday, June 19, 2020

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0467; Product Identifier 2020–NM–056–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all The Boeing Company Model 717–200 airplanes. This proposed AD was prompted by a report which indicated that during takeoff, both the captain's and first officer's airspeed indications froze at 80 knots. This proposed AD would require modifying the air data heat (ADH) system to display the proper airspeed indications, testing, and any applicable corrective actions. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 3, 2020.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0467.

Examining the AD Docket

You may examine the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0467; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Eric Igama, Aerospace Engineer, Systems and Equipment Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5388; fax: 562–627–5210; email: *roderick.igama@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0467; Product Identifier 2020–NM–056–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. The FAA will consider all comments received by the closing date and may amend this NPRM because of those comments.

The FAA will post all comments, without change, to *https://www.regulations.gov,* including any personal information you provide. The FAA will also post a report summarizing each substantive verbal contact received about this proposed AD.

Discussion

The FAA has received a report which indicated that during takeoff, both the captain's and first officer's airspeed indications froze at 80 knots. A review of the weather at the departure airport indicated an outside air temperature of 25 degrees Fahrenheit and wind at approximately 20 knots in light snow. The airplane had been waiting in this weather condition for about two hours for de-icing before takeoff. A review of the flight data recorder from this event indicated the airspeed became irregular and could not be read during takeoff until the airplane reached 6,000 feet above ground level. The recorded data also indicated that the pitot tube was possibly blocked with ice.

Pitot tubes blocked by ice, if not addressed, could affect the airspeed indication provided to the flightcrew through the ADH system and result in loss of aircraft controllability.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Boeing Alert Service Bulletin 717–30A0009, dated March 31, 2020. This service information describes procedures for modifying the ADH system by installing new wires between the station (STA) 110 relay panel and the left radio rack, and doing tests and applicable corrective actions until the tests are passed. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

The FAA is proposing this AD because the agency evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Other Relevant Rulemaking

Group 1 airplanes in Boeing Alert Service Bulletin 717–30A0009, dated March 31, 2020, are identified as airplanes with a concurrent requirement: Boeing Alert Service Bulletin 717–30A0003. AD 2007–13–01, Amendment 39–15105 (72 FR 33852, June 20, 2007) (''AD 2007–13–01'') requires accomplishing the actions

specified in Boeing Alert Service Bulletin 717–30A0003, Revision 2, dated November 28, 2006. AD 2007–13–01 requires operators to accomplish the actions (changing the wiring for the air data sensor heating system) within 24 months after July 25, 2007 (the effective date of AD 2007–13–01). The FAA issued that AD to address the display of suspect or erratic airspeed indications during heavy rain conditions, which could reduce the ability of the flightcrew to maintain the safe flight and landing of the airplane. Since AD 2007–13–01 already requires the concurrent service information, the FAA has not included Boeing Alert Service Bulletin 717–30A0003, Revision 2, dated November 28, 2006, as a concurrent requirement in this proposed AD.

Proposed AD Requirements

This proposed AD would require accomplishment of the actions identified as ''RC'' (required for compliance) in the Accomplishment Instructions of Boeing Alert Service Bulletin 717–30A0009, dated March 31, 2020, described previously except for any differences identified as exceptions in the regulatory text of this proposed AD.

For information on the procedures and compliance times, see this service information at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0467.

Costs of Compliance

The FAA estimates that this proposed AD affects 113 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Modification *	12 work-hours × $85 per hour = $1,020	$4,863	$5,883	$664,779

* The modification costs include the costs for testing. The FAA has received no definitive data on the costs of the corrective actions necessary to pass the testing.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

The FAA is issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA has determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2020–0467; Product Identifier 2020–NM–056–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by August 3, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 717–200 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 30, Ice and rain protection.

(e) Unsafe Condition

This AD was prompted by a report which indicated that during takeoff, both the captain's and first officer's airspeed indicators froze at 80 knots. The FAA is issuing this AD to address pitot tubes blocked by ice, which could affect the airspeed indication provided to the flightcrew through the air data heat (ADH) system and result in loss of aircraft controllability.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

Except as specified in paragraph (h) of this AD: At the applicable times specified in paragraph 1.E., ''Compliance,'' of Boeing Alert Service Bulletin 717–30A0009, dated March 31, 2020, do all applicable actions identified as ''RC'' (required for compliance) in, and in accordance with, the Accomplishment Instructions of Boeing Alert Service Bulletin 717–30A0009, dated March 31, 2020.

(h) Exception to Service Information Specifications

Where Boeing Alert Service Bulletin 717–30A0009, dated March 31, 2020, uses the phrase ''the original issue date of this service bulletin,'' this AD requires using ''the effective date of this AD.''

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your

principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *9-ANM-LAACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Los Angeles ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (i)(4)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Related Information

(1) For more information about this AD, contact Eric Igama, Aerospace Engineer, Systems and Equipment Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5388; fax: 562–627–5210; email: *roderick.igama@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110 SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

Issued on June 4, 2020.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–13198 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0544; Airspace Docket No. 19–AAL–93]

RIN 2120–AA66

Proposed Removal of Air Traffic Service (ATS) Route V–482; Alaska

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke one Alaskan Very High Frequency Omnidirectional Range (VOR) Federal Airway (V–482) in the state of Alaska. The proposed removal is required due to tree encroachment on the Johnstone Point VOR/Distance Measuring Equipment (DME) that renders the airway unusable.

DATES: Comments must be received on or before August 3, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590; telephone: 1 (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2020–0544; Airspace Docket No. 19–AAL–93 at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* FAA Order 7400.11D, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11D at NARA, email: *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: Kenneth Ready, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify the route structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify both docket numbers (FAA Docket No. FAA–2020–0544; Airspace Docket No. 19–AAL–93) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2020–0544; Airspace Docket No. 19–AAL–93.'' The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned

with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined during normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019, and effective September 15, 2019. FAA Order 7400.11D is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11D lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is proposing removal of V–482 due to tree encroachment on the Johnstone Point VOR/DME that renders the airway unusable. The Johnstone Point VOR/DME is located on Hinchinbrook Island, with no bridges or roads to access the island except a small landing strip. It is cost prohibitive to mitigate the tree encroachment. There are 3 other airways (V–481, B–25, and T–226) with a more direct route to Gulkana, AK. Additionally, IFR traffic could receive air traffic control (ATC) radar vectors through the area. Visual flight rules pilots who elect to navigate via the airways through the affected area could also take advantage of the adjacent ATS routes or ATC service listed previously.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 to remove Alaskan VOR Federal airway V–482.

V–482: V–482 currently extends between Johnstone Point, AK to Gulkana, AK. This action proposes to remove the entire route.

Alaskan VOR Federal Airways are published in paragraph 6010(b) of FAA Order 7400.11D dated August 8, 2019, and effective September 15, 2019, which is incorporated by reference in 14 CFR 71.1. The Alaskan VOR Federal Airway listed in this document will be subsequently published in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'' prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order 7400.11D, Airspace Designations and Reporting Points, dated August 8, 2019 and effective September 15, 2019, is amended as follows:

Paragraph 6010(b) Alaskan VOR Federal Airways.

* * * * *

V–482 [Remove]

* * * * *

Issued in Washington, DC, on June 12, 2020.

Scott M. Rosenbloom,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–13132 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 166

[Docket No. USCG–2019–0279]

RIN 1625–AC57

Shipping Safety Fairways Along the Atlantic Coast

AGENCY: Coast Guard, DHS.

ACTION: Advance notice of proposed rulemaking.

SUMMARY: The Coast Guard seeks comments regarding the possible establishment of shipping safety fairways (''fairways'') along the Atlantic Coast of the United States identified in the Atlantic Coast Port Access Route Study. This potential system of fairways is intended to ensure that traditional navigation routes are kept free from obstructions that could impact navigation safety.

DATES: Comments and related material must be received by the Coast Guard on or before August 18, 2020.

ADDRESSES: You may submit comments identified by docket number USCG–2019–0279 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email George Detweiler, Coast Guard; telephone 202–372–1566, email *George.H.Detweiler@uscg.mil.*

SUPPLEMENTARY INFORMATION:

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I. Public Participation and Request for Comments

The Coast Guard views public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this potential rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit your comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If you cannot submit your material by using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this advance notice of proposed rulemaking document (ANPRM) for alternate instructions. Documents mentioned in this ANPRM as being available in the docket, and all public comments, will be available in our online docket at *https://www.regulations.gov,* and can be viewed by following that website's instructions. Additionally, if you visit the online docket and sign up for email alerts, you will be notified when comments are posted or if a notice of proposed rulemaking is published.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

The Coast Guard does not plan to hold a public meeting, but we will consider doing so if public comments indicate that a meeting would be helpful. We would issue a separate **Federal Register** notice to announce the date, time, and location of such a meeting.

II. Abbreviations

ACPARS Atlantic Coast Port Access Route Study
AIS Automatic Identification System
BOEM Bureau of Ocean Energy Management
DHS Department of Homeland Security
EEZ Exclusive Economic Zone
FR Federal Register
PARS Port Access Route Study
§ Section
U.S.C. United States Code
UNCLOS United Nations Convention of the Law of the Sea

III. Background

This advanced notice of proposed rulemaking (ANPRM) seeks comments regarding the possible establishment of shipping safety fairways (''fairways'') along the Atlantic Coast of the United States based on navigation safety corridors identified in the Atlantic Coast Port Access Route Study (ACPARS). In this section, we provide background information on fairways, ACPARS, and related port access route studies.

A. Shipping Safety Fairways

Section 70003 of Title 46 United States Code directs the Secretary of the department in which the Coast Guard resides to designate necessary fairways that provide safe access routes for vessels proceeding to and from U.S. ports.[1] Designation as a fairway keeps an area free of fixed structures. This designation recognizes the generally paramount right of navigation over other uses in the designated areas.[2] The Coast Guard is coordinating its possible establishment of fairways[3] along the Atlantic Coast, as well as complementary port approaches and international entry and departure zones, with the Bureau of Ocean Energy Management (BOEM) to minimize the impact on offshore energy leases.

Under 46 U.S.C. 70003, fairways are designated through federal regulations. Regulations governing fairways in 33 CFR part 166 provide that fixed offshore structures are not permitted within fairways because these structures would jeopardize safe navigation. The Coast Guard may establish, modify, or relocate existing fairways to improve navigation safety or accommodate offshore activities such as mineral exploitation and exploration. 46 U.S.C. 70003(e)(3); 33 CFR 166.110.

Before establishing or adjusting fairways, 46 U.S.C. 70003(c)(1) requires the Coast Guard to study potential traffic density and assess the need for safe access routes for vessels. During this process, the Coast Guard considers the views of the maritime community, environmental groups, and other stakeholders to reconcile the need for safe access routes with reasonable waterway uses. *See* 46 U.S.C. 70003(c)(3). The Coast Guard attempts to recognize and minimize each identifiable cost, and balance cost impacts against the needs of safe navigation.

B. Atlantic Coast Port Access Route Study

On May 11, 2011, the Coast Guard chartered the ACPARS workgroup to address the potential navigational safety risks associated with offshore developments and to support future marine planning efforts. The workgroup analyzed the entire Atlantic Coast and focused on waters located seaward of existing port approaches within the U.S. Exclusive Economic Zone (EEZ). The Coast Guard used Automatic Identification System (AIS) data and information from shipping organizations to identify traditional navigation routes.

The Coast Guard announced the availability of the final ACPARS report and requested public comment in the **Federal Register** on March 14, 2016 (81 FR 13307). After considering comments submitted in response to that notice, the Coast Guard determined that the final report was complete as published and announced this finding in the **Federal Register** on April 5, 2017 (82 FR 16510). The final ACPARS report is available in the docket for this rulemaking, in the docket for the ACPARS itself (docket number USCG–2011–0351), and also at *https://www.navcen.uscg.gov/?pageName=PARSReports.*

The ACPARS workgroup identified navigation safety corridors[4] along the

[1] Chapter 700 was added December 4, 2018, by Sec. 401 of *Public Law 115–282,* 132 Stat. 4253. This fairways designation authority was previously reflected in *33 U.S.C. 1223.*

[2] See limitations on such designations in 46 U.S.C. 70003(b).

[3] A *fairway* or *shipping safety fairway* is a lane or corridor in which no artificial island or fixed structure, whether temporary or permanent, will be permitted. Temporary underwater obstacles may be permitted under certain conditions described for specific areas. Aids to navigation approved by the Coast Guard may be established in a fairway. See 33 CFR 166.105(a).

[4] *Navigation Safety Corridor* is a term used in the ACPARS final report for areas required by vessels to safely transit along a customary navigation route under all situations. A navigation safety corridor is not a routing measure and should not be confused with fairways, two-way routes, or traffic separation schemes. The ACPARS recommended that the

Continued

Atlantic Coast that have the width necessary for navigation and sufficient buffer areas.[5] The ACPARS Final Report identified deep draft routes for navigation and recommended that they be given priority consideration over other uses for consistency with the United Nations Convention of the Law of the Sea (UNCLOS).[6] Article 78 of UNCLOS states that, ''[t]he exercise of the rights of the coastal State over the continental shelf must not infringe or result in any unjustifiable interference with navigation and other rights and freedoms of other States as provided for in this Convention.'' [7] The ACPARS final report also identified coastal navigation routes and safety corridors of an appropriate width for seagoing tows.[8] The report recommended that the Coast Guard consider developing the navigation safety corridors it identifies in its Appendix VII—which include ones for deep draft vessels and ones closer to shore for towing vessels—into official shipping safety fairways or other appropriate vessel routing measures.[9] Analysis of the sea space required for vessels to maneuver led to the development of marine planning guidelines that were included in the ACPARS final report and that the workgroup considered when identifying the navigation safety corridors in its Appendix VII.

C. Port Approaches and International Entry and Departure Transit Areas PARS Integral to Efficiency of Possible Atlantic Coast Fairways

On March 15, 2019, the Coast Guard announced a study of port approaches and international entry and departure areas in the **Federal Register** (84 FR 9541).[10] This study will consider access routes from ports along the Atlantic Coast to the navigation safety corridors the ACPARS report recommended that we consider developing as fairways or other appropriate vessel routing measures. The ports to be considered in this study are economically important, support military operations, or have been identified to be strategically critical to national defense. The study will also examine areas associated with customary international trade routes seaward of the navigation safety corridors identified in the ACPARS. The creation of unimpeded transit lanes from the potential fairways outlined in the ACPARS final report to ports, and from those potential fairways to international transit areas, would help ensure the safe and efficient flow of commerce and enhance national security.

Similar to the ACPARS methodology, AIS data and information from shipping organizations will again be used to identify and verify the customary navigation routes that are followed by ships in open-water situations where no obstructions exist. This will allow the Coast Guard to identify areas where structures could jeopardize safe navigation and impede commerce. These studies will provide a mechanism to engage stakeholders with potentially competing uses of the waters of the U.S. EEZ in an effort to reduce impacts to those uses.

IV. Discussion of Action Under Consideration

The Coast Guard is considering establishing fairways, as defined in 33 CFR 166.105, to protect maritime commerce and safe navigation amidst extensive offshore development on the Atlantic Coast.

A. Potential Fairways Identified in the ACPARS

The ACPARS identified nine primary navigation safety corridors that may be suitable for designation as fairways.[11] Three of these are coastwise primary navigation safety corridors which would most likely be used by smaller and slower moving vessels. Initial evaluations suggest that the highest conflict between transiting vessels and alternative undertakings in offshore regions—such as resource exploration and development, production of renewable energy, environmental preservation and protection, and resource conservation and defense—are likely to occur in these near-coast regions. Six offshore fairways were also recommended in the ACPARS final report. The offshore fairways are most likely to be used by larger and faster-moving deep-draft vessels.

B. Descriptions of Potential Fairways

The nine fairways identified by the ACPARS final report are described as follows, all geographic points are based on North American Datum of 1983: [12]

1. The potential St. Lucie to New York Fairway is about 1,350 miles long, approximately 10 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of Miami, FL; Port Everglades, FL; the Port of Virginia; the Port of Baltimore, MD; the Port of Philadelphia, PA; the Port of Wilmington, DE; and the Port of New York and New Jersey. This potential fairway is an area enclosed by rhumb lines joining points at:

THE ST. LUCIE TO NEW YORK FAIRWAY

Latitude	Longitude
38°58′51″ N	074°00′42″ W
39°17′01″ N	073°56′04″ W *
39°45′42″ N	073°54′22″ W *
39°45′42″ N	073°37′40″ W *
39°11′38″ N	073°40′30″ W
38°40′33″ N	073°54′44″ W
36°42′14″ N	074°21′12″ W
34°33′21″ N	074°52′32″ W
33°57′08″ N	075°20′14″ W
32°49′15″ N	076°06′42″ W
31°37′49″ N	076°51′25″ W
29°36′06″ N	078°06′19″ W
27°46′56″ N	079°12′18″ W
27°13′15″ N	079°31′17″ W
27°23′50″ N	079°36′19″ W
27°50′56″ N	079°21′12″ W
29°40′10″ N	078°15′08″ W
31°41′47″ N	077°00′15″ W
32°53′17″ N	076°15′27″ W
34°01′24″ N	075°28′48″ W
34°36′25″ N	075°02′00″ W
36°06′17″ N	074°40′11″ W
36°43′37″ N	074°31′02″ W
38°42′09″ N	074°04′30″ W
38°58′51″ N	074°00′42″ W

* Crosses the Cape Charles to Montauk Point Fairway.

2. The potential Delaware Bay Connector Fairway is about 125 miles long, approximately 10 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of Miami, FL; Port Everglades, FL; Port Canaveral, FL; and the Port of Virginia; the Port of Baltimore, MD; the Port of Philadelphia, PA; the Port of Wilmington, DE; and also to the Port of

identified navigation safety corridors be considered for designation as fairways or other routing measures.

[5] See pages i, 11, and 12, and Appendix VII of the ACPARS Final Report which is available in the docket.

[6] See page i of the ACPARS Final Report.

[7] *Dec. 10, 1982, 1833 U.N.T.S. 397,* 430.

[8] See pages i and 11, and Appendix VII (p. 7) of the ACPARS Final Report.

[9] See pages 12 and 16 of the ACPARS Final Report.

[10] *International Entry and Departure Transit Areas* are navigation routes followed by vessels entering or departing from the United States through an international seaport. International entry and departure transit areas connect navigation safety corridors identified in the ACPARS to the outer limit of the U.S. EEZ. *Port Approaches* are navigation routes followed by vessels entering or departing a seaport from or to a primary transit route. Port approaches link seaports to navigation safety corridors identified in the ACPARS.

[11] United States Coast Guard, ''Atlantic Coast Port Access Route Study: Final Report,'' July 8, 2015, p. 16 and Appendix VII, ''Identification of Alongshore Towing Vessel and Major Deep Draft Routes.''

[12] The North American Datum of 1983 (NAD 83) is the horizontal and geometric control datum for the United States, Canada, Mexico, and Central America. NAD 83 was released in 1986. A geodetic datum or reference frame is an abstract coordinate system with a reference surface (such as sea level) that serves to provide known locations to begin surveys and create maps.

New York and New Jersey, by linking with the St. Lucie to New York Fairway in the vicinity of Cape Henry, VA.[13] This potential fairway is an area enclosed by rhumb lines joining points at:

THE DELAWARE BAY CONNECTOR FAIRWAY

Latitude	Longitude
36°06′17″ N	074°40′11″ W
37°52′59″ N	074°42′50″ W
38°05′39″ N	074°32′53″ W
36°43′37″ N	074°31′02″ W
36°06′17″ N	074°40′11″ W

3. The potential St. Lucie to Chesapeake Bay Nearshore Fairway is about 1,200 miles long, approximately 5 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of Miami, FL; Port Everglades, FL; Port Canaveral, FL; the Port of Jacksonville, FL; Kings Bay, GA; the Port of Brunswick, GA; the Port of Savannah, GA; the Port of Charleston, SC; the Port of Morehead City, NC; the Port of Wilmington, NC; the Port of Virginia,; and the Port of Baltimore, MD. This potential fairway is an area enclosed by rhumb lines joining points at:

THE ST. LUCIE TO CHESAPEAKE BAY NEARSHORE FAIRWAY

Latitude	Longitude
27°10′12″ N	080°03′04″ W
27°22′58″ N	080°07′20″ W
27°44′21″ N	080°10′14″ W
28°38′07″ N	080°21′01″ W
30°56′24″ N	080°45′09″ W
31°22′43″ N	080°34′10″ W
31°31′32″ N	080°29′18″ W
31°49′26″ N	080°17′05″ W
31°57′30″ N	080°06′05″ W
33°20′02″ N	077°50′47″ W
33°28′47″ N	077°35′05″ W
34°18′07″ N	076°23′59″ W
35°09′05″ N	075°17′23″ W
35°35′43″ N	075°19′23″ W
36°15′49″ N	075°35′37″ W
36°35′21″ N	075°43′52″ W
36°35′09″ N	075°38′39″ W
36°17′21″ N	075°29′56″ W
35°36′38″ N	075°13′27″ W
35°07′04″ N	075°11′13″ W
34°14′24″ N	076°20′01″ W
33°24′47″ N	077°31′29″ W
33°15′52″ N	077°47′28″ W
31°53′39″ N	080°02′10″ W
31°46′08″ N	080°12′24″ W
31°28′58″ N	080°24′08″ W
31°19′07″ N	080°30′22″ W
30°55′58″ N	080°40′02″ W
28°38′50″ N	080°16′06″ W
27°45′00″ N	080°05′18″ W

[13] To see an illustration of this linkage, see the Mid Atlantic Chart in the docket.

THE ST. LUCIE TO CHESAPEAKE BAY NEARSHORE FAIRWAY—Continued

Latitude	Longitude
27°23′53″ N	080°02′26″ W
27°11′28″ N	079°58′17″ W
27°10′12″ N	080°03′04″ W

4. The potential St. Lucie to Chesapeake Bay Offshore Fairway is about 1,200 miles long, approximately 10 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of Miami, FL; Port Everglades, FL; Port Canaveral, FL; the Port of Jacksonville, FL; Kings Bay, GA; the Port of Brunswick, GA; the Port of Savannah, GA; Charleston, SC; the Port of Morehead City, NC; the Port of Wilmington, NC; and the Port of Virginia. It is located seaward of the St. Lucie to Chesapeake Bay Nearshore Fairway. This potential fairway is an area enclosed by rhumb lines joining points at:

THE ST. LUCIE TO CHESAPEAKE BAY OFFSHORE FAIRWAY[14]

Latitude	Longitude
27°11′28″ N	079°58′17″ W
27°45′00″ N	080°05′18″ W
28°38′50″ N	080°16′06″ W
30°55′58″ N	080°40′02″ W
31°19′07″ N	080°30′22″ W
31°28′58″ N	080°24′08″ W
31°46′08″ N	080°12′24″ W
31°53′39″ N	080°02′10″ W
33°15′52″ N	077°47′28″ W
33°24′47″ N	077°31′29″ W
34°14′24″ N	076°20′01″ W
35°10′58″ N	075°06′08″ W
35°59′41″ N	075°06′58″ W
36°35′09″ N	075°38′39″ W
36°38′54″ N	075°32′10″ W
36°01′48″ N	074°59′01″ W
35°06′32″ N	074°58′03″ W
34°08′12″ N	076°13′25″ W
33°18′05″ N	077°25′30″ W
33°09′00″ N	077°41′48″ W
31°47′03″ N	079°55′54″ W
31°40′38″ N	080°04′37″ W
31°24′48″ N	080°15′25″ W
31°15′38″ N	080°21′14″ W
30°55′07″ N	080°29′47″ W
28°40′16″ N	080°06′15″ W
27°13′02″ N	079°48′27″ W
27°11′28″ N	079°58′17″ W

[14] Portions of BOEM North Carolina Lease OCS–A 0508, in OCS sub-block 6664D are located within protraction NJ18–11. This potential fairway overlaps a portion of this sub-block by 120 meters at its widest point. This is a renewable energy lease for wind-generated energy. We have placed a chart in the docket that displays specific areas where the potential St. Lucie to Chesapeake Bay Offshore Fairway overlap areas of this lease. The chart is entitled ''Chart Showing Overlap of BOEM North Carolina Lease OCS–A 0508.''

5. The potential Cape Charles to Montauk Point Fairway is about 400 miles long, varies from approximately 5 to 10 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of New York and New Jersey; the Port of Philadelphia, PA; the Port of Wilmington, DE; and the Port of Baltimore, MD. This potential fairway is an area enclosed by rhumb lines joining points at:

THE CAPE CHARLES TO MONTAUK POINT FAIRWAY[15] [16]

Latitude	Longitude
37°07′24″ N	075°40′59″ W
37°32′04″ N	075°25′53″ W
37°50′37″ N	075°12′06″ W
37°59′42″ N	075°01′23″ W
38°04′21″ N	074°54′04″ W
38°21′43″ N	074°41′01″ W †
38°26′49″ N	074°37′11″ W †
38°30′53″ N	074°34′07″ W
38°44′16″ N	074°32′52″ W ††
38°50′05″ N	074°32′20″ W ††
38°58′12″ N	074°31′35″ W
39°07′51″ N	074°31′24″ W
39°24′49″ N	074°13′47″ W
39°40′32″ N	074°02′55″ W
39°45′42″ N	073°54′22″ W
39°54′39″ N	073°39′43″ W
40°02′33″ N	073°26′46″ W ‡
40°10′45″ N	073°13′18″ W ‡
40°21′01″ N	072°56′29″ W ‡
40°23′05″ N	072°53′05″ W ‡
40°29′17″ N	072°42′55″ W
40°31′21″ N	072°39′31″ W
40°51′49″ N	072°05′57″ W
41°01′54″ N	071°32′17″ W
40°31′42″ N	072°21′59″ W ‡
40°29′38″ N	072°25′24″ W ‡
40°23′25″ N	072°35′36″ W
40°21′21″ N	072°39′00″ W ‡
40°05′14″ N	073°05′37″ W ‡
39°57′08″ N	073°19′03″ W

[15] Portions of BOEM Maryland Lease OCS–A 0490, in the following OCS blocks and sub-blocks are located within protraction NI18–05: 6726K, 6726N, 6726O, 6726P, 6775, 6776, 6777E, 6777I, 6777J, 6777M, 6777N, 6825, 6826, 6827A, 6827B, 6827C, 6827E, 6827F, 6827H, 6827I, and 6827M. This is a renewable energy lease for wind-generated energy. We have placed a chart in the docket that displays specific areas where the potential Cape Charles to Montauk Point Fairway overlap areas of this lease. The chart is entitled ''Chart Showing Overlap of BOEM Maryland Lease OCS–A–0490, and New Jersey Leases OCS–A–0498 and OCS–A–0499.''

[16] Portions of BOEM New Jersey Leases OCS–A 0498 and OCS–A 0499 (123 sub-blocks) were found to overlap with this potential fairway. One hundred of these 123 sub-blocks were identified in BOEM's ATLW–5 Final Sale Notice (FSN) as potentially being not available for development. These are renewable energy leases for wind-generated energy. We have placed a chart in the docket that displays specific areas where the potential Cape Charles to Montauk Point Fairway overlap areas of these leases. The chart is entitled ''Chart Showing Overlap of BOEM Maryland Lease OCS–A–0490, and New Jersey Leases OCS–A–0498 and OCS–A–0499.''

THE CAPE CHARLES TO MONTAUK POINT FAIRWAY [15] [16]—Continued

Latitude	Longitude
39°45′42″ N	073°37′40″ W ‡‡
39°38′23″ N	073°54′48″ W ‡‡
39°36′12″ N	073°59′57″ W
39°22′41″ N	074°09′36″ W
39°06′27″ N	074°26′26″ W
38°58′02″ N	074°26′35″ W
38°50′42″ N	074°27′16″ W ††
38°43′39″ N	074°27′56″ W ††
38°29′41″ N	074°29′14″ W
38°23′38″ N	074°33′47″ W †
38°18′03″ N	074°37′58″ W †
38°01′44″ N	074°50′13″ W
37°56′49″ N	074°57′58″ W
37°48′15″ N	075°08′04″ W
37°30′12″ N	075°21′28″ W
37°05′38″ N	075°36′30″ W
37°07′24″ N	075°40′59″ W

† Crosses the Off Delaware Bay Southern Approach Cutoff Fairway.
†† Crosses the Off Delaware Eastern Approach Cutoff Fairway.
‡ Crosses Traffic Separation Scheme.
‡‡ Crosses the St. Lucie to New York Fairway.

6. The potential Chesapeake Bay to Delaware Bay: Eastern Approach Cutoff Fairway is about 200 miles long, approximately 10 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of Virginia; the Port of Baltimore, MD; the Port of Philadelphia, PA; and the Port of Wilmington, DE. This potential fairway is an area enclosed by rhumb lines joining points at:

THE CHESAPEAKE BAY TO DELAWARE BAY: EASTERN APPROACH CUTOFF FAIRWAY

Latitude	Longitude
36°57′07″ N	075°35′54″ W
37°04′32″ N	075°29′41″ W
38°04′39″ N	074°43′07″ W
38°14′35″ N	074°35′05″ W *
38°20′25″ N	074°30′22″ W *
38°41′54″ N	074°13′57″ W
38°42′09″ N	074°04′30″ W
38°05′39″ N	074°32′53″ W
37°52′59″ N	074°42′50″ W
37°19′37″ N	075°08′42″ W
36°52′24″ N	075°34′11″ W
36°57′07″ N	075°35′54″ W

* Crosses the Off Delaware Bay Southern Approach Cutoff Fairway.

7. The potential Off Delaware Bay: Southern Approach Cutoff Fairway is about 20 miles long, approximately 10 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of Miami, FL; Port Everglades, FL; Port Canaveral, FL; and the Port of Virginia; the Port of Baltimore, MD; the Port of Philadelphia, PA; and the Port of Wilmington, DE, by linking with the St. Lucie to New York Fairway in the vicinity of Cape Henlopen, DE.[17] This potential fairway is an area enclosed by rhumb lines joining points at:

THE OFF DELAWARE BAY: SOUTHERN APPROACH CUTOFF FAIRWAY

Latitude	Longitude
38°14′35″ N	074°35′05″ W
38°18′03″ N	074°37′58″ W
38°21′43″ N	074°41′01″ W
38°27′00″ N	074°45′24″ W
38°28′48″ N	074°39′18″ W
38°23′38″ N	074°33′47″ W
38°20′25″ N	074°30′22″ W
38°14′35″ N	074°35′05″ W

8. The potential Off Delaware Bay: Eastern Approach Cutoff Fairway is about 50 miles long, approximately 10 nautical miles wide, and includes the customary route taken by vessels transiting between the Port of Miami, FL; Port Everglades, FL; Port Canaveral, FL; by linking the St. Lucie to New York Fairway in the vicinity of Cape May, NJ; or the Port of Virginia and the Port of Baltimore, MD; and the Port of Philadelphia, PA; and the Port of Wilmington, DE, by linking with the Chesapeak Bay to Delaware Bay Eastern Approach Cutoff in the vicinity of Cape May.[18] This potential fairway is an area enclosed by rhumb lines joining points at:

THE OFF DELAWARE BAY: EASTERN APPROACH CUTOFF FAIRWAY

Latitude	Longitude
38°41′54″ N	074°13′57″ W
38°43′39″ N	074°27′56″ W *
38°44′16″ N	074°32′52″ W *
38°44′27″ N	074°34′21″ W
38°50′05″ N	074°32′20″ W
38°50′42″ N	074°27′16″ W
38°53′30″ N	074°04′39″ W
38°58′51″ N	074°00′42″ W
38°42′09″ N	074°04′30″ W
38°41′54″ N	074°13′57″ W

* Crosses the Cape Charles to Montauk Point Fairway.

9. The potential Long Island Fairway is about 150 miles long, approximately 5 nautical miles wide, and includes the customary route taken by vessels transiting between the Long Island Sound Eastern Entrances; the Port of Groton, CT; the Port of New Haven Harbor, CT; and the Port of New York and New Jersey. This potential fairway is an area enclosed by rhumb lines joining points at:

THE LONG ISLAND FAIRWAY

Latitude	Longitude
40°28′15″ N	073°38′59″ W
40°31′52″ N	073°39′54″ W
40°35′59″ N	073°11′39″ W
41°06′36″ N	071°30′06″ W
41°03′06″ N	071°28′15″ W
40°32′12″ N	073°11′28″ W
40°28′15″ N	073°38′59″ W

You can find three charts depicting and labelling the locations of these potential fairways in the docket. The Northern Area chart illustrates all nine. As numbered in the tables above, the Mid-Atlantic Area chart illustrates potential fairways 1, 2, 3, 4, 5, and 8, and the Southern Area chart illustrates potential fairways 1, 3, and 4. These charts only show the portion of the potential fairway in the area covered by the chart. Additionally, two charts depicting and labelling the locations of overlaps between the proposed fairways and existing BOEM leases are contained in the docket: Chart Showing Overlap of BOEM Maryland Lease OCS–A–0490, and New Jersey Leases OCS–A–0498 and OCS–A–0499; and Chart Showing Overlap of BOEM North Carolina Lease OCS–A 0508.

C. Study of Potential Port Approach Fairways

As announced in the **Federal Register** on March 15, 2019, the Coast Guard is also conducting Port Access Route Studies in accordance with 46 U.S.C. 70003(c) to determine whether or not fairways should be established or whether other routing measures for existing port approaches would be more appropriate. 84 FR 9541. These port approach fairways would provide access to the potential fairways identified in the ACPARS final report and in this ANPRM, would be important to the safe and efficient movement of ships and cargo, and would be critical to sustaining interstate and international commerce.

Each Coast Guard district commander will study the ports in their district that are economically significant, support military operations, or are critical to national defense. For an example of this multi-Coast Guard District effort, see a recent notice announcing PARS for approaches to the Chesapeake Bay, Virginia (84 FR 65398, November 27, 2019). Results of each PARS will be published separately in the **Federal Register** by the district commander.

Like the ACPARS, these PARS will use AIS data and information from

[17] To see an illustration of this linkage, see the Northern Area Chart in the docket.

[18] To see an illustration of this linkage, see the Northern Area Chart in the docket.

stakeholders to identify and verify customary navigation routes. Each PARS will identify potential conflicts involving alternative activities in the studied area, such as wind energy generation and offshore mineral exploration and exploitation.

The following 23 U.S. ports are initially under consideration for PARS:

PORTS UNDER CONSIDERATION FOR PARS
Kennebec River/Bath, ME.
Port of Portland, ME.
Port of Portsmouth, NH.
Port of New Bedford, MA.
Port of Boston, MA.
Narragansett Bay, RI.
Long Island Sound Eastern Entrances.
Port of Groton, CT.
Port of New Haven, CT.
Port of New York and New Jersey, including Port Elizabeth and Newark.
Port of Philadelphia, PA, including Camden-Gloucester City, NJ, Port of Wilmington, DE.
Port of Baltimore, MD.
Port of Virginia, including Norfolk, Newport News and Hampton Roads, VA.
Port of Morehead City, NC.
Port of Wilmington, NC.
Port of Charleston, SC.
Port of Savannah, GA.
Port of Brunswick, GA.
Kings Bay, GA.
Port of Jacksonville, FL.
Port Canaveral, FL.
Port Everglades, FL.
Port of Miami, FL.

D. International Entry and Departure Transit Areas

We also announced studies related to international entry and departure transit areas seaward of the potential fairways in the U.S. EEZ. 84 FR 9541. International entry and departure transit areas are integral to the safe, efficient, and unimpeded flow of ships. Fairways established based on the studies of international entry and departure transit areas would be used by vessels coming from a foreign port and transiting to a coastwise or offshore fairway or directly to a port approach leading to a U.S. port. It is important that fairways for regions of the U.S. EEZ between principal international ports and the United States are considered to ensure the safe and direct movement of ships and cargo between international origins and destinations. Each route or fairway would be a link in a chain connecting ports in the United States and abroad, and each link should be as robust and effective as the routes identified in the ACPARS.

V. Information Requested

Public participation will help the Coast Guard decide whether to establish coastwise and offshore fairways and, if so, how to balance ship routing with offshore development activities and other uses. The Coast Guard seeks public comments, positive or negative, on the impacts that the nine potential fairways under consideration may have on navigational safety and on other activities in these offshore areas to aid us in developing a proposed rule and the supporting analyses. Where possible and pertinent, please provide sources, citations and references to back up or justify your responses. Also, for all pertinent responses, please provide a detailed explanation of how you arrived at this conclusion and the underlying assessment that supports your conclusion. Finally, for all numerical responses please provide us with sufficient information to recreate your calculations.

We seek public feedback on the following questions:

1. Do the nine potential fairways provide safe and efficient routes for vessels transiting to and from international ports to the United States? Why or why not? If not, what would you recommend instead?

2. Are the ACPARS-potential fairways described in this ANPRM, or similar ones, necessary for ensuring a safe and orderly passage for vessels transiting among U.S. domestic ports of call? Why or why not? Please explain your answer, including your specific comments on how the fairways described in this ANPRM would affect maritime traffic patterns, navigational safety and access to ports.

3. Are there any positive or negative impacts of not establishing the nine fairways noted in this ANPRM? If so, please describe them.

4. If these potential fairways are established, what persons, entities, or organizations would be positively or negatively impacted? In other words, which groups of people, businesses, or industries (maritime and non-maritime) would be positively or negatively impacted by these potential fairways?

5. What other offshore uses may be positively or negatively affected by the potential fairways? Please include specific locations, potential impact, and associated costs or benefits. Please also describe the safety significance of the potential fairways on the activity.

6. Do the nine potential fairways unduly limit offshore development? If so, is there a cost model or structure that should be considered for analysis? What are the limitations of the cost model? If so, why do you believe the proposal would limit offshore development and what specific development would it limit?

7. From an environmental perspective, would the potential fairways described in this ANPRM negatively impact living marine resources? If so, which marine resources would be impacted and how? What measures within the Coast Guard's jurisdiction should be considered to avoid, minimize, or mitigate any such impacts?

8. Beyond the environmental impacts mentioned in question 7, are there any other positive or negative environmental impacts from these potential fairways? If so, please provide detail as to how and what would be impacted. To the degree possible, please provide the data, impact assessments, and other pertinent background information necessary to understand and reproduce your results.

9. What mitigation measures within the Coast Guard's jurisdiction could be used to relieve the economic and safety impacts of the potential fairways on other offshore uses? What are the expected costs and associated benefits of the suggested mitigation measures?

10. Are there additional measures that should be considered to improve safety or relieve an economic burden imposed by these potential fairways? What are the expected costs and associated benefits of the suggested additional measures?

11. Are there other variables that should be considered in developing this system of potential fairways? If so, please indicate particular issues and the specific areas to which they pertain.

13. Besides the Coast Guard's noted intention and purpose of this rulemaking, what positive aspects would this proposal produce for the safety of maritime transportation?

14. Have there been any offshore developments built or installed in the past 10 years that have impacted traffic patterns, navigational safety, or maritime commerce? If so, were the net impacts positive or negative? Please provide a detailed explanation of how you arrived at this conclusion.

15. Please offer any other comments or suggestions that may improve this initiative.

Please submit comments or concerns you may have in accordance with the ''Public Participation and Request for Comments'' section above.

This notice is issued under the authority of 46 U.S.C. 70003 and 5 U.S.C. 552.

Dated: June 10, 2020.

R.V. Timme,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy.

[FR Doc. 2020–12910 Filed 6–18–20; 8:45 am]

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DEPARTMENT OF COMMERCE

Patent and Trademark Office

37 CFR Parts 2 and 7

[Docket No. PTO–T–2019–0027]

RIN 0651–AD42

Trademark Fee Adjustment

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of proposed rulemaking.

SUMMARY: The United States Patent and Trademark Office (Office or USPTO) proposes to set or adjust certain trademark fees, as authorized by the Leahy-Smith America Invents Act (AIA), as amended by the Study of Underrepresented Classes Chasing Engineering and Science Success Act of 2018 (SUCCESS Act). The proposed fees are intended to recover the prospective aggregate costs of future strategic and operational trademark and Trademark Trial and Appeal Board (TTAB or Board) goals (based on workload projections included in the USPTO fiscal year (FY) 2021 Congressional Justification), including associated administrative costs. The proposed fees will further USPTO strategic objectives by: Better aligning fees with costs, protecting the integrity of the trademark register, improving the efficiency of agency processes, and ensuring financial sustainability to facilitate effective trademark operations. Before a final rule is issued, the USPTO will consider the state of the U.S. economy, the operational needs of the agency, and public comments submitted pursuant to this rulemaking. The USPTO will make adjustments as necessary to the substance and timing of any final rule based on all of these considerations.

DATES: Written comments must be received on or before August 3, 2020.

ADDRESSES: The USPTO prefers that comments be submitted electronically via email to *TMFRNotices@uspto.gov.* Written comments may also be submitted by mail to Commissioner for Trademarks, P.O. Box 1451, Alexandria, VA 22313–1451, attention Catherine Cain; by hand delivery to the Trademark Assistance Center, Concourse Level, James Madison Building-East Wing, 600 Dulany Street, Alexandria, Virginia 22314, attention Catherine Cain; or via the Federal eRulemaking Portal. See the Federal eRulemaking Portal website (*https://www.regulations.gov*) for additional instructions on providing comments via the portal. All comments submitted directly to the USPTO or provided on the Federal eRulemaking Portal should include the docket number (PTO–T–2019–0027).

Although comments may be submitted by postal mail, the USPTO prefers to receive comments electronically because the Office may more easily share such comments with the public. The USPTO prefers that comments submitted electronically be in plain text, but they also may be submitted in portable document format (PDF) or a word processing file format (DOC or DOCX). Comments not submitted electronically should be submitted on paper in a format that facilitates convenient digital scanning into PDF.

The comments will be available for public inspection on the USPTO's website at *http://www.uspto.gov,* on the Federal eRulemaking Portal, and at the Office of the Commissioner for Trademarks, Madison East, Tenth Floor, 600 Dulany Street, Alexandria, Virginia 22314. Because comments will be made available for public inspection, information that is not desired to be made public, such as an address or phone number, should not be included.

FOR FURTHER INFORMATION CONTACT: Catherine Cain, Office of the Deputy Commissioner for Trademark Examination Policy, at 571–272–8946, or by email at *TMPolicy@uspto.gov.*

SUPPLEMENTARY INFORMATION: The USPTO conducted a fee assessment in January 2019 that formed the basis for this regulatory process to propose adjusting and setting new trademark user fees. While trademark-related costs of operations have risen, trademark fees have not changed since January 2017. The revenue and workload assumptions in this notice of proposed rulemaking (NPRM) are based on the assumptions found in the FY 2021 Congressional Justification. However, projections of aggregate revenues and costs are based on point-in-time estimates, and the circumstances surrounding these assumptions can change quickly. Notably, since the FY 2021 Congressional Justification was published, fee collections have been lower than anticipated, in part due to lower than expected application filings as a result of the COVID–19 outbreak.

The USPTO is also mindful of the current difficulties many USPTO users are experiencing as a result of the pandemic. The USPTO has undertaken many efforts to provide various types of relief, including deadline extensions and fee postponements. Ultimately, the goal of the USPTO is to ensure not only that businesses and entrepreneurs can weather this storm, but that they can hit the ground running once it passes.

The USPTO anticipates that the earliest any proposed trademark fee changes could take effect is October 2020. Before a final rule is issued, the USPTO will consider the state of the U.S. economy, the operational needs of the agency, and public comments submitted pursuant to this NPRM. The USPTO will make adjustments as necessary to the substance and timing of any final rule based on all of these considerations.

As part of the multi-year fee-setting process, the Trademark Public Advisory Committee (TPAC) held a public hearing at the USPTO on September 23, 2019. The Office considered and analyzed all comments, advice, and recommendations received from the TPAC before publishing this NPRM. The USPTO is now moving to the next step in the process. This NPRM proposes changes to fees and also proposes new fees in order to solicit public comment.

Purpose: The USPTO protects consumers and provides benefits to businesses by effectively and efficiently carrying out the trademark laws of the United States. As a fee funded agency, appropriate fees are critically important for the USPTO to maintain the quality and timeliness of examination and other services, and to stabilize and modernize aging information technology (IT) infrastructure. The fee schedule proposed in this rulemaking will recover the USPTO's aggregate estimated future costs and ensure the USPTO can achieve strategic and operational goals, such as effectively using resources to maintain low trademark pendency and high quality, fostering business effectiveness (ensuring quality results for employees and managers), stabilizing and modernizing trademark IT systems, continuing programs for stakeholder and public outreach, enhancing operations of the TTAB, and ensuring financial sustainability to facilitate effective trademark operations.

Section 10 of the AIA authorizes the Director of the USPTO (Director) to set or adjust by rule any fee established, authorized, or charged under the Trademark Act of 1946, 15 U.S.C. 1051

et seq., as amended (the Trademark Act or the Act) for any services performed by, or materials furnished by, the Office. *See* section 10 of the AIA, Public Law 112–29, 125 Stat. 284, 316–17, as amended by the SUCCESS Act, Public Law 115–273, 132 Stat. 4158. Section 10 of the AIA prescribes that trademark fees may be set or adjusted only to recover the aggregate estimated costs to the USPTO for processing, activities, services, and materials relating to trademarks, including administrative costs to the USPTO with respect to such trademark and TTAB operations. However, this authority includes the flexibility to set individual fees to advance key policy objectives. Thus, the Director may set individual fees at, below, or above their respective associated costs, while taking into account the aggregate estimated costs to the USPTO.

Section 10 of the AIA also establishes certain procedural requirements for setting or adjusting fee regulations, including public hearings by, and input from, the TPAC. *See* section 10(c) of the AIA, Public Law 112–29, 125 Stat. at 317. Accordingly, on August 28, 2019, the Director notified the TPAC of the USPTO's intent to set or adjust trademark fees and submitted a preliminary trademark fee proposal with supporting materials, available at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

On September 23, 2019, the TPAC held a public hearing in Alexandria, Virginia. Transcripts of this hearing and comments submitted to the TPAC in writing are available for review at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

The TPAC subsequently released a report (TPAC report), dated October 31, 2019, regarding the preliminary proposed fees. The report recognized that fee adjustments are warranted to achieve strategic and operational goals and evaluated the various proposed fees in view of the USPTO's stated rationales for setting or adjusting fees for certain services and activities, as well as the public comments regarding the fee proposals. The TPAC report expressed support for an increase in fees that would support USPTO operations by recovering costs and maintaining a sufficient operating reserve but raised concerns regarding some of the proposed fee increases and their potential impact on customers. The TPAC report offered recommendations to address these concerns. The report is available at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

After careful consideration of the comments and recommendations provided in the TPAC report and in testimony by users at the public hearing, and keeping in mind the fee setting goals of this proposed rule, the USPTO has made various changes to the initial fee proposal, including the withdrawal of proposed fees for filing a motion for summary judgment and for filing a request for suspension and remand and the proposed increase in the fee for filing an affidavit under section 15 of the Act. Other fees in the preliminary proposal were retained or modified, as reflected in this proposed rule and explained in further detail below. The USPTO seeks comments on the fee proposals, including in relation to the current environment.

The USPTO estimates, based on the assumptions found in the FY 2021 Congressional Justification, that the additional aggregate revenue derived from the proposed fee schedule will recover the future costs of implementing strategic and operational goals, including the cost of necessary IT stabilization and modernization activities, with the expectation that the proposal will gradually build the operating reserve to achieve sustainable funding that will mitigate the risk of immediate unplanned financial disruptions. Under this proposal, based on the assumptions found in the FY 2021 Congressional Justification, the Office estimates reaching the optimal six-month trademark operating reserve level in FY 2025.

Summary of major provisions: The USPTO proposes to set or adjust trademark fees codified in 37 CFR parts 2 and 7. Fees are proposed to be increased for all application filing types (*i.e.,* paper applications, applications filed via the Trademark Electronic Application System (TEAS), and requests for extension of protection under section 66(a) of the Trademark Act, 15 U.S.C. 1141f). The proposed per-class fee increases range from $25 for a TEAS Plus application to $150 for a paper application. Fee increases of $100 per class are also proposed for filing affidavits or declarations of use or excusable non-use under section 8 or section 71 of the Act (section 8 or section 71 affidavits), 15 U.S.C. 1058, 1141k. As described in further detail below, these proposed increases address policy considerations related to ensuring a more accurate register as well as reflecting increased processing costs to the Office in handling these filings.

This proposed rule creates two levels of fees for petitions, one for petitions to the Director under §§ 2.146 and 2.147 and a lower fee for a petition to revive an abandoned application under § 2.66. Currently, the fees for these petitions are $200 if filed on paper and $100 if filed through TEAS. The USPTO proposes to set the fee for petitions under §§ 2.146 and 2.147 at $350 if filed on paper and $250 if filed through TEAS. The fees for a petition to revive under § 2.66 are proposed to be set at $250 if filed on paper and $150 if filed through TEAS. These proposed fees take into account the different processing costs of these filings.

New fees are proposed for requests for reconsideration under § 2.63(b)(3) that are filed more than three months after the issue date of a final action (at $500 for paper filing and $400 for filing through TEAS or the Electronic System for Trademark Trials and Appeals (ESTTA)). Requests for reconsideration are documents filed after a final action that respond to the outstanding refusals or requirements (*see* Trademark Manual of Examining Procedure (TMEP) § 709.05). They include an applicant's request to the TTAB, filed within six months of the issue date of a final action, whether filed with or after a notice of appeal and whether it is denominated as a request for reconsideration or is captioned as something else, such as a request for remand. It does not include any filing with the TTAB after the applicant has filed its appeal brief (*see* Trademark Trial and Appeal Board Manual of Procedure (TBMP) § 1209.04). This new proposed fee, imposed when the filing is more than three months after the issue date of a final action, is designed to encourage applicants to submit these filings earlier in the response period and to recover costs associated with processing all requests for reconsideration.

A new $50 fee is also proposed for filing a letter of protest, along with new regulations that codify letter-of-protest procedures. The new proposed fee and procedures are designed to help offset processing costs and deter the filing of unsupported or irrelevant letters of protest, while not discouraging the filing of relevant, well-supported letters of protest. The new regulatory section is based on existing, longstanding procedures for letters of protest, which are currently set forth in the TMEP, as well as the procedures set out in the patents rules in 37 CFR 1.290 and 1.291 and the Manual of Patent Examining Procedure (MPEP) governing third-party submissions concerning pending applications, which serve a function similar to letters of protest.

The Office proposes a new fee structure to encourage registrants to proactively perform sufficient due

diligence before filing a section 8 or section 71 affidavit to determine the goods or services for which the registered mark is no longer in use and delete them from the registration. The USPTO herein proposes two fee levels for amendments to registrations to delete goods, services, and/or classes. The USPTO proposes a $0 fee if the only amendment made in a request under section 7 of the Act (section 7 request), 15 U.S.C. 1057(e), that is filed prior to submission of a section 8 or section 71 affidavit is the deletion of goods, services, and/or classes. As always, no additional fee would be incurred for section 8 or section 71 affidavits that specify fewer than all of the goods or services listed in the registration when the affidavit is filed, which results in the deletion of goods or services not included in the affidavit from the registration. However, if goods, services, and/or classes are deleted in a section 7 request, a response to Office action, or a voluntary amendment after submission and prior to acceptance of a section 8 or section 71 affidavit, the proposed per-class fee of $250 for submissions filed through TEAS and $350 for submissions permitted to be filed on paper would be charged. To implement the new fee requirement, corresponding new regulations are also proposed at §§ 2.161(c) and 7.37(c). In addition, the USPTO proposes to revise the section titles and restructure §§ 2.161 and 7.37 to set out the requirements for section 8 and section 71 affidavits more clearly. Except for the new provision regarding the fee required for deletions made after submission and prior to acceptance of the affidavit, the substantive text of §§ 2.161 and 7.37 has not otherwise been revised.

Finally, as discussed below, 16 fees related to TTAB filings are established or adjusted in this proposed rule: 10 fees would be increased for initiating a proceeding, and six new filing fees would be established. The new and adjusted fees are generally designed to recover more of the costs of TTAB procedures, to reduce the extent to which they are subsidized by trademark fee collections, and to advance policy objectives. The USPTO also proposes to revise § 2.114(a) to provide that a partial refund of the filing fee for a petition to cancel may be made in cases involving only a nonuse or abandonment claim, when default judgment is entered in the case, where there was no appearance by a defendant, and where no filings were made other than the petition to cancel.

Rulemaking goals and strategies: Consistent with federal fee setting standards, the Office conducted a biennial review of fees, costs, and revenues that began in 2019 and found that fee adjustments are necessary to provide the resources needed to improve trademark operations and to implement the USPTO 2018–2022 Strategic Plan (Strategic Plan). As a result, the proposed fee adjustments outlined in this proposed rule directly align with the Office's strategic goals and key objectives as outlined in this section. Consistent with the USPTO's strategic goals and obligations under the AIA, the overall objective of this rulemaking is to ensure the fee schedule generates sufficient revenue to recover the prospective aggregate costs of trademark and TTAB strategic improvements and operations, including the associated administrative costs. Fees must be set at levels projected to cover the cost of future budgetary requirements and maintain an operating reserve at a sufficient level. Trademark applications in FY 2019 represented filings in a record number of over 673,000 classes of goods/services. However, in the last two recessions, new application filings declined (2001, by −21.0%; 2002, by −12.7%; and 2009, by −12.3%), demonstrating the sensitivity of trademark filings, and therefore total revenues, to general economic conditions. So far, the current economic downturn has produced similar estimates of trademark application filing declines. However, during ordinary economic times, application filings generally have increased by an average historical rate of between 7% and 8% per year. USPTO anticipates a return to this historical trend as trademark applicants return to expected activities. To ensure its ability to keep pace with demand, the USPTO is in the midst of a multi-year IT systems and infrastructure upgrade, which is critical to the future of the U.S. trademark registration system and represents a significant cost to the Office.

The current fee schedule is insufficient to meet future budgetary requirements to: (1) Meet the expenses that will result from projected filings based on expectations for fee revenues; (2) recover the costs necessary to support trademark and TTAB operations and administrative services; (3) make necessary investments in IT systems, intellectual property (IP) policy, and USPTO programs related to trademark and TTAB operations; and (4) achieve optimal operating reserve levels to ensure financial sustainability. Budgetary requirements have increased by 22% from FY 2019 to FY 2020 to address unplanned pay raises, additional review for potential fraud, post-registration audits, agency administrative operations, and continued investments in IT that require additional funding beginning in FY 2020. Without the proposed fee adjustments, based on the assumptions found in the FY 2021 Congressional Justification, budgetary requirements would exceed revenues and available operating reserve balances beginning in FY 2022 through FY 2025 (*see* Table 1).

TABLE 1—TRADEMARK FINANCIAL OUTLOOK WITHOUT PROPOSED FEES—FY 2021–FY 2025

	Dollars in millions				
	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Projected Fee Collections	$367	$390	$412	$430	$447
Other Income	6	6	6	6	6
Total Projected Fee Collections and Other Income	373	396	418	436	453
Budgetary Requirements	419	460	462	478	497
Funding to (+) and from (−) Operating Reserve	−46	−64	−44	−42	−44
EOY Operating Reserve Balance	26	(38)	(81)	(123)	(167)
Over/(Under) $75M Minimum Level	(49)	(113)	(156)	(198)	(242)
Over/(Under) Optimal Level	(184)	(268)	(312)	(362)	(415)

Table 2 below shows the available revenue and operating reserve balances by fiscal year, including the proposed fee rates in the projected fee collections. The numbers in the table below can be found in the FY 2021 Congressional

Justification and were developed in late calendar year 2019, prior to the COVID–19 outbreak. Under current circumstances, it is difficult to predict what the actual numbers will be. However, since USPTO was projecting insufficient funding even during an economic expansion (*see* Table 1) and the trademark financial outlook has only worsened since the onset of the pandemic, USPTO still believes that a fee increase will be necessary to put the Office on a sustainable financial path.

TABLE 2—TRADEMARK FINANCIAL OUTLOOK INCLUDING PROPOSED FEES—FY 2021–FY 2025

	Dollars in millions				
	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025
Projected Fee Collections	$445	$472	$498	$519	$539
Other Income	6	6	6	6	6
Total Projected Fee Collections and Other Income	451	478	504	525	545
Budgetary Requirements	419	460	462	478	497
Funding to (+) and from (−) Operating Reserve	31	18	42	47	48
EOY Operating Reserve Balance	103	121	163	211	259
Over/(Under) $75M Minimum Level	28	46	88	136	184
Over/(Under) Optimal Level	(107)	(109)	(68)	(28)	10

Additional information on estimated costs can be found in the USPTO FY 2021 Congressional Justification at *https://www.uspto.gov/about-us/performance-and-planning/budget-and-financial-information,* which includes two revenue estimates, one based on the current fee schedule and another based on this proposed rule (*see* Appendix IV: USPTO Fees—Change from FY 2020 PB to FY 2021 PB).

The USPTO, as a fully fee-funded agency, retains an operating reserve to ensure sufficient financial resources are available to support and promote public confidence in the U.S. IP system. The operating reserve enables the USPTO to maintain operations by absorbing and responding to immediate and temporary changes in its economic and operating environments or circumstances, such as unexpected economic downturns, reducing the risk for short-term financial actions and providing the security for long-term strategic investments, such as IT development projects that are crucial to operations and customer support. An adequate operating reserve also allows the USPTO to continue serving its users in the event of a short-term lapse in congressional appropriations or a sudden economic downturn. Trademark filings exhibit a strong connection to domestic and global economic activity, responding quickly to economic shocks, as experienced in the 2001–2002 and 2009 recessions and most recently in 2020. The operating reserve is the primary tool to mitigate the sudden impact of these unforeseen events.

Another fee setting goal of this rulemaking is to set individual fees to further key IP protection policy objectives while taking into account the cost of a particular service. The USPTO seeks to enhance trademark protection for IP rights holders by offering application-processing options and promoting IP protection strategies.

Aligning fees with costs: The first fee setting policy consideration is to set and adjust trademark fees to more closely align those fees with the costs of providing the relevant services. The overall goal is to achieve total cost recovery from fee collections for trademark and TTAB operations, including associated administrative services. In determining which fees to set or adjust, this proposed rule targets changes to the category of fees where the gap between the cost of the service and the current fee rate is the greatest, and addresses policy objectives. Application filing fees, petition fees, and TTAB fees do not fully cover the costs of processing and examination for those services. Instead, these costs are recovered or subsidized from fees paid for intent-to-use and post-registration maintenance filings that return more than the costs of processing such filings. For example, using FY 2019 earned revenue compared to costs or expenses, application filing fees recovered 65% of expenses, petition (trademark processing) fees recovered 50% of expenses, and TTAB fees recovered just 31% of expenses (*see* Table 3).

TABLE 3—EARNED REVENUE VS. EXPENSE BY TRADEMARK PRODUCT

Trademark products	FY 2019 earned revenue	FY 2019 expense	FY 2019 variance	Earned revenue vs. expense or cost recovery (%)
Application Filings	$190,457,284	$291,678,207	($101,220,923)	65
Intent to Use/Use Fees	49,885,175	17,154,805	32,730,370	291
Trademark Processing Fees	2,619,600	5,212,800	(2,593,200)	50
Maintaining Exclusive Rights	79,942,987	13,991,853	65,951,134	571
Madrid Protocol	4,294,675	1,006,834	3,287,841	427
Other Trademark Fees	10,571,283	8,902,431	1,668,852	119
Trademark Trial and Appeal Board	8,452,900	27,633,083	(19,180,183)	31
Total	346,223,905	365,580,013	(19,356,109)	

The proposed fee schedule would increase the percentage of fee revenues for application filings by 21%, for petition filings by 101%, and for TTAB filings by 58% overall, thereby increasing the cost recovery for these services (*see* Table 4). If the proposed fee schedule were implemented, based on the assumptions found in the FY

2021 Congressional Justification, the USPTO projects that trademark fee collections in total would increase by an average of 21% per year, or $77 million, to $92 million per year over the five-year planning period as compared to the baseline (*see* Table 5).

TABLE 4—INCREASE IN CUMULATIVE REVENUE, BY PRODUCT

Trademark products	Projected cumulative revenue, FY 2021–2025		Increase (%)
	Current fee rates (baseline)	NPRM fee rates	
Application Filings	$1,078,986,925	$1,300,666,600	21
Maintaining Exclusive Rights	517,806,550	659,008,548	27
Intent to Use/Use	292,887,325	292,887,325	0
Madrid	29,201,550	42,258,078	45
TTAB	52,602,400	83,164,508	58
Petition	17,508,400	35,147,450	101
Other Processing Fees	58,391,905	58,391,905	0
Total	2,047,385,055	2,471,524,413	21

TABLE 5—ANNUAL INCREASES IN AGGREGATE REVENUE

	FY 2021	FY 2022	FY 2023	FY 2024	FY 2025	Average
Aggregate Revenue—Baseline	$367,001,856	$390,327,171	$412,360,921	$430,391,196	$447,303,911	$409,477,011
Aggregate Revenue—NPRM	$443,946,233	$471,660,715	$497,754,151	$519,026,516	$539,136,798	$494,304,883
$ Increase	$76,944,377	$81,333,544	$85,393,230	$88,635,320	$91,832,887	$84,827,872
% Increase	21.0%	20.8%	20.7%	20.6%	20.5%	20.7%

Estimated revenues are based on adjustments made from public comments included in this rulemaking.

Protecting the integrity of the trademark register: The second fee setting policy consideration is to set or adjust fees to improve the accuracy of the trademark register. The accuracy of the trademark register as a reflection of marks that are actually in use in commerce in the U.S. for the goods/services identified in the registrations listed therein serves a critical purpose for the public and for all registrants. An accurate register allows the public to rely on the register to determine potential trademark rights. By registering trademarks, the USPTO has a significant role in protecting consumers, as well as providing important benefits to American businesses, by allowing them to strengthen and safeguard their brands and related investments. The public relies on the register to determine whether a chosen mark is available for use or registration. When a person's search of the register discloses a potentially confusingly similar mark, that person may incur a variety of resulting costs and burdens, such as those associated with investigating the actual use of the disclosed mark to assess any conflict, initiating proceedings to cancel the registration or oppose the application of the disclosed mark, engaging in civil litigation to resolve a dispute over the mark, or changing business plans to avoid the use of that person's chosen mark. In addition, such persons may incur costs and burdens unnecessarily if a registered mark is not actually in use in commerce in the U.S. or is not in use in commerce in connection with all the goods/services identified in the registration. An accurate and reliable trademark register helps avoid such needless costs and burdens.

This proposed rule sets and adjusts fees to encourage actions by trademark filers that help facilitate more efficient processing and the prompt conclusion of application prosecution by assessing fees for requests for reconsideration filed more than three months after a final Office action and for second and subsequent extension requests to file appeal briefs. In addition, filings that may result in a less accurate register, including post-registration filings to maintain registrations that may include goods or services for which the mark is no longer in use, are among those filings targeted under this objective. The new fee structure for requests for reconsideration and requests to delete goods, services, and/or classes from a registration would protect the integrity of the register and the efficiency of the process by incentivizing both more timely filings and proactive action by applicants and registrants. The increased efficiencies realized through the proposed rule will benefit all applicants and registrants by allowing registrations to be granted sooner and more efficiently by removing unused marks and unsupported goods and services from the register.

Improving the efficiency of USPTO processes: The third fee setting policy consideration pertains to improving the efficiency of the trademark and TTAB processes. To that end, this proposed rule targets changes to fees that will administratively improve application and appeal processing by incentivizing more complete and timely filings and prosecution. For example, TEAS Plus, the lowest-cost TEAS application filing option, has more stringent initial application requirements and thus tends to result in a more complete application, which expedites processing, shortens pendency, minimizes manual processing and the potential for data-entry errors, and is thus more efficient for both the filer and the USPTO. While the per-class fee for TEAS Plus would increase by $25 to $250 under this proposal, the per-class fee for TEAS Standard, which has less stringent initial application requirements, is proposed to increase by $75 to $350, resulting in a difference of $100 in the per-class fees of the respective filing options (double the current difference of $50), providing an increased financial incentive to choose the TEAS Plus filing option.

Ensuring financial sustainability to facilitate effective trademark operations: The fourth fee setting policy consideration pertains to ensuring

sufficient revenue to recover the aggregate costs of trademark operations in future years. Additional fees are necessary to fund the multi-year project to upgrade IT systems and infrastructure, while also maintaining a sufficient operating reserve balance to ensure sustainable funding that will mitigate the risk of unplanned financial disruptions that could threaten operations and planned investments. Operating reserves are intended to mitigate operational risk caused by a lack of financial resources. The USPTO defines an optimal balance and a minimum acceptable balance for each operating reserve—the patent operating reserve and the trademark operating reserve. The optimal balances set the goal for building and maintaining the operating reserves. The optimal trademark reserve has been determined to be six months of operating or budgetary requirements based on a review of environmental risk factors and financial volatility. Risks related to spending and fee collections are analyzed, considering the likelihood and consequence of each and its impact to financial stability, in determining the optimal reserve levels.

An increase in fees will provide a stable financial foundation to fulfill the USPTO mission and maintain performance. The budgetary requirements of the USPTO are comprised of substantial fixed costs, which may require increased fee rates to ensure revenue sufficient to recover aggregate costs. The trademark fee schedule proposed here, based on the assumptions found in the FY 2021 Congressional Justification, will produce sufficient revenue to recover the aggregate costs of trademark and TTAB operations, including executing USPTO strategic goals, policy objectives, and initiatives in FY 2020 and beyond; creating a better and fairer cost-recovery system that balances subsidizing costs to encourage broader usage of IP rights-protection mechanisms and participation by more trademark owners; promoting a strong incentive for more efficient filing behaviors; and protecting the federal trademark register as a reliable indicator of marks in use in commerce. The projections of aggregate revenues and costs are based on point-in-time estimates and assumptions that are subject to change. There is considerable uncertainty in estimating both fee collections and budgetary requirements in ordinary times, and even more so now. In addition to the pandemic, a number of other risks could materialize (*e.g.,* even lower applications volumes, decreased renewals, the recompetitions of major contracts, lease renewals, changing assumptions about Presidentially authorized or congressionally mandated employee pay raises, etc.) that could change the USPTO's budgetary outlook. These estimates are refreshed annually in the formulation of the USPTO's Budget, and the USPTO continues to gain new data as the pandemic unfolds. As noted above, in addition to these dynamics factors, the budgetary requirements of the USPTO are comprised of substantial fixed costs, which could also influence increased fee rates to ensure aggregate revenue recovers aggregate costs.

Individual fee rationale: Based on the assumptions found in the FY 2021 Congressional Justification, the USPTO projects the aggregate revenue generated from current and proposed trademark fees will recover the prospective aggregate costs of its trademark and TTAB operations and associated administrative services. However, each individual proposed fee is not set at an amount equal to the estimated cost of performing the activities related to the fee. Instead, as described above, some of the proposed fees are set to address increases in budgetary requirements as well as balance several key policy factors, and executing these policy factors through the trademark fee schedule is consistent with the goals and objectives outlined in the Strategic Plan. Once the cost recovery and key policy objectives are considered, fees are set at, above, or below individual cost-recovery levels for the service provided. Additional details on the cost methodologies used to derive the historical fee unit expenses can be found in ''USPTO Fee Setting—Activity Based Information and Trademark Fee Unit Expense Methodology'' at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

Trademark application filing fees: This proposed rule would increase all application filing fees by varying amounts. The filing fee for a paper trademark application would increase by $150, from $600 per class to $750 per class. The TEAS Plus application filing fee would increase by $25, from $225 per class to $250 per class. The TEAS Standard application filing fee would increase by $75, from $275 per class to $350 per class. The fee for filing an application under section 66(a) of the Act would increase by $100, from the equivalent of $400 per class, as paid in Swiss francs, to the equivalent of $500 per class, as paid in Swiss francs.

Also proposed is a decrease of the processing fee from $125 to $100 per class for failure to meet the filing requirements under § 2.22(a) for a TEAS Plus application. Thus, if the processing fee is required in a TEAS Plus application, the resulting per-class fee would equal the per-class fee for a TEAS Standard application. If a decrease in the processing fee were not enacted, the per-class fee for an application initially filed as TEAS Plus would exceed the fee for TEAS Standard, creating a disincentive to choose TEAS Plus, which, as noted above, tends to be more efficient for both filers and the USPTO.

Fees for paper trademark filings: This proposed rule maintains the cost differential for all paper filings to better align fees with costs, with all trademark processing fees for paper filings set $100 to $200 higher than the corresponding electronic filing fees (per class, when applicable). Overall, it is more costly for the USPTO to process paper filings than electronic filings, and that cost is not recovered by the current fees for paper filings. Raising the fees for paper filings will help offset the higher processing costs and move the USPTO closer to total cost recovery.

At present, most filings are submitted electronically. For example, in FY 2019, less than 0.02% of initial applications were filed on paper. Moreover, a final rule published on July 31, 2019 (84 FR 37081), which became effective on February 15, 2020 (84 FR 69330), requires all applicants, registrants, and parties to TTAB proceedings to file electronically through TEAS all trademark applications based on section 1 and/or section 44 of the Act, 15 U.S.C. 1051, 1126, and all submissions filed with the USPTO concerning applications or registrations, with limited exceptions. Thus, an increase to paper filing fees would have no impact on the vast majority of applicants and registrants who are required to file documents electronically.

Other trademark processing fees: The USPTO also proposes to increase certain other trademark processing fees to further key policy goals. This proposed rule sets out increases to the fees for petitions to the Director as well as section 8 and section 71 affidavits. In addition, this proposed rule sets new fees and procedural regulations for filing a letter of protest and new fees for filing a request for reconsideration more than three months after a final Office action, and for deleting goods, services, and/or classes from a registration after submission and prior to acceptance of a section 8 or section 71 affidavit.

(1) Petitions to the Director in trademark matters: The USPTO proposes to establish two levels of fees for petitions. This proposed rule would increase the current fee for filing a

petition to the Director for petitions filed under §§ 2.146 or 2.147. It would also establish a separate fee for petitions to revive filed under § 2.66 that would be less than the fee for petitions filed under §§ 2.146 or 2.147. The proposed fees are intended to facilitate effective trademark operations. The fee for electronically filing a petition to the Director under §§ 2.146 or 2.147 would increase from $100 to $250, and the fee for filing on paper would increase from $200 to $350. The fee for electronically filing a petition to revive an abandoned application under § 2.66 would increase from $100 to $150, and the fee for filing on paper would increase from $200 to $250.

Generally, petitions under § 2.146 extend the trademark registration and post-registration processes by introducing additional processing and examination into the timeline, which may lead to applications and registration maintenance documents remaining pending for longer periods of time, potentially blocking others. By increasing fees for these filings, the USPTO would discourage misuse of the process through unnecessary filings that delay prosecution of an application or registration maintenance document. The comments provided in the TPAC report received by the USPTO also generally supported the increases to the fees for petitions to the Director under § 2.146 and a smaller increase for petitions under § 2.66.

(2) Section 8 or section 71 affidavits: Fees from post-registration filings have historically been set to recover more than the costs of processing the filings. The fees are used to offset cost recovery for application processing and examination as well as TTAB proceedings and appeals. In general, fewer post-registration maintenance filings are made by pro se and foreign registrants. Compounding this issue, pro se and foreign owners comprise a growing share of new applicants. Based on recent pre-pandemic trends, the overall percentage of registrations being maintained is decreasing. Therefore, the USPTO anticipates that it will face a continuing decrease in revenue from maintenance filings going forward if adjustments are not made. Increasing fees for section 8 and section 71 affidavits is necessary to continue to provide cost-recovery offsets and allow other fees to remain below their individual unit costs.

Increased fees are also proposed for these filings in part because of the post-registration audit program, which was implemented as a result of the 2012 Post-Registration Proof-of-Use Pilot Program. During the pilot program, section 8 or section 71 affidavits for 500 registrations were reviewed as to actual use of the marks in connection with the goods and/or services identified in the registrations in order to assess the accuracy and integrity of the trademark register. The findings of the pilot program demonstrated a need for ongoing measures for additional review of these filings on a permanent basis. Since codifying the authority to require additional information and evidence concerning the use of registered marks in connection with section 8 and 71 maintenance filings in 2017 (82 FR 6259), the USPTO has conducted additional reviews of the actual use of the marks in 8,276 section 8 or section 71 affidavits through January 1, 2020. In more than 50% of the registrations undergoing the additional review, the registrations have either been removed from the register or had goods or services deleted, resulting in a more accurate trademark register. The proposed fee increases would support the cost of this additional review.

(3) Letters of protest in trademark applications: The USPTO proposes a new $50 fee for filing a letter of protest. A letter of protest allows a third party to bring to the attention of the USPTO evidence bearing on the registrability of a mark in a pending application. The letter-of-protest procedure exists for the administrative convenience of the Office and is not a substitute for the statutory opposition and cancellation procedures available to third parties who believe they would be damaged by registration of the involved mark. It is intended to aid in examination without causing undue delay and without compromising the integrity and objectivity of the ex parte examination process, which involves only the applicant and the Office. For this reason, the protestor is not permitted to submit legal arguments, contact the examining attorney assigned to the subject application, or participate in any Office proceedings relating to the protest or the application to which it is directed. The limited involvement of the third party ends with the filing of the protest. The questions of whether or not evidence is relevant to a refusal ground appropriate in ex parte examination, a refusal should be made, or a registration will issue are matters for the Office to determine during the ex parte examination process that occurs between the applicant and the Office acting on behalf of the public.

Filing a letter of protest currently requires no fee, but the Office incurs costs associated with the work of reviewing and processing each letter. The filing volume for letters of protest has steadily increased in recent years, with the USPTO receiving 2,726 in FY 2017, 3,480 in FY 2018, and 4,106 in FY 2019. Thus, letters of protest continue to generate increasing additional expenses, and under the current schedule where letters can be filed without any fee, these expenses would likely only increase in the future.

Many preliminary commenters expressed concerns about this proposed fee, noting that letters of protest provide a valuable service to the USPTO and should not be discouraged by requiring a fee for submission. The USPTO recognizes that, in many cases, letters of protest assist the Office in obtaining evidence to support refusals of registration, helping to avoid marks that are ineligible for registration being placed on the trademark register. Currently, all letters of protest must be reviewed in accordance with the procedures set out in TMEP § 1715 to determine whether: (1) The issue raised is an appropriate subject for a letter of protest; (2) the protest was submitted before or after publication of the subject application; (3) the nature, amount, and format of the evidence complies with the requirements set out in the TMEP; and (4) the submitted evidence meets the relevant standard for entry in the record and review by the examining attorney. If the letter of protest is filed before publication of the subject application, the evidence must be relevant to the identified ground(s) for refusal, and the entry of evidence into the application record merely serves to bring the submitted evidence to the attention of the examining attorney, who determines whether a refusal or requirement should be raised or ultimately made final. If the letter of protest is filed on the date of, or within 30 days after, publication of the subject application, the evidence must establish a prima facie case for refusal on the identified ground(s), such that failure to issue a refusal would likely result in the issuance of a registration in violation of the Act or regulations under parts 2 or 7 of this section.

In FY 2019, the evidence in approximately 25% of pre-publication letters of protest and 94% of post-publication letters of protest was not forwarded to the examining attorney. This suggests that a significant portion of filings do not contain relevant information or evidence, or are otherwise unnecessary. These filings generate additional costs without a corresponding benefit.

Seeking to balance the commenters' concerns with the need to recover some costs, the proposed fee of $50 is set at a level high enough to partially offset processing costs and deter the filing of

unsupported or irrelevant filings, but low enough so as not to discourage the filing of relevant, well-supported letters of protest. This fee level is also consistent with the TPAC recommendations in that it falls within the $20 to $100 fee range suggested by the TPAC report.

In connection with this proposed fee, the USPTO also proposes a new regulatory section, at 37 CFR 2.149, which sets out the procedures for letters of protest. The new regulatory section is based on the existing longstanding procedures for letters of protest, which are currently set forth in the TMEP, with appropriate modifications that more closely align the procedures with those for similar third-party submissions and protests in patent applications under 37 CFR 1.290 and 1.291 and as set out in MPEP §§ 1134 and 1901. This action is being undertaken at this time due to the rising volume of letters of protest in recent years, which has resulted in the need to codify procedures for submission of such protests in the regulations.

Under the procedures set forth in the proposed regulatory text at § 2.149, a letter of protest must be timely filed through TEAS and must include: (1) The proposed fee; (2) the serial number of the pending application that is the subject of the protest; (3) an itemized evidence index that includes identification of the documents, or portions of documents, being submitted as evidence and a concise factual statement of the relevant grounds for refusal of registration appropriate in ex parte examination that each identified item supports; and (4) a clear and legible copy of the supporting evidence identified in the evidence index. As noted above, if the letter of protest is filed before publication of the subject application, the evidence must be relevant to the identified ground(s) for refusal. If filed on or within 30 days after publication of the subject application, the evidence must establish a prima facie case for refusal on the identified grounds, such that failure to issue a refusal or make a requirement would likely result in issuance of a registration in violation of the Act or regulations under parts 2 or 7 of this section.

The letter-of-protest process is intended to provide an opportunity for the protestor to efficiently and effectively provide relevant evidence in support of the proposed legal grounds for refusing registration of the application identified in the submission. It is inappropriate for the protestor to ''dump'' evidence and leave it to the Office to determine its possible relevance. Therefore, an index is required for all submissions listing the documents submitted as evidence and the ground(s) for refusal each item of evidence supports. In addition, the proposed procedures also require that the submission not total more than 10 items of evidence in support of a specified ground of refusal and more than 75 total pages of evidence without a detailed and sufficient explanation that establishes the special circumstances that necessitate providing more than 10 items of evidence per refusal ground or more than 75 total pages of evidence. This requirement encourages the submission of evidence that is succinct, not duplicative, and limited to the most relevant evidence. It should be a rare situation in which more than 10 items of evidence or 75 total pages of evidence is necessary to support the proposed legal grounds for refusal. However, some examples of situations that might constitute such special circumstances are when: (1) A subject application includes multiple classes and the protestor needs to provide evidence of relatedness of the goods/services for all classes in the application; (2) evidence submitted to support a refusal for descriptiveness consists of fewer than 10 discrete items, but each item comprises multiple pages, totaling more than 75 pages; or (3) a protestor raises more than one ground for refusal and the evidence necessary to support all grounds raised totals more than 10 items or 75 pages.

A letter of protest submitted by a third party is not made part of the application record to preserve the ex parte nature of examination. If the USPTO determines that the submission complies with the proposed regulations, only the specified grounds for refusal and the provided evidence relevant to the grounds for refusal would be included in the application record for consideration by the examining attorney. A third party filing a letter of protest will not receive any communication from the USPTO relating to the submission other than acknowledgement that it has been received by the Office and notification of whether the submission is found to be compliant or non-compliant. Also, the Office will not accept amendments to a non-compliant submission that was previously filed or requests to reconsider a compliance determination. Rather, the third party may submit a new letter of protest that is compliant if the time period for submitting a letter of protest has not closed. A protestor does not, by the mere filing of a protest, obtain a ''right'' to argue the protest before the Office. As noted above, the questions of whether or not evidence is relevant to a refusal ground appropriate in ex parte examination, a refusal will be made, or a registration will issue are matters for the Office to determine as part of the ex parte examination process that occurs between the applicant and the Office acting on behalf of the public. Therefore, the proposed procedures also provide that: (1) The Office's determination whether to include submitted evidence in the record of an application would be final and non-petitionable, (2) the limited involvement of the third party ends with the filing of the letter of protest, and (3) the third party may not directly contact the examining attorney assigned to the application.

(4) Requests for reconsideration in trademark applications: The USPTO proposes a new fee for a request for reconsideration filed more than three months, but within six months, after the issue date of a final action or with a petition to revive an abandoned application. The proposed fee is $400 for a TEAS submission and $500 for a paper submission. No fee would be incurred for requests filed within three months of the issue date of a final action.

As noted above, a request for reconsideration is a document filed within six months of the issue date of a final action that responds to the outstanding refusals or requirements. In some cases, it may also be filed with a petition to revive an application abandoned for failure to respond to a final action within the six-month response period. In such cases, the request for reconsideration would be filed more than six months after the issue date of the final action. It also includes an applicant's request to the TTAB, filed within six months of the issue date of a final action, whether filed with or after a notice of appeal and whether it is denominated as a request for reconsideration or is captioned as something else, such as a request for remand (*see* TMEP § 709.05 and TBMP § 1209.04). In some cases, multiple requests are filed. Examining attorneys must review the request(s) for reconsideration and take appropriate action, which frequently involves issuing a subsequent Office action that discusses any new evidence submitted with the request. In some circumstances, Office procedure requires the examining attorney to issue a new refusal, with a new six-month response deadline.

Because requests for reconsideration require additional examination, they generate additional costs for the USPTO. In addition, requests for reconsideration

lengthen the examination process, thereby increasing overall examination pendency, particularly when filed later in the response period or after the filing of a notice of appeal and prior to the expiration of six months from the issue date of the final action. The proposed fee is intended to recover costs associated with requests for reconsideration and encourage applicants to submit these filings earlier in the response period for the final action.

The TPAC report expressed concerns that the proposed fee was too high and could discourage the filing of requests for reconsideration, which often resolve issues and avoid the need for an appeal. The TPAC report therefore suggested that the Office consider not charging a fee for requests filed within three months of the final Office action. The USPTO has considered and adopted the suggestion from the TPAC report.

(5) Deletion of goods, services, and/or classes from registrations: The USPTO initially proposed fees for each good or service deleted as a result of a post-registration audit or an adverse TTAB finding of $200 if submitted on paper or $100 if submitted through TEAS. The TPAC report expressed concerns regarding how the fees would be assessed because it could be difficult to determine what is a separate good or service in some situations, and some registrants with extensive goods and services could potentially be assessed onerous fees to delete specific goods or services within a class. The TPAC report supported a fee for the deletion of goods or services as a result of a post-registration audit if the proposed fees were charged per each class in which goods or services are deleted. The report also supported a no-fee option for voluntarily cancelling goods or services from a registration at any time prior to an audit. The TPAC report did not support the proposed new fees following an adverse TTAB finding, stating that it would be unclear when the fee would apply and how it would be implemented.

Currently, amendments to registrations may be made by filing a section 7 request for amendment or correction of a registration for $100, if submitted through TEAS, or $200, if filed on paper. After consideration of the TPAC response, the USPTO proposes to set a $0 fee for a section 7 request that is filed through TEAS prior to the submission of a section 8 or section 71 affidavit and consists only of a request to delete specified goods, services, and/or classes. As noted above, no additional fee would be incurred for section 8 or section 71 affidavits that specify fewer than all of the goods or services listed in the registration when the affidavit is filed, which results in the deletion of goods or services not included in the affidavit from the registration. However, if goods, services, and/or classes are deleted in a section 7 request, a response to Office action, or a voluntary amendment filed after submission and prior to acceptance of a section 8 or section 71 affidavit, the USPTO proposes a new fee of $250 per class, if filed through TEAS, or $350 per class, if a paper filing is permitted, for deleting goods, services, and/or classes from the registration.

The proposed no-fee option would be available to, and the $250 (or $350) per-class fee would be assessed against, all registrants. Thus, they are not related to a post-registration proof-of-use audit or a TTAB finding. The proposals are intended to improve the accuracy and integrity of the register by encouraging all registrants to proactively perform sufficient due diligence before filing a section 8 or section 71 affidavit to determine the goods, services, and/or classes for which the registered mark is no longer in use and delete them from the registration.

TTAB fees: The Office proposes to set or adjust 16 TTAB-related fees: 10 fees would be increased for initiating a proceeding, and six new filing fees would be established. The TTAB would also obtain discretion to grant a refund of a portion of the filing fee for a petition to cancel.

(1) Existing fees at the TTAB: In an attempt to address better alignment of fees with the costs of providing TTAB services, the initial fee proposal presented to the TPAC included an across-the-board increase in TTAB fees for petitions for cancellation, notices of opposition, and ex parte appeals of $200 per class. The TPAC report generally supported an increase in filing fees for petitions to cancel and notices of opposition on the basis that the proposed increases are justified on a cost-recovery rationale, noting the high average unit cost for these proceedings. The TPAC report and some commenters observed that many petitions to cancel and notices of opposition are decided by default judgment. Commenters objecting to the preliminary proposed fee increase for petitions to cancel expressed their belief that the increase could deter filings based on abandonment or nonuse, which would impact the USPTO's objective of removing marks from the trademark register that are no longer being used.

In consideration of these observations, the Office proposes an increase of $200 per class for petitions for cancellation and notices of opposition. The Office also proposes to amend § 2.114(a) to allow the USPTO discretion to refund a portion of the petition fee in cases of default judgment where there is no appearance by a defendant and no filings are made other than the petition to cancel, reflecting reduced work needed on the part of the TTAB; consequently, this amount is in excess of that required to offset TTAB costs. The resulting lower net fee for a petition to cancel that meets these characteristics also furthers the policy goal of not discouraging the filing of petitions to cancel by petitioners with knowledge that a registered mark is no longer in use, or was never put to use, and therefore should be removed from the register. The refund would be in the amount of $200. Compared to cancellation proceedings, an opposition is less likely to be determined by default judgment based on abandonment or nonuse, because the applicants involved tend to be actively engaged with the USPTO through the examination process up to the opposition, and the Office is not proposing to allow for refunds concerning notices of opposition.

The TPAC report expressed some concern about the preliminary proposed increase for filing a notice of ex parte appeal, noting that, for various reasons, many appeals are resolved before an appeal brief is filed. Some commenters expressed their belief that the proposed increase would negatively impact small businesses and individuals. In consideration of the comments, the Office herein proposes to increase the filing fees for a notice of appeal to $325 per class if filed on paper and $225 per class if filed through ESTTA, which is a $25 increase (rather than the $200 increase to both fees in the preliminary proposal).

Fee increases are proposed for filing requests for an extension of time to file an opposition. Under the current structure, applicants may request: (1) An initial 30-day extension for no fee, (2) a subsequent 60-day extension for a fee of $100 for electronic filings and $200 for paper filings, and (3) a final 60-day extension for a fee of $200 for electronic filings and $300 for paper filings. The Office proposes to maintain this tiered structure with an increase of $100 for the first 60-day electronic extension and $200 for the final 60-day electronic extension. Paper-filed extension requests are proposed to increase by $200 for each filing. The current and proposed filing fees are per application, not per class.

These proposed fees are designed to yield efficiencies by encouraging

potential opposers to make decisions regarding filing an opposition sooner, thus reducing delays to applicants whose filings have been made the subject of extensions of time to oppose. Additionally, by encouraging earlier decisions to initiate proceedings, the uncertainty experienced by these applicants will be ameliorated by having their applications proceed to determination on the merits sooner. This should also help to protect the integrity of the trademark register by encouraging timely decisions and filings to ensure that the rights of other applicants and the public are not adversely affected.

The TPAC report expressed some concerns over the proposed increase in these fees, noting that extension fees were implemented about three years prior and that raising them may result in a higher number of oppositions being filed because the decision is rushed. Some commenters were concerned that the proposed increases would impact smaller entities and deter parties from working to settle prior to filing a notice of opposition. Given that the USPTO also proposes increasing the fee for the notice of opposition, the USPTO believes that the proposed fees for extensions of time to oppose should encourage earlier calculated decisions based on all of the available information, including fees. Furthermore, the tiered fee structure reduces the likelihood of potential opposers using the extensions merely to delay registration of pending applications.

Approximately two-thirds of the cost of TTAB operations is subsidized currently by revenue from other trademark processing fees. The proposed increases in these TTAB fees will not recover the full costs of TTAB operations but will increase revenues by 7% to bring fees closer to the costs in order to provide better alignment between costs and fees and bring the TTAB closer to full cost recovery. In general, the TPAC commenters supported most of the proposed fee increases with some modification because of the recognized costs for processing and the cost differential.

Finally, these fees will help offset TTAB processing costs. In FY 2019, the USPTO received 20,502 requests for extensions of time to file a notice of opposition. It is customary for requests that delay processing of records, such as extensions, to incur a fee, which offsets costs associated with processing the filing, as well as the overall cost of processing appeals and trials. These fees are necessary to help attain primary Office goals of recovering the aggregate costs of operations, along with key policy considerations, such as encouraging efficient processing.

(2) Fees for filing an appeal brief at the TTAB: The Office proposes an increase in the fee for filing a notice of appeal of $25 per class, based on inflation, and the establishment of new fees for filing an appeal brief of $300 per class if filed on paper and $200 per class if filed through ESTTA. In its initial proposal submitted to the TPAC, the Office had proposed raising the current fees for filing a notice of appeal to the TTAB by $200 per class and also instituting new fees for filing briefs in a notice of appeal. The TPAC supported maintaining the current fees for filing a notice of appeal and the proposed new fees for filing an appeal brief. This modification addresses the TPAC report recommendations to apply the majority of the aggregate increases in appeal fees to the costs incurred when an appeal brief is filed, which increases the likelihood that the appeal will have to be decided on the merits.

(3) Fees for filing requests for extension of time to file an appeal brief at the TTAB: New fees are proposed for second and subsequent requests for extensions of time to file an appeal brief. The proposed fees are $200 per application if filed on paper and $100 per application if filed through ESTTA. No fee is proposed for a first request for extension of time to file an appeal brief.

In its report on the initial proposal, the TPAC expressed support for the proposed new fees. Some commenters objected to the proposed new fees, expressing their belief that minimal USPTO resources are required to process such requests and that they increase the overall costs to smaller entities. These proposed fees yield efficiencies by encouraging applicants to move forward with their appeals, resulting in a quicker resolution of the appeal, the pendency of which can adversely impact the rights of other applicants and registrants. Implementing a two-tiered fee structure minimizes costs to smaller entities, as there is no fee for a first request for extension of time to file the appeal brief.

(4) Fees for oral hearing at the TTAB: A new fee is proposed for a request for an oral hearing. The proposed fee is $500 per proceeding.

In its report on the initial proposal, the TPAC expressed support for the proposed new fee, noting that the TTAB incurs significant costs in conducting oral hearings and all users subsidize the few parties requesting oral hearings. Some commenters opposed the fee due to the impact on small businesses and individuals. Oral hearings are not requested in the vast majority of cases before the TTAB. They are optional and are most useful when cases involve complex issues, a complex record, or highly technical goods and services. The proposed fee would help offset the costs of scheduling and conducting the hearing, as well as the maintenance of equipment for remote participation.

Discussion of Proposed Rule Changes

The USPTO proposes to revise § 2.6(a)(1)(i) to increase the per-class fee for filing an initial application on paper from $600 to $750.

The USPTO proposes to revise § 2.6(a)(1)(ii) to increase the per-class fee for filing an application under section 66(a) of the Act from $400 to $500.

The USPTO proposes to revise § 2.6(a)(1)(iii) to increase the per-class fee for filing a TEAS Standard application from $275 to $350.

The USPTO proposes to revise § 2.6(a)(1)(iv) to increase the per-class fee for filing a TEAS Plus application from $225 to $250.

The USPTO proposes to revise § 2.6(a)(1)(v) to decrease the processing fee under § 2.22(c) from $125 to $100 per class.

The USPTO proposes to add § 2.6(a)(11)(iii) to establish a fee of $0 for filing a section 7 request to amend a registration through TEAS prior to submission of a section 8 or section 71 affidavit and that consists only of the deletion of goods, services, and/or classes.

The USPTO proposes to revise § 2.6(a)(12)(i) and (ii) to increase the per-class fee for filing a section 8 affidavit from $225 to $325 for a paper submission and from $125 to $225 for a TEAS submission.

The USPTO proposes to add § 2.6(a)(12)(iii) and (iv) to establish fees for the deletion of goods, services, and/or classes after submission and prior to acceptance of a section 8 affidavit. The proposed § 2.6(a)(12)(iii) and (iv) set the per-class fee at $350 for a paper submission and $250 for a TEAS submission.

The USPTO proposes to revise § 2.6(a)(15) to establish separate fees for petitions to the Director under §§ 2.146 or 2.147 and petitions to revive an abandoned application under § 2.66. The proposed revisions to § 2.6(a)(15)(i) and (ii) set the fee for filing a petition to the Director under §§ 2.146 or 2.147 at $350 for a paper submission and $250 for a TEAS submission. The proposed addition of § 2.6(a)(15)(iii) and (iv) set the fee for filing a petition to revive an abandoned application under § 2.66 at

$250 for a paper submission and $150 for a TEAS submission.

The USPTO proposes to revise § 2.6(a)(16)(i) and (ii) to increase the per-class fee for filing a petition to cancel from $500 to $700 for a paper submission and from $400 to $600 for an ESTTA submission.

The USPTO proposes to revise § 2.6(a)(17)(i) and (ii) to increase the per-class fee for filing a notice of opposition from $500 to $700 for a paper submission and from $400 to $600 for an ESTTA submission.

The USPTO proposes to revise § 2.6(a)(18) to increase the fee for filing an ex parte appeal and to establish new fees for requests for an extension of time to file an appeal brief and for filing a brief in an ex parte appeal. The proposed revisions to § 2.6(a)(18)(i) and (ii) increase the per-class fee for filing an ex parte appeal from $300 to $325 for a paper submission and from $200 to $225 for an ESTTA submission. The proposed addition of § 2.6(a)(18)(iii) sets the per-application fee for filing a first request for an extension of time to file an appeal brief at $0. The proposed addition of § 2.6(a)(18)(iv) and (v) sets the per-application fee for filing a second or subsequent request for an extension of time to file an appeal brief at $200 for a paper submission and $100 for an ESTTA submission. The proposed addition of § 2.6(a)(18)(vi) and (vii) set the per-class fee for filing a brief in an ex parte appeal at $300 for a paper submission and $200 for an ESTTA submission.

The USPTO proposes to revise § 2.6(a)(22)(i) and (ii) to increase the fee for filing a request for an extension of time to file a notice of opposition pursuant to § 2.102(c)(1)(ii) or (c)(2) from $200 to $400 for a paper submission and from $100 to $200 for an ESTTA submission.

The USPTO proposes to revise § 2.6(a)(23)(i) and (ii) to increase the fee for filing a request for an extension of time to file a notice of opposition pursuant to § 2.102(c)(3) from $300 to $500 for a paper submission and from $200 to $400 for an ESTTA submission.

The USPTO proposes to add § 2.6(a)(24) to establish a fee for filing a request for an oral hearing before the TTAB of $500 per proceeding.

The USPTO proposes to add § 2.6(a)(25) to establish a fee of $50 for the filing of a letter of protest per subject application.

The USPTO proposes to add § 2.6(a)(26) to set out fees for a request for reconsideration filed more than three months after a final action and within six months of the issue date of a final action or with a petition to revive an abandoned application. The USPTO proposes to add § 2.6(a)(26)(i) to establish a fee of $0 for filing a request for reconsideration within three months after the issue date of a final action through TEAS. The USPTO proposes to add § 2.6(a)(26)(ii) and (iii) to establish a fee of $500 for a paper submission and $400 for a TEAS or ESTTA submission for a request for reconsideration filed more than three months after and within six months of the issue date of a final Office action.

The USPTO proposes to revise § 2.114(a) to provide that a partial refund of the fee for a petition to cancel, equal to the increase in that fee otherwise proposed by this rulemaking, may be made in cases of default judgment where there was no appearance by a defendant and no filings are made other than the petition to cancel.

The USPTO proposes to add § 2.149, which codifies the procedures and requirements for letters of protest.

The USPTO proposes to revise the section title and to restructure § 2.161 to set out the requirements for section 8 affidavits or declarations more clearly. The USPTO also proposes to add, at revised § 2.161(c), a provision stating that if goods, services, and/or classes are deleted from a registration after submission and prior to the acceptance of a section 8 affidavit or declaration, the deletion must be accompanied by the relevant fee under proposed § 2.6(a)(12)(iii) or (iv) for each class from which goods, services, and/or classes are deleted.

The USPTO proposes to revise § 7.6(a)(6)(i) and (ii) to increase the per-class fee for filing a section 71 affidavit from $225 to $325 for a paper submission and from $125 to $225 for a TEAS submission.

The USPTO proposes to add § 7.6(a)(6)(iii) and (iv) to establish fees for the deletion of goods, services, and/or classes after submission and prior to acceptance of a section 71 affidavit. The proposed § 7.6(a)(iii) and (iv) set the per-class fee at $350 for a paper submission and $250 for a TEAS submission.

The USPTO proposes to revise the section title and to restructure § 7.37 to set out the requirements for section 71 affidavits or declarations more clearly. The USPTO also proposes to add, at revised § 7.37(c), a provision stating that if goods, services, and/or classes are deleted from a registration after submission and prior to acceptance of a section 71 affidavit or declaration, the deletion must be accompanied by the relevant fee under proposed § 7.6(a)(6)(iii) or (iv) for each class from which goods, services, and/or classes are deleted.

Rulemaking Requirements

A. America Invents Act: This rulemaking proposes to set and adjust fees under section 10(a) of the AIA as amended by the SUCCESS Act. Section 10(a) of the AIA authorizes the Director to set or adjust by rule any trademark fee established, authorized, or charged under the Trademark Act for any services performed by, or materials furnished by, the USPTO (*see* section 10 of the AIA, Pub. L. 112–29, 125 Stat. 284, 316–17, as amended by Pub. L. 115–273, 132 Stat. 4158). Section 10(e) of the AIA sets forth the general requirements for rulemakings that set or adjust fees under this authority. In particular, section 10(e)(1) requires the Director to publish in the **Federal Register** any proposed fee change under section 10 and include in such publication the specific rationale and purpose for the proposal, including the possible expectations or benefits resulting from the proposed change. For such rulemakings, the AIA requires that the USPTO provide a public comment period of not less than 45 days.

The TPAC advises the Under Secretary of Commerce for Intellectual Property and Director of the USPTO on the management, policies, goals, performance, budget, and user fees of trademark operations. When adopting fees under section 10 of the AIA, the AIA requires the Director to provide the TPAC with the proposed fees at least 45 days prior to publishing them in the **Federal Register**. The TPAC then has at least 30 days within which to deliberate, consider, and comment on the proposal, as well as hold a public hearing(s) on the proposed fees. The TPAC must make a written report available to the public of the comments, advice, and recommendations of the committee regarding the proposed fees before the USPTO issues any final fees. The USPTO will consider and analyze any comments, advice, or recommendations received from the TPAC before finally setting or adjusting fees.

Consistent with the requirements of the AIA, on August 28, 2019, the Director notified the TPAC of the USPTO's intent to set or adjust trademark fees and submitted a preliminary trademark fee proposal with supporting materials. The preliminary trademark fee proposal and associated materials are available at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

The TPAC held a public hearing in Alexandria, Virginia, on September 23, 2019. Transcripts of this hearing and

comments submitted to the TPAC in writing are available for review at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.* The TPAC subsequently issued a report, dated October 31, 2019, regarding the preliminary proposed fees. The report can be found online at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

B. Initial Regulatory Flexibility Analysis: The USPTO publishes this Initial Regulatory Flexibility Analysis (IRFA) as required by the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) to examine the impact of the USPTO's proposed changes to trademark fees on small entities and to seek the public's views. Under the RFA, whenever an agency is required by 5 U.S.C. 553 (or any other law) to publish an NPRM, the agency must prepare and make available for public comment an IRFA, unless the agency certifies under 5 U.S.C. 605(b) that the proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities (*see* 5 U.S.C. 603, 605). This IRFA incorporates the discussion of the proposed changes in the preamble above.

Items 1–5 below discuss the five items specified in 5 U.S.C. 603(b)(1)–(5) to be addressed in an IRFA. Item 5 below discusses alternatives to this proposal that the USPTO considered.

1. Description of the Reasons That Action by the USPTO Is Being Considered

The USPTO proposes setting and adjusting certain trademark fees as authorized by section 10 of the AIA, as amended by Public Law 115–273, 132 Stat. 4158 (the SUCCESS Act). The fee schedule proposed under section 10 in this rulemaking will, based on the assumptions found in the FY 2021 Congressional Justification, recover the aggregate estimated costs to the USPTO while achieving strategic and operational goals, such as implementing measures to maintain trademark pendency and high trademark quality, modernizing the trademark IT systems, continuing important programs for stakeholder and public outreach, enhancing operations of the TTAB, and maintaining a sufficient operating reserve. Aggregate costs are estimated through the USPTO budget formulation process with the annual preparation of a five-year performance-based budget request. Revenues are estimated based on the projected demand (workload) for trademark products and services and fee rates.

2. Succinct Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The policy objectives of the proposed rule are to: (1) Better align fees with costs, (2) protect the integrity of the trademark register, (3) improve the efficiency of USPTO processes related to trademark and TTAB operations, and (4) ensure financial sustainability to facilitate effective trademark operations. The legal basis for the proposed rule is section 10 of the AIA, as amended, which provides the authority for the Director to set or adjust by rule any fee established, authorized, or charged under the Trademark Act of 1946, 15 U.S.C. 1051 *et seq.,* as amended. *See also* section 31 of the Trademark Act, 15 U.S.C. 1113.

3. Description of and, Where Feasible, Estimate of the Number of Affected Small Entities

The USPTO does not collect or maintain statistics in trademark cases on small- versus large-entity applicants, and this information would be required in order to determine the number of small entities that would be affected by the proposed rule.

This proposed rule would apply to any entity filing trademark documents with the USPTO. The USPTO estimates, based on the assumptions found in the FY 2021 Congressional Justification, that during the first full fiscal year under the fees as proposed, the USPTO would expect to collect approximately $77 million more in trademark processing and TTAB fees in FY 2021. The USPTO would receive an additional $40 million in fees from applications for the registration of a mark, including requests for extension of protection and subsequent designations; $3 million more from petitions, letters of protest, and requests for reconsideration; and $28 million more for section 8 and section 71 affidavits. TTAB fees would increase by $6 million.

Trademark fees are collected for trademark-related services and products at different points in time in the trademark application examination process and over the lifecycle of the registration. Approximately 55% of all trademark fee collections are from application filing fees. Fees for TTAB proceedings and appeals comprise 2.5% of revenues. Fees from other trademark activities, petitions, assignments and certifications, and Madrid processing are approximately 5% of revenues. Fees for filing post-registration and intent-to-use filings, which subsidize the costs of filing, search, examination, and TTAB activities, comprise 37.5%.

The USPTO's five-year estimated aggregate trademark fee revenue is based on the number of trademark applications and other fee-related filings it expects to receive for a given fiscal year and work it expects to process in a given fiscal year (an indicator of future fee workload and budgetary requirements). Within the iterative process for estimating aggregate revenue, the USPTO adjusts individual fee rates up or down based on policy and cost considerations and then multiplies the resulting fee rates by appropriate workload volumes to calculate a revenue estimate for each fee, which is then used to calculate the aggregate revenue. Additional details about the USPTO's aggregate revenue, including projected workloads by fee, are available at *https://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

4. Description of the Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule, Including an Estimate of the Classes of Small Entities Which Will Be Subject to the Requirement and the Type of Professional Skills Necessary for Preparation of the Report or Record

The proposed rule imposes no new reporting or recordkeeping requirements. The main purpose of the proposed rule is to set and adjust trademark fees. However, the rule proposes new procedural regulations at 37 CFR 2.149 for the submission of letters of protest. The USPTO does not collect or maintain statistics in trademark cases on small versus large entity applicants and is unable to provide an estimate of the classes of small entities that will be subject to the new procedural requirements.

5. Description of Any Significant Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Rule on Small Entities

The USPTO considered four alternatives, based on the assumptions found in the FY 2021 Congressional Justification, before recommending this proposal: (1) The adjustments included in this proposal, (2) an across-the-board adjustment of 22%, (3) the unit cost of providing services based on FY 2019 costs, and (4) no change to the baseline of current fees. The alternatives are each explained here with additional information regarding how each proposal was developed and the aggregate revenue estimated. A description of the Aggregate Revenue Methodologies is available at *http://*

www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.

The USPTO proposes to set or adjust trademark fees codified in 37 CFR parts 2 and 7. Fees are adjusted for all application filing types (*i.e.,* paper applications, applications filed via TEAS, and requests for extension of protection under section 66(a) of the Trademark Act (15 U.S.C. 1141f)). The USPTO also proposes to set or adjust certain other trademark processing fees to further effective administration of the trademark system. For example, the proposed rule increases the fees for certain petitions to the Director as well as section 8 and section 71 affidavits, sets a new fee and proposes procedural regulations for filing a letter of protest, and sets new fees for filing a request for reconsideration more than three months after a final Office action and for deleting goods, services, and/or classes from a registration after submission and prior to acceptance of a section 8 or section 71 affidavit.

The USPTO chose the alternative proposed in this rule because it will enable the Office to achieve its goals effectively and efficiently without unduly burdening small entities, erecting barriers to entry, or stifling incentives to innovate. The alternative proposed here secures the USPTO's objectives for meeting the strategic goals of encouraging broader usage of IP rights-protection mechanisms and participation by more trademark owners and more efficient resolution of appeals and inter partes proceedings at the TTAB by increasing revenue to meet the Office's aggregate future costs. In particular, the new fee structure for requests for reconsideration and requests to delete goods, services, and/or classes from a registration would protect the integrity of the register and the efficiency of the process by incentivizing both more timely filings and proactive action by applicants and registrants. The increased efficiencies realized through the proposed rule will benefit all applicants and registrants by allowing registrations to be granted sooner and more efficiently by removing unused marks and unsupported goods and services from the register. All trademark applicants should benefit from the efficiency that will be realized under the proposed alternative.

With regard to the new regulations governing the filing of letters of protest, the USPTO anticipates that the impact to affected entities would be small. The proposed fee of $50 is set at a level high enough to recognize there are processing costs and deter the filing of unsupported or irrelevant filings, but low enough so as not to discourage the filing of relevant, well-supported letters of protest. In addition, the new procedural regulations for filing letters of protest are not anticipated to significantly impact affected entities because the proposed new regulations are based on existing informal procedures set out in the TMEP.

Finally, the proposed new provision at § 2.114(a) provides that a partial refund of the fee for a petition to cancel may be made in cases of default judgement where there was no appearance by a defendant and no filings were made other than the petition to cancel. This change would likely balance the cost recovery obtained from the increase in the fee for a petition to cancel, a case type that has increased markedly in recent years, against the benefit of having petitions to cancel filed to remove registrations from the register when petitioners have determined through their investigations that the registered marks are no longer in use. In such situations, default judgments often result, efficiently clearing the register of marks that would otherwise stand as potential bars to applications seeking to register similar marks. This reduces costs for applicants filing such applications.

The proposed fee schedule for this alternative (labeled ''Alternative 1—Proposed Alternative'') is available in the document entitled ''Initial Regulatory Flexibility Act Tables'' at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

Another alternative to setting and adjusting the proposed fees that was considered was to increase all fees by the same 22% across the board. This alternative would maintain the status quo structure of cost recovery, where processing and examination costs are subsidized by fees paid for intent-to-use and post-registration maintenance filings (both of which exceed the cost of performing these services), given that all fees would be adjusted by the same escalation factor. This structure would promote innovation strategies and allow applicants to gain access to the trademark system through fees set below cost, while registrants pay maintenance fees above cost to subsidize the below-cost front-end fees. This alternative was ultimately rejected. Although this alternative generates sufficient aggregate revenue to recover aggregate operating costs, unlike the proposed fee structure, there would be no improvements in fee schedule design. As such, this alternative would not accomplish the stated objective of enhancing the integrity of the register by incentivizing users to maintain accurate goods and services. Further, it would not enhance the efficiency of the process, as it would offer no new incentives for users to timely file applications and other filings or to resolve appeals and inter partes proceedings at the TTAB more expeditiously. The proposed fee schedule for this alternative (labeled ''Alternative 2—Across-the-Board Adjustment'') is available in the document entitled ''Initial Regulatory Flexibility Act Tables'' at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

A third alternative that was considered was to set all trademark fees to allow for the USPTO to recover 100% of the unit costs associated with each product or service provided, based on the historical unit costs of the products and services provided by the USPTO. The USPTO uses activity based information to determine the unit costs of activities that contribute to the services and processes provided by individual fees. It is common practice in the federal government to set a particular fee at a level that recovers the cost of a given good or service. In Office of Management and Budget (OMB) Circular A–25, User Charges, the OMB states that user charges (fees) should be sufficient to recover the full cost to the federal government of providing the particular service, resource, or good, when the government is acting in its capacity as sovereign. Under the unit cost recovery alternative, fees are generally set in line with the FY 2019 cost of providing the product or service. This alternative would produce a structure in which application and processing fees would increase significantly for all applicants and intent-to-use and post-registration maintenance filing fees would decrease dramatically when compared with current fees. In addition, these fees would change from year to year with the ebb and flow in the number of applications submitted. This alternative was rejected because it was determined that the unit costs for any given product or service can vary from year to year, such that a yearly review of all, and an adjustment to many, trademark fees would be continually required and could also lead to consumer confusion regarding the amount at which any given trademark fee was currently set and what the relevant fee would be in the future. Additionally, this alternative does not address improvements in fee design to accomplish the stated objectives of encouraging broader usage of IP rights-protection mechanisms and participation by more trademark owners as well as practices that improve the

efficiency of the process. The USPTO recognizes that this approach does not account for changes in the fee structure or inflationary factors that could likely increase the costs of certain trademark services and necessitate higher fees in the out-years. However, the USPTO contends that the FY 2019 data is the best unit cost data available to inform this analysis. The proposed fee schedule for this alternative (labeled ''Alternative 3—Unit Cost Recovery'') is available in the document entitled ''Initial Regulatory Flexibility Act Tables'' at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

A final alternative to setting and adjusting the proposed fees would be to take no action at this time regarding trademark fees and to leave all trademark fees as currently set. This alternative was rejected because, due to changes in demand for certain services and rising costs, the Office has determined that a fee increase is needed to meet future budgetary requirements as described in the FY 2021 Budget. As previously explained, the proposed fee schedule will assist in promoting access to the trademark system, protecting the integrity of the register, and promoting the efficiency of the trademark registration process by incentivizing: (1) Maintenance of registrations for goods and services for which marks are actually in use, (2) more timely filing of applications and other documents, and (3) faster resolution of appeals and inter partes proceedings at the TTAB. The fee schedule for this alternative (labeled ''Alternative 4—Baseline—Current Fee Schedule'') is available in the document entitled ''Initial Regulatory Flexibility Act Tables'' at *http://www.uspto.gov/about-us/performance-and-planning/fee-setting-and-adjusting.*

6. Identification, to the Extent Practicable, of All Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule

The proposed rule would not duplicate, overlap, or conflict with any other federal rules.

C. Executive Order 12866 (Regulatory Planning and Review): This rule has been determined to be Significant for purposes of Executive Order 12866 (Sept. 30, 1993).

D. Executive Order 13563 (Improving Regulation and Regulatory Review): The USPTO has complied with Executive Order 13563 (Jan. 18, 2011). Specifically, the USPTO has, to the extent feasible and applicable: (1) Made a reasoned determination that the benefits justify the costs of the rule; (2) tailored the rule to impose the least burden on society consistent with obtaining the regulatory objectives; (3) selected a regulatory approach that maximizes net benefits; (4) specified performance objectives; (5) identified and assessed available alternatives; (6) provided the public with a meaningful opportunity to participate in the regulatory process, including soliciting the views of those likely affected prior to issuing a notice of proposed rulemaking, and provided online access to the rulemaking docket; (7) attempted to promote coordination, simplification, and harmonization across government agencies and identified goals designed to promote innovation; (8) considered approaches that reduce burdens and maintain flexibility and freedom of choice for the public; and (9) ensured the objectivity of scientific and technological information and processes, to the extent applicable.

E. Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs): This proposed rule is not expected to be subject to the requirements of Executive Order 13771 (Jan. 30, 2017) because this proposed rule is expected to involve a transfer payment.

F. Executive Order 13132 (Federalism): This rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (Aug. 4, 1999).

G. Executive Order 13175 (Tribal Consultation): This rulemaking will not: (1) Have substantial direct effects on one or more Indian tribes; (2) impose substantial direct compliance costs on Indian tribal governments; or (3) preempt tribal law. Therefore, a tribal summary impact statement is not required under Executive Order 13175 (Nov. 6, 2000).

H. Executive Order 13211 (Energy Effects): This rulemaking is not a significant energy action under Executive Order 13211 because this rulemaking is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required under Executive Order 13211 (May 18, 2001).

I. Executive Order 12988 (Civil Justice Reform): This rulemaking meets applicable standards to minimize litigation, eliminate ambiguity, and reduce burden as set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 (Feb. 5, 1996).

J. Executive Order 13045 (Protection of Children): This rulemaking does not concern an environmental risk to health or safety that may disproportionately affect children under Executive Order 13045 (Apr. 21, 1997).

K. Executive Order 12630 (Taking of Private Property): This rulemaking will not affect a taking of private property or otherwise have taking implications under Executive Order 12630 (Mar. 15, 1988).

L. Congressional Review Act: Under the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*), prior to issuing any final rule, the USPTO will submit a report containing the final rule and other required information to the United States Senate, the United States House of Representatives, and the comptroller general of the Government Accountability Office. The changes in this rulemaking are not expected to result in an annual effect on the economy of $100 million or more, a major increase in costs or prices, or significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets. Therefore, this rulemaking is not expected to result in a ''major rule'' as defined in 5 U.S.C. 804(2).

M. Unfunded Mandates Reform Act of 1995: The changes set forth in this rulemaking do not involve a Federal intergovernmental mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, of $100 million (as adjusted) or more in any one year, or a Federal private sector mandate that will result in the expenditure by the private sector of $100 million (as adjusted) or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions are necessary under the provisions of the Unfunded Mandates Reform Act of 1995. *See* 2 U.S.C. 1501 *et seq.*

N. National Environmental Policy Act: This rulemaking will not have any effect on the quality of the environment and is thus categorically excluded from review under the National Environmental Policy Act of 1969. *See* 42 U.S.C. 4321 *et seq.*

O. National Technology Transfer and Advancement Act: The requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) are not applicable because this rulemaking does not contain provisions that involve the use of technical standards.

P. Paperwork Reduction Act: This rule involves information collection requirements that are subject to review and approval by OMB under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collections of information involved with this proposed rule have been reviewed and previously approved by OMB under OMB control numbers 0651–0009, 0651–0027, 0651–0028, 0651–0040, 0651–0050, 0651–0051, 0651–0054, 0651–0055, 0651–0056, and 0651–0061. This action proposes to set or increase certain trademark fees, which would increase the annual non-hour cost burdens $42,483,850, as set out in the following table:

OMB control No.	Information collection title	Estimated increase in cost burdens (fees) due to proposed rule
0651–0009	Applications for Trademark Registration	$23,410,200
0651–0040	Trademark Trial and Appeal Board (TTAB) Actions	4,833,700
0651–0050	Response to Office Action and Voluntary Amendment Forms	7,006,500
0651–0051	Madrid Protocol	325,100
0651–0054	Substantive Submissions Made During Prosecution of the Trademark Application	3,045,650
0651–0055	Post Registration (Trademark Processing)	3,862,700

This estimated cost burden increase is based on the currently OMB approved response volumes associated with these information collections, which may be slightly different than the workflow forecasts cited in other parts of this proposed rule. In addition, any updates to the aforementioned information collections as a result of this proposed rulemaking will be submitted to OMB for approval prior to the effective date of the final rule.

Comments regarding the collection of information associated with this proposed rule, including suggestions for reducing the burden, may be sent to the Commissioner for Trademarks, by mail to P.O. Box 1451, Alexandria, VA 22313–1451, attention Catherine Cain; by hand delivery to the Trademark Assistance Center, Concourse Level, James Madison Building-East Wing, 600 Dulany Street, Alexandria, Virginia 22314, attention Catherine Cain; or by electronic mail message via the Federal eRulemaking Portal (*https://www.regulations.gov*). All comments submitted directly to the USPTO or provided on the Federal eRulemaking Portal should include the docket number (PTO–T–2019–0027).

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information has a currently valid OMB control number.

List of Subjects

37 CFR Part 2

Administrative practice and procedure, Courts, Lawyers, Trademarks.

37 CFR Part 7

Administrative practice and procedure, Trademarks.

For the reasons stated in the preamble and under the authority contained in section 10(a) of the AIA, 15 U.S.C. 1113, 1123, and 35 U.S.C. 2, as amended, the USPTO proposes to amend parts 2 and 7 of title 37 as follows:

PART 2—RULES OF PRACTICE IN TRADEMARK CASES

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C. 1113, 1123; 35 U.S.C. 2; sec. 10, Pub. L. 112–29, 125 Stat. 284, unless otherwise noted. Sec. 2.99 also issued under secs. 16, 17, 60 Stat. 434; 15 U.S.C. 1066, 1067.

■ 2. Amend § 2.6 by:

■ a. Revising paragraphs (a)(1)(i) through (v);

■ b. Adding paragraph (a)(11)(iii);

■ c. Revising paragraphs (a)(12), (15) through (18), (22), and (23); and

■ d. Adding paragraphs (a)(24) through (26).

The revisions and additions read as follows:

§ 2.6 Trademark fees.

(a) * * *

(1) * * *

(i) For filing an application on paper, per class—$750.00

(ii) For filing an application under section 66(a) of the Act, per class—$500.00

(iii) For filing a TEAS Standard application, per class—$350.00

(iv) For filing a TEAS Plus application under § 2.22, per class—$250.00

(v) Additional processing fee under § 2.22(c), per class—$100.00

* * * * *

(11) * * *.

(iii) For filing an amendment to a registration prior to submission of an affidavit under section 8 or section 71 of the Act and consisting only of the deletion of goods, services, and/or classes—$0.00

(12) *Affidavit under section 8.* (i) For filing an affidavit under section 8 of the Act on paper, per class—$325.00

(ii) For filing an affidavit under section 8 of the Act through TEAS, per class—$225.00

(iii) For deleting goods, services, and/or classes after submission and prior to acceptance of an affidavit under section 8 of the Act on paper, per class—$350.00

(iv) For deleting goods, services, and/or classes after submission and prior to acceptance of an affidavit under section 8 of the Act through TEAS, per class—$250.00

* * * * *

(15) *Petitions to the Director.* (i) For filing a petition under § 2.146 or § 2.147 on paper—$350.00

(ii) For filing a petition under § 2.146 or § 2.147 through TEAS—$250.00

(iii) For filing a petition under § 2.66 on paper—$250.00

(iv) For filing a petition under § 2.66 through TEAS—$150.00

(16) *Petition to cancel.* (i) For filing a petition to cancel on paper, per class—$700.00

(ii) For filing a petition to cancel through ESTTA, per class—$600.00

(17) *Notice of opposition.* (i) For filing a notice of opposition on paper, per class—$700.00

(ii) For filing a notice of opposition through ESTTA, per class—$600.00

(18) *Ex parte appeal.* (i) For filing an ex parte appeal to the Trademark Trial and Appeal Board on paper, per class—$325.00

(ii) For filing an ex parte appeal to the Trademark Trial and Appeal Board through ESTTA, per class—$225.00

(iii) For filing a first request for an extension of time to file an appeal brief, per application—$0.00

(iv) For filing a second or subsequent request for an extension of time to file an appeal brief on paper, per application—$200.00

(v) For filing a second or subsequent request for an extension of time to file an appeal brief through ESTTA, per application—$100.00

(vi) For filing an appeal brief on paper, per class—$300.00

(vii) For filing an appeal brief through ESTTA, per class—$200.00

* * * * *

(22) *Extension of time for filing a notice of opposition under § 2.102(c)(1)(ii) or (c)(2).* (i) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(1)(ii) or (c)(2) on paper—$400.00

(ii) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(1)(ii) or (c)(2) through ESTTA—$200.00

(23) *Extension of time for filing a notice of opposition under § 2.102(c)(3).* (i) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(3) on paper—$500.00

(ii) For filing a request for an extension of time to file a notice of opposition under § 2.102(c)(3) through ESTTA—$400.00

(24) *Oral hearing.* For filing a request for an oral hearing before the Trademark Trial and Appeal Board, per proceeding—$500.00

(25) *Letter of protest.* For filing a letter of protest, per subject application—$50.00

(26) *Request for reconsideration.* (i) For filing a request for reconsideration within three months after the issue date of a final Office action through TEAS—$0.00

(ii) For filing a request for reconsideration more than three months after and within six months of the issue date of a final Office action, or with a petition under § 2.66, on paper—$500.00

(iii) For filing a request for reconsideration more than three months after and within six months of the issue date of a final Office action, or with a petition under § 2.66, through TEAS or ESTTA—$400.00

* * * * *

■ 3. Amend § 2.114 by revising paragraph (a) to read as follows:

§ 2.114 Answer.

(a)(1) If no answer is filed within the time initially set, or as later may be reset by the Board, the petition may be decided as in the case of default. The failure to file a timely answer tolls all deadlines, including the discovery conference, until the issue of default is resolved.

(2) If the cancellation proceeding is based solely on abandonment or nonuse and default judgment is entered with no appearance by the defendant, and no filings are made other than the petition to cancel, $200 of the petition to cancel fee may be refunded.

* * * * *

■ 4. Add § 2.149 before the center heading ''Certificate'' to read as follows:

§ 2.149 Letters of protest against pending applications.

(a) A third party may submit, for consideration and entry in the record of a trademark application, objective evidence relevant to the examination of the application for a ground for refusal of registration if the submission is made in accordance with this section.

(b) A party protesting multiple applications must file a separate submission under this section for each application.

(c) Any submission under this section must be filed no later than 30 days after the date the application is published for opposition under section 12(a) of the Act and § 2.80 of this part. If the subject application cannot be withdrawn from issuance of a registration while consideration of the protest is pending, the protest may be considered untimely.

(d)(1) If the letter of protest is filed before publication of the subject application, the evidence must be relevant to the identified ground(s) for refusal, such that it is appropriate for the examining attorney to consider whether to issue a refusal or make a requirement under the Act or this part.

(2) If the letter of protest is filed on or within 30 days after the date of publication of the subject application, the evidence must establish a prima facie case for refusal on the identified ground(s), such that failure to issue a refusal or to make a requirement would likely result in issuance of a registration in violation of the Act or this part.

(e) Filing a submission under this section does not stay or extend the time for filing a notice of opposition.

(f) Any submission under this section must be made in writing, filed through TEAS, and include:

(1) The fee required by § 2.6(a)(25);

(2) The serial number of the pending application that is the subject of the protest;

(3) An itemized evidence index that does not identify the protestor or its representatives, does not contain legal argument, and includes:

(i) An identification of the documents, or portions of documents, being submitted as evidence. The submission may not total more than 10 items of evidence in support of a specified ground of refusal and more than 75 total pages of evidence without a detailed and sufficient explanation that establishes the special circumstances that necessitate providing more than 10 items of evidence per refusal ground or more than 75 total pages of evidence; and

(ii) A concise factual statement of the relevant ground(s) for refusal of registration appropriate in ex parte examination that each item identified supports; and

(4) A clear and legible copy of each item identified in the evidence index where:

(i) Copies of third-party registrations come from the electronic records of the Office and show the current status and title of the registration;

(ii) Evidence from the internet includes the date the evidence was published or accessed and the complete URL address of the website; and

(iii) Copies of printed publications identify the publication name and date of publication.

(g) Any submission under this section may not be entered or considered by the Office if:

(1) Any part of the submission is not in compliance with this section;

(2) The application record shows that the examining attorney already considered the refusal ground(s) specified in the submission; or

(3) A provision of the Act or parts 2 or 7 of this chapter precludes acceptance of the submission.

(h) If a submission is determined to be in compliance with this section, only the specified ground(s) for refusal and the provided evidence relevant to the ground(s) for refusal will be included in the application record for consideration by the examining attorney. An applicant need not and should not reply to the entry into the application record of such evidence in the absence of an Office action issuing that includes such evidence.

(i) Any determination whether to include in an application record the ground(s) or evidence for a refusal of registration in a submission under this section is not petitionable.

(j) A third party filing a submission under this section will not receive any communication from the Office relating to the submission other than acknowledgement that it has been received by the Office and notification of whether the submission is found to be compliant or non-compliant with this section. Communications with the third party will not be made of record in the application. The Office will not accept amendments to a non-compliant submission that was previously filed. Instead, a third party who previously filed a non-compliant submission may

file another submission that meets the requirements of paragraph (f) of this section, provided the time period for filing a submission in paragraph (c) of this section has not closed.

(k) The limited involvement of the third party ends with the filing of the submission under this section. The third party may not directly contact the examining attorney assigned to the application.

■ 5. Revise § 2.161 to read as follows:

§ 2.161 Requirements for a complete affidavit or declaration of use in commerce or excusable nonuse; requirement for the submission of additional information, exhibits, affidavits or declarations, and specimens; and fee for deletions of goods, services, and/or classes from a registration.

(a) *Requirements for a complete affidavit or declaration.* A complete affidavit or declaration under section 8 of the Act must:

(1) Be filed by the owner within the period set forth in § 2.160(a);

(2) Include a verified statement attesting to the use in commerce or excusable nonuse of the mark within the period set forth in section 8 of the Act. This verified statement must be executed on or after the beginning of the filing period specified in § 2.160(a);

(3) Include the U.S. registration number;

(4)(i) Include the fee required by § 2.6 for each class that the affidavit or declaration covers;

(ii) If the affidavit or declaration is filed during the grace period under section 8(a)(3) of the Act, include the grace period surcharge per class required by § 2.6;

(iii) If at least one fee is submitted for a multiple-class registration, but the fee is insufficient to cover all the classes, and the class(es) to which the fee(s) should be applied are not specified, the Office will issue a notice requiring either submission of the additional fee(s) or specification of the class(es) to which the initial fee(s) should be applied. Additional fees may be submitted if the requirements of § 2.164 are met. If the additional fee(s) are not submitted within the time period set out in the Office action and the class(es) to which the original fee(s) should be applied are not specified, the Office will presume that the fee(s) cover the classes in ascending order, beginning with the lowest numbered class;

(5)(i) Specify the goods, services, or nature of the collective membership organization for which the mark is in use in commerce, and/or the goods, services, or nature of the collective membership organization for which excusable nonuse is claimed under paragraph (a)(6)(ii) of this section; and

(ii) Specify the goods, services, or classes being deleted from the registration, if the affidavit or declaration covers fewer than all the goods, services, or classes in the registration;

(6)(i) State that the registered mark is in use in commerce; or

(ii) If the registered mark is not in use in commerce on or in connection with all the goods, services, or classes specified in the registration, set forth the date when such use of the mark in commerce stopped and the approximate date when such use is expected to resume; and recite facts to show that nonuse as to those goods, services, or classes is due to special circumstances that excuse the nonuse and is not due to an intention to abandon the mark; and

(7) Include one specimen showing how the mark is in use in commerce for each class in the registration, unless excusable nonuse is claimed under paragraph (a)(6)(ii) of this section. When requested by the Office, additional specimens must be provided. The specimen must meet the requirements of § 2.56.

(8) Additional requirements for a collective mark: In addition to the above requirements, a complete affidavit or declaration pertaining to a collective mark must:

(i) State that the owner is exercising legitimate control over the use of the mark in commerce; and

(ii) If the registration issued from an application based solely on section 44 of the Act, state the nature of the owner's control over the use of the mark by the members in the first affidavit or declaration filed under paragraph (a)(1) of this section.

(9) Additional requirements for a certification mark: In addition to the above requirements, a complete affidavit or declaration pertaining to a certification mark must:

(i) Include a copy of the certification standards specified in § 2.45(a)(4)(i)(B);

(A) *Submitting certification standards for the first time.* If the registration issued from an application based solely on section 44 of the Act, include a copy of the certification standards in the first affidavit or declaration filed under paragraph (a)(1) of this section; or

(B) *Certification standards submitted in prior filing.* If the certification standards in use at the time of filing the affidavit or declaration have not changed since the date they were previously submitted to the Office, include a statement to that effect; if the certification standards in use at the time of filing the affidavit or declaration have changed since the date they were previously submitted to the Office, include a copy of the revised certification standards;

(ii) State that the owner is exercising legitimate control over the use of the mark in commerce; and

(iii) Satisfy the requirements of § 2.45(a)(4)(i)(A) and (C).

(10) For requirements of a complete affidavit or declaration of use in commerce or excusable nonuse for a registration that issued from a section 66(a) basis application, see § 7.37.

(b) *Requirement for the submission of additional information, exhibits, affidavits or declarations, and specimens.* The Office may require the owner to furnish such information, exhibits, affidavits or declarations, and such additional specimens as may be reasonably necessary to the proper examination of the affidavit or declaration under section 8 of the Act or for the Office to assess and promote the accuracy and integrity of the register.

(c) *Fee for deletions of goods, services, and/or classes from a registration.* Deletions by the owner of goods, services, and/or classes from a registration after submission and prior to acceptance of the affidavit or declaration must be accompanied by the relevant fee in § 2.6(a)(12)(iii) or (iv).

PART 7—RULES OF PRACTICE IN FILINGS PURSUANT TO THE PROTOCOL RELATING TO THE MADRID AGREEMENT CONCERNING THE INTERNATIONAL REGISTRATION OF MARKS

■ 6. The authority citation for 37 CFR part 7 continues to read as follows:

Authority: 15 U.S.C. 1123, 35 U.S.C. 2, unless otherwise noted.

■ 7. Amend § 7.6 by revising paragraph (a)(6) read as follows:

§ 7.6 Schedule of U.S. process fees.

(a) * * *

(6) *Affidavit under section 71.* (i) For filing an affidavit under section 71 of the Act on paper, per class—$325.00

(ii) For filing an affidavit under section 71 of the Act through TEAS, per class—$225.00

(iii) For deleting goods, services, and/or classes after submission and prior to acceptance of an affidavit under section 71 of the Act on paper, per class—$350.00

(iv) For deleting goods, services, and/or classes after submission and prior to acceptance of an affidavit under section 71 of the Act through TEAS, per class—$250.00

* * * * *

■ 8. Revise § 7.37 to read as follows:

§ 7.37 Requirements for a complete affidavit or declaration of use in commerce or excusable nonuse; requirement for the submission of additional information, exhibits, affidavits or declarations, and specimens; and fee for deletions of goods, services, and/or classes from a registration.

(a) *Requirements for a complete affidavit or declaration.* A complete affidavit or declaration under section 71 of the Act must:

(1) Be filed by the holder of the international registration within the period set forth in § 7.36(b);

(2) Include a verified statement attesting to the use in commerce or excusable nonuse of the mark within the period set forth in section 71 of the Act. The verified statement must be executed on or after the beginning of the filing period specified in § 7.36(b). A person who is properly authorized to sign on behalf of the holder is:

(i) A person with legal authority to bind the holder;

(ii) A person with firsthand knowledge of the facts and actual or implied authority to act on behalf of the holder; or

(iii) An attorney as defined in § 11.1 of this chapter who has an actual written or verbal power of attorney or an implied power of attorney from the holder.

(3) Include the U.S. registration number;

(4)(i) Include the fee required by § 7.6 for each class that the affidavit or declaration covers;

(ii) If the affidavit or declaration is filed during the grace period under section 71(a)(3) of the Act, include the grace period surcharge per class required by § 7.6;

(iii) If at least one fee is submitted for a multiple-class registration, but the fee is insufficient to cover all the classes, and the class(es) to which the fee(s) should be applied are not specified, the Office will issue a notice requiring either submission of the additional fee(s) or specification of the class(es) to which the initial fee(s) should be applied. Additional fees may be submitted if the requirements of § 7.39 are met. If the additional fee(s) are not submitted within the time period set out in the Office action, and the class(es) to which the original fee(s) should be applied are not specified, the Office will presume that the fee(s) cover the classes in ascending order, beginning with the lowest numbered class;

(5)(i) Specify the goods, services, or nature of the collective membership organization for which the mark is in use in commerce, and/or the goods, services, or nature of the collective membership organization for which excusable nonuse is claimed under paragraph (a)(6)(ii) of this section; and

(ii) Specify the goods, services, or classes being deleted from the registration, if the affidavit or declaration covers fewer than all the goods, services, or classes in the registration;

(6)(i) State that the registered mark is in use in commerce; or

(ii) If the registered mark is not in use in commerce on or in connection with all the goods, services, or classes specified in the registration, set forth the date when such use of the mark in commerce stopped and the approximate date when such use is expected to resume; and recite facts to show that nonuse as to those goods, services, or classes is due to special circumstances that excuse the nonuse and is not due to an intention to abandon the mark; and

(7) Include one specimen showing how the mark is in use in commerce for each class in the registration, unless excusable nonuse is claimed under paragraph (a)(6)(ii) of this section. When requested by the Office, additional specimens must be provided. The specimen must meet the requirements of § 2.56 of this chapter.

(8) Additional requirements for a collective mark: In addition to the above requirements, a complete affidavit or declaration pertaining to a collective mark must:

(i) State that the holder is exercising legitimate control over the use of the mark in commerce; and

(ii) State the nature of the holder's control over the use of the mark by the members in the first affidavit or declaration filed under paragraph (a)(1) of this section.

(9) Additional requirements for a certification mark: In addition to the above requirements, a complete affidavit or declaration pertaining to a certification mark must:

(i) Include a copy of the certification standards specified in § 2.45(a)(4)(i)(B) of this chapter;

(A) *Submitting certification standards for the first time.* In the first affidavit or declaration filed under paragraph (a)(1) of this section, include a copy of the certification standards; or

(B) *Certification standards submitted in prior filing.* If the certification standards in use at the time of filing the affidavit or declaration have not changed since the date they were previously submitted to the Office, include a statement to that effect; if the certification standards in use at the time of filing the affidavit or declaration have changed since the date they were previously submitted to the Office, include a copy of the revised certification standards;

(ii) State that the holder is exercising legitimate control over the use of the mark in commerce; and

(iii) Satisfy the requirements of § 2.45(a)(4)(i)(A) and (C) of this chapter.

(b) *Requirement for the submission of additional information, exhibits, affidavits or declarations, and specimens.* The Office may require the holder to furnish such information, exhibits, affidavits or declarations, and such additional specimens as may be reasonably necessary to the proper examination of the affidavit or declaration under section 71 of the Act or for the Office to assess and promote the accuracy and integrity of the register.

(c) *Fee for deletions of goods, services, and/or classes from a registration.* Deletions by the holder of goods, services, and/or classes from a registration after submission and prior to acceptance of the affidavit or declaration must be accompanied by the relevant fee in § 7.6(a)(6)(iii) or (iv).

Dated: June 12, 2020.

Andrei Iancu,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2020–13262 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–16–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR 83

[EPA–HQ–OAR–2020–00044; FRL 10011–13–OAR]

RIN 2060–AU51

Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process; Extension of Comment Period and Public Hearing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking; extension of comment period and notification of public hearing.

SUMMARY: On June 11, 2020, the Environmental Protection Agency (EPA) published the proposed rulemaking ''Increasing Consistency and Transparency in Considering Benefits and Costs in the Clean Air Act Rulemaking Process.'' The EPA is extending the comment period on the proposed rulemaking. The EPA is also announcing that a virtual public hearing

will be held for the proposed rulemaking.

DATES:

Comments: The comment period for the proposed rulemaking published June 11, 2020 (85 FR 35612), is extended. The EPA must receive comments on the proposed action on or before August 3, 2020.

Public hearing: The EPA will hold a virtual public hearing on July 1, 2020. Please refer to the **SUPPLEMENTARY INFORMATION** section for additional information on the public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2020–00044, by any of the following methods:

• *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID No. EPA–HQ–OAR–2020–00044 for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document. Out of an abundance of caution for members of the public and our staff, the EPA Docket Center and Reading Room was closed to public visitors on March 31, 2020, to reduce the risk of transmitting COVID–19. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov* or email, as there is a temporary suspension of mail delivery to EPA, and no hand deliveries are currently accepted. For further information on EPA Docket Center services and the current status, please visit us online at *https://www.epa.gov/dockets.*

Virtual Public Hearing. The virtual public hearing will be held via teleconference July 1, 2020. Refer to the **SUPPLEMENTARY INFORMATION** section below for additional information.

FOR FURTHER INFORMATION CONTACT: Leif Hockstad, Office of Air Policy and Program Support, Office of Air and Radiation, Environmental Protection Agency, Mail Code 6103A, 1200 Pennsylvania Avenue NW, Washington, DC 20460; (202) 343–9432; email address: *hockstad.leif@epa.gov.*

SUPPLEMENTARY INFORMATION: This document extends the public comment period for the proposed rulemaking to ensure that the public has sufficient time to review and comment on the proposal. The comment period on the proposed rulemaking will close on August 3, 2020.

The EPA is proposing processes that it would be required to undertake in promulgating regulations under the CAA to ensure that information regarding the benefits and costs of regulatory decisions is provided and considered in a consistent and transparent manner. The public hearing will provide interested parties the opportunity to present data, views, or arguments concerning EPA's proposed requirements for benefits and costs analyses for CAA rulemakings. Written statements and supporting information submitted during the comment period will be considered with the same weight as any oral comments and supporting information presented at the public hearings.

Written Comments. Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2020–00044, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The EPA is temporarily suspending its Docket Center and Reading Room for public visitors to reduce the risk of transmitting COVID–19. Written comments submitted by mail are temporarily suspended and no hand deliveries will be accepted. Our Docket Center staff will continue to provide remote customer service via email, phone, and webform. We encourage the public to submit comments via *https://www.regulations.gov.* For further information and updates on EPA Docket Center services, please visit us online at *https://www.epa.gov/dockets.*

The EPA continues to carefully and continuously monitor information from the Centers for Disease Control and Prevention (CDC), local area health departments, and our Federal partners so that we can respond rapidly as conditions change regarding COVID–19.

Participation in Virtual Public Hearing. Please note that EPA is deviating from its typical approach because the President has declared a national emergency. Because of current CDC recommendations, as well as state and local orders for social distancing to limit the spread of COVID–19, EPA cannot hold in-person public meetings at this time. The EPA will begin pre-registering speakers and attendees for the hearing upon publication of this document in the **Federal Register**. The EPA will accept registrations on an individual basis. To register to speak at the virtual hearing, individuals may use the online registration form available via EPA's Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process web page for this hearing (*https://www.epa.gov/environmental-economics/increasing-consistency-and-transparency-considering-costs-and-benefits*) or contact Leif Hockstad at (202) 343–9432 or *hockstad.leif@epa.gov.* The last day to pre-register to speak at the hearing will be June 26, 2020. On June 30, 2020, the EPA will post a general agenda for the hearing that will list pre-registered speakers in approximate order at: *https://www.epa.gov/environmental-economics/increasing-consistency-and-transparency-considering-costs-and-benefits.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearing to run either ahead of schedule or behind schedule. Additionally, requests to speak will be taken the day of the hearing at the end of each session as timing allows. The EPA will make every effort to accommodate all speakers.

Each commenter will have 5 minutes to provide oral testimony. The EPA recommends submitting the text of your oral comments as written comments to the rulemaking docket. The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral comments and supporting information presented at the public hearing.

The EPA is also asking hearing attendees to pre-register for the hearing, even those who don't intend to provide testimony. This will help the EPA ensure that sufficient phone lines will be available.

Please note that any updates made to any aspect of the hearing logistics, including potential additional sessions, will be posted online at the EPA's Increasing Consistency and Transparency in Considering Costs and Benefits in the Rulemaking Process website (*https://www.epa.gov/environmental-economics/increasing-consistency-and-transparency-considering-costs-and-benefits*). While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to determine if there are any updates.

If you require the services of a translator or special accommodations such as audio description, please pre-register for the hearing and describe your needs by June 26, 2020. EPA may not be able to arrange accommodations without advanced notice.

How can I get copies of the proposed action and other related information?

The EPA has also established the official public docket for the proposed action under Docket ID No. EPA–HQ–OAR–2020–00044. A copy of the proposed action is available at *https://www.epa.gov/environmental-economics/increasing-consistency-and-transparency-considering-costs-and-benefits,* and any detailed information related to the proposed action will be available in the public docket prior to the public hearings. Verbatim transcripts of the hearings and written statements will be included in the rulemaking docket.

John Shoaff,

Director, Office of Air Policy and Program Support.

[FR Doc. 2020–13222 Filed 6–18–20; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 85, No. 119

Friday, June 19, 2020

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

West Virginia Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The West Virginia Resource Advisory Committee (RAC) will hold a virtual meeting. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with the Act. RAC information can be found at the following website: *https://cloudapps-usda-gov.secure.force.com/FSSRS/RAC_Page?id=001t0000002JcuqAAC.*

DATES: The meeting will be held on July 21, 2020, at 9:00 a.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held with virtual attendance only. For virtual meeting information, please reach out to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Monongahela National Forest Headquarters Building. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Julie Fosbender, RAC Coordinator, by phone at 304–635–4446 or via email at *julie.fosbender@usda.gov.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Discuss, evaluate and recommend Title II project proposals.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by July 15, 2020, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Julie Fosbender, RAC Coordinator, Monongahela National Forest Headquarters Building, 200 Sycamore Street, Elkins, West Virginia 26241; by email to *julie.fosbender@usda.gov*; or via facsimile to 304–637–0582.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case-by-case basis.

Dated: June 16, 2020.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2020–13283 Filed 6–18–20; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–38–2020]

Foreign-Trade Zone (FTZ) 126—Reno, Nevada; Notification of Proposed Production Activity; Tesla, Inc. (Battery Penthouse Controllers); McCarren and Sparks, Nevada

Tesla, Inc. (Tesla) submitted a notification of proposed production activity to the FTZ Board for its facilities in McCarren and Sparks, Nevada. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on June 10, 2020.

Tesla already has authority to produce lithium-ion batteries, electric motors, and stationary energy storage systems within Subzone 126D. The current request would add a finished product and eleven foreign status materials/components to the scope of authority. Pursuant to 15 CFR 400.14(b), additional FTZ authority would be limited to the specific foreign-status materials/components and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt Tesla from customs duty payments on the foreign-status materials/components used in export production. On its domestic sales, for the foreign-status materials/components noted below and in the existing scope of authority, Tesla would be able to choose the duty rate during customs entry procedures that apply to battery penthouse controllers (duty rate 2.7%). Tesla would be able to avoid duty on foreign-status components which become scrap/waste. Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

The materials/components sourced from abroad include battery penthouse controllers, plastic carriers, aluminum gaskets, gearbox casings, power converters, radial bearings, resolver sensors, rotor rings, unsaturated polyester imide resin, plastic vents, and voltage measurement boards (duty rate ranges from duty-free to 6.5%). The request indicates that certain materials/components are subject to special duties under Section 232 of the Trade

Expansion Act of 1962 (Section 232) or Section 301 of the Trade Act of 1974 (Section 301), depending on the country of origin. The applicable Section 232 and Section 301 decisions require subject merchandise to be admitted to FTZs in privileged foreign status (19 CFR 146.41).

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is July 29, 2020.

A copy of the notification will be available for public inspection in the ''Reading Room'' section of the Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Juanita Chen at *juanita.chen@trade.gov* or 202–482–1378.

Dated: June 15, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–13268 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–120]

Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof From the People's Republic of China: Preliminary Affirmative Countervailing Duty Determination, Preliminary Negative Critical Circumstances Determination, and Alignment of Final Determination With Final Antidumping Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that producers and/or exporters subject to this investigation received countervailable subsidies. Interested parties are invited to comment on this preliminary determination.

DATES: Applicable June 19, 2020.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

This preliminary determination is made in accordance with section 703(b) of the Tariff Act of 1930, as amended (the Act). Commerce published the notice of initiation of this investigation on February 18, 2020.[1] On March 26, 2020, Commerce postponed the preliminary determination of this investigation and reset the deadline to June 15, 2020.[2]

For a complete description of the events that followed the initiation of this investigation, *see* the Preliminary Decision Memorandum.[3] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix II to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The signed and electronic versions of the Preliminary Decision Memorandum are identical in content.

Scope of the Investigation

The products covered by this investigation are certain large vertical shaft engines. For a complete description of the scope of this investigation, *see* Appendix I.

Scope Comments

In accordance with the Preamble to Commerce's regulations,[4] the *Initiation Notice* set aside a period of time for parties to raise issues regarding product coverage (*i.e.,* scope).[5] Certain interested parties commented on the scope of the investigation as it appeared in the *Initiation Notice.* For a summary of the product coverage comments submitted to the record for this preliminary determination, and accompanying discussion and analysis of all comments timely received, *see* the Preliminary Decision Memorandum. Commerce has not modified the scope language as it appeared in the *Initiation Notice. See* Appendix I.

Period of Investigation

The period of investigation is January 1, 2019 through December 31, 2019.

Methodology

Commerce is conducting this investigation in accordance with section 701 of the Act. For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that confers a benefit on the recipient, and that the subsidy is specific.[6] For a full description of the methodology underlying our preliminary conclusions, *see* the Preliminary Decision Memorandum.

In making these findings, Commerce relied, in part, on facts available. For further information, *see* ''Use of Facts Otherwise Available and Adverse Inferences'' in the Preliminary Decision Memorandum.

Alignment

In accordance with section 705(a)(1) of the Act and 19 CFR 351.210(b)(4), and based on the petitioners'[7] request,[8] we are aligning the final countervailing duty (CVD) determination in this investigation with the final determination in the companion antidumping duty (AD) investigation of certain large vertical shaft engines from China. Consequently, the final CVD determination will be issued on the same date as the final AD determination, which is currently scheduled to be issued no later than October 26, 2020, unless postponed.

Preliminary Negative Determination of Critical Circumstances

The Petition[9] included an allegation that critical circumstances exist with

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[1] *See Certain Vertical Shaft Engines Between 223cc and 999cc, and Parts Thereof from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 83 FR 8835 (February 18, 2020) (*Initiation Notice*).

[2] *See Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation,* 85 FR 17042 (March 26, 2020).

[3] *See* Memorandum, ''Decision Memorandum for the Preliminary Affirmative Determination and Preliminary Negative Critical Circumstances Determination in the Countervailing Duty Investigation of Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *See Antidumping Duties; Countervailing Duties, Final Rule,* 62 FR 27296, 27323 (May 19, 1997).

[5] *See Initiation Notice.*

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] The petitioners are the Coalition of American Vertical Engine Producers and its individual members.

[8] *See* Petitioners' Letter, ''Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the People's Republic of China: Request to Align Countervailing Duty Investigation Final Determination with Antidumping Duty Investigation Final Determination,'' dated June 5, 2020.

[9] *See* Petitioners' Letter, ''Petitions for the Imposition of Antidumping and Countervailing Duties on Certain Vertical Shaft Engines Between 225cc and 999cc, and Parts Thereof from the

Continued

respect to imports of the subject merchandise. The petitioners alleged, based on trade statistics, that there is a reasonable basis to believe or suspect that critical circumstances exist with regard to imports of large vertical shaft engines [10] Based on monthly shipment information requested from the mandatory respondents as well as publicly available trade statistics, Commerce is preliminarily determining that critical circumstances do not exist within the meaning of section 703(e)(1) of the Act. For further information, *see* the Preliminary Decision Memorandum.

All-Others Rate

Sections 703(d)(1)(A)(i) and 705(c)(5)(A) of the Act provide that in the preliminary determination, Commerce shall determine an estimated all-others rate for companies not individually examined. This rate shall be an amount equal to the weighted average of the estimated subsidy rates established for those companies individually examined, excluding any rates that are zero, *de minimis,* or based entirely under section 776 of the Act.

In this investigation, Commerce calculated individual estimated countervailable subsidy rates for Loncin Motor Co. (Loncin) and Chongqing Zongshen General Power Machine Co., Ltd. (Zhongshen) that are not zero, *de minimis,* or based entirely on the facts otherwise available. Commerce calculated the all-others rate using a weighted average of the individual estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged values for the merchandise under consideration.[11]

Preliminary Determination

Commerce preliminarily determines that the following estimated countervailable subsidy rates exist:

Producers/exporters	Subsidy rate (percent)
Loncin Motor Co	19.61
Chongqing Zongshen General Power Machine Co	37.75
All Others	30.98

Suspension of Liquidation

In accordance with section 703(d)(1)(B) and (d)(2) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise as described in the scope of the investigation section entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**. Further, pursuant to 19 CFR 351.205(d), Commerce will instruct CBP to require a cash deposit equal to the rates indicated above.

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties in this preliminary determination within five days of its public announcement, or if there is no public announcement, within five days of the date of this notice in accordance with 19 CFR 351.224(b).

Verification

As provided in section 782(i)(1) of the Act, Commerce intends to verify the information relied upon in making its final determination.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this investigation. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than seven days after the deadline date for case briefs.[12] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this investigation are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, limited to issues raised in the case and rebuttal briefs, must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number; the number of participants; whether any participant is a foreign national; and a list of the issues to be discussed. If a request for a hearing is made, Commerce intends to hold the hearing at the U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, at a time and date to be determined. Parties should confirm by telephone the date, time, and location of the hearing two days prior to the scheduled date.

Parties are reminded that briefs and hearing requests are to be filed electronically using ACCESS and that electronically filed documents must be received successfully in their entirety by 5 p.m. Eastern Time on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until July 17, 2020, unless extended.[13]

International Trade Commission Notification

In accordance with section 703(f) of the Act, Commerce will notify the International Trade Commission (ITC) of its determination. If Commerce's final determination is affirmative, the ITC will make its final determination before the later of 120 days after the date of this preliminary determination or 45 days after Commerce's final determination.

Notification to Interested Parties

This determination is issued and published pursuant to sections 703(f) and 777(i) of the Act and 19 CFR 351.205(c).

Dated: June 15, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation consists of spark-ignited, non-road, vertical shaft engines, whether finished or unfinished, whether assembled or unassembled, primarily for riding lawn mowers and zero-turn radius lawn mowers. Engines meeting this physical description may also be for other non-hand-held outdoor power equipment such as, including but not

People's Republic of China,'' dated January 15, 2020 (the Petition).

[10] *See* Volume IV of the Petition at 3–6.

[11] With two respondents under examination, Commerce normally calculates (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010). As complete publicly ranged sales data was available, Commerce based the all-others rate on the publicly ranged sales data of the mandatory respondents. For a complete analysis of the data, *see* the All-Others Rate Calculation Memorandum, dated concurrently with this **Federal Register** notice.

[12] *See* 19 CFR 351.309; *see also* 19 CFR 351.303 (for general filing requirements).

[13] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 29615 (May 18, 2020).

limited to, tow-behind brush mowers, grinders, and vertical shaft generators. The subject engines are spark ignition, single or multiple cylinder, air cooled, internal combustion engines with vertical power take off shafts with a minimum displacement of 225 cubic centimeters (cc) and a maximum displacement of 999cc. Typically, engines with displacements of this size generate gross power of between 6.7 kilowatts (kw) to 42 kw.

Engines covered by this scope normally must comply with and be certified under Environmental Protection Agency (EPA) air pollution controls title 40, chapter I, subchapter U, part 1054 of the Code of Federal Regulations standards for small non-road spark-ignition engines and equipment. Engines that otherwise meet the physical description of the scope but are not certified under 40 CFR part 1054 and are not certified under other parts of subchapter U of the EPA air pollution controls are not excluded from the scope of this proceeding. Engines that may be certified under both 40 CFR part 1054 as well as other parts of subchapter U remain subject to the scope of this proceeding.

For purposes of this investigation, an unfinished engine covers at a minimum a sub-assembly comprised of, but not limited to, the following components: Crankcase, crankshaft, camshaft, piston(s), and connecting rod(s). Importation of these components together, whether assembled or unassembled, and whether or not accompanied by additional components such as an oil pan, manifold, cylinder head(s), valve train, or valve cover(s), constitutes an unfinished engine for purposes of this investigation. The inclusion of other products such as spark plugs fitted into the cylinder head or electrical devices (*e.g.,* ignition modules, ignition coils) for synchronizing with the motor to supply tension current does not remove the product from the scope. The inclusion of any other components not identified as comprising the unfinished engine subassembly in a third-country does not remove the engine from the scope.

The engines subject to this investigation are typically classified in the Harmonized Tariff Schedule of the United States (HTSUS) at subheadings: 8407.90.1020, 8407.90.1060, and 8407.90.1080. The engine subassemblies that are subject to this investigation enter under HTSUS 8409.91.9990. Engines subject to this investigation may also enter under HTSUS 8407.90.9060 and 8407.90.9080. The HTSUS subheadings are provided for convenience and customs purposes only, and the written description of the merchandise under investigation is dispositive.

Appendix II

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope Comments
IV. Scope of the Investigation
V. Injury Test
VI. Preliminary Negative Determination of Critical Circumstances
VII. New Subsidy Allegation
VIII. Alignment
IX. Diversification of China's Economy
X. Subsidies Valuation
XI. Benchmarks and Interest Rates
XII. Use of Facts Otherwise Available and Adverse Inferences
XIII. Analysis of Programs
XIV. Calculation of the All-Others Rate
XV. ITC Notification
XVI. Verification
XVII. Disclosure and Public Comment
XVIII. Recommendation

[FR Doc. 2020–13270 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–913]

Certain New Pneumatic Off-the-Road Tires From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Results of Administrative Review and Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On June 5, 2020, the United States Court of International Trade (the Court) sustained the Department of Commerce's (Commerce) remand redetermination pertaining to the 2015 administrative review of the countervailing duty (CVD) order on certain new pneumatic off-the-road tires (OTR Tires) from the People's Republic of China (China). Commerce is notifying the public that the Court has made a final judgment that is not in harmony with the final results of the 2015 administrative review, and that Commerce is amending the final results of the 2015 administrative review with respect to Guizhou Tyre Co., Ltd. (Guizhou Tyre) and non-selected companies.

DATES: Applicable June 15, 2020.

FOR FURTHER INFORMATION CONTACT: Chien-Min Yang, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5484.

SUPPLEMENTARY INFORMATION:

Background

On April 13, 2018, Commerce published its *Final Results* pertaining to mandatory respondents Guizhou Tyre and Xuzhou Xugong Tyres Co., Ltd. (Xuzhou Xugong), along with other exporters.[1] The period of review (POR) is January 1, 2015 through December 31, 2015. In the *Final Results,* Commerce found that the use of adverse facts available (AFA) was warranted in determining the countervailability of the Export Buyer's Credit Program (EBCP) because the Government of China (GOC) did not provide the requested information needed to allow Commerce to fully analyze this program and, thus, had not cooperated to the best of its ability in response to our information requests.[2] Guizhou Tyre challenged Commerce's determination to apply AFA with respect to this program, and Commerce's finding that the synthetic rubber market was not distorted during the POR, as well as other aspects of the *Final Results.*

On May 15, 2019, the Court remanded the *Final Results* to Commerce to: (1) Reconsider our decision to apply AFA with respect to the EBCP; and (2) reconsider or further explain our market distortion decision with respect to the synthetic rubber market in China.[3] On August 27, 2019, Commerce reconsidered its decision to apply AFA with respect to the EBCP and provided additional explanation in support of its treatment of the program. Commerce also reexamined its synthetic rubber market distortion finding, providing a more detailed analysis of market conditions, and continued to find that the synthetic rubber market was not distorted in China during the POR.

On December 10, 2019, the Court affirmed Commerce's additional explanation and finding of market distortion in the Chinese synthetic rubber market.[4] However, the Court ordered that Commerce reconsider its decision to apply AFA with respect to the EBCP, holding that Commerce had not established that a gap in the record existed such that the agency needed to rely on facts otherwise available.[5]

On March 5, 2020, Commerce reconsidered its decision to apply AFA in evaluating use of the EBCP and determined, under protest, that the EBCP program was not used by the

[1] *See Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2015,* 83 FR 16055 (April 13, 2018) (*Final Results*), and accompanying Issues and Decision Memorandum (IDM), as amended, *Certain New Pneumatic Off-the-Road Tires from the People's Republic of China: Amended Final Results of Countervailing Duty Administrative Review, 2015,* 83 FR 32078 (July 11, 2018).

[2] *See* IDM at 13–14.

[3] *See Guizhou Tyre Co., Ltd. et al.* v. *United States,* 389 F. Supp. 3d 1315, 1329 (May 15, 2019).

[4] *See Guizhou Tyre Co., Ltd. et al.* v. *United States,* 415 F. Supp. 3d 1335, 1339–40 (December 10, 2019) (*Second Remand Order*).

[5] *See Second Remand Order,* 415 F. Supp. 3d 1335, 1340–44 (December 10, 2019).

respondents.[6] Accordingly, Commerce calculated a revised subsidy rate of 29.44 percent for Guizhou Tyre and other non-selected companies.[7]

On June 5, 2020, the Court sustained Commerce's *Second Remand Results* and entered final judgement.[8]

Timken Notice

In its decision in *Timken,*[9] as clarified by *Diamond Sawblades,*[10] the Court of Appeals for the Federal Circuit held that, pursuant to section 516A(e) of the Act, Commerce must publish a notice of a court decision that is not in harmony with a Commerce determination and must suspend liquidation of entries pending a conclusive court decision. The Court's June 5, 2020 final judgment sustaining Commerce's *Second Remand Results* constitutes a final decision of the Court that is not in harmony with Commerce's *Final Results.*[11] This notice is published in fulfillment of the *Timken* publication requirements. Accordingly, Commerce will continue the suspension of liquidation of the OTR Tires subject to this review pending expiration of the period of appeal or, if appealed, pending a final and conclusive court decision.

Amended Final Results

Because there is now a final court decision, we are amending the *Final Results* with respect to the countervailing duty rates calculated for Guizhou Tyre and the non-selected companies. Based on the *Second Remand Results,* as affirmed by the Court, the revised countervailing subsidy rates for Guizhou Tyre and the non-selected companies, from January 1, 2015 through December 31, 2015, are 29.44 percent.[12]

In the event that the Court's ruling is not appealed, or, if appealed, is upheld by a final and conclusive court decision, Commerce will instruct Customs and Border Protection to assess countervailing duties on unliquidated entries of subject merchandise based on the revised subsidy rates summarized above.

[6] *See* Results of Redetermination Pursuant to Court Remand (March 5, 2020) (*Second Remand Results*) at 3–4.

[7] *Id.* at 4–5.

[8] *See Guizhou Tyre Co., Ltd. et al.* v. *United States,* CIT Slip Op. 20–81, Consol. Ct. No. 18–00100 (June 5, 2020).

[9] *See Timken Co.* v. *United States,* 893 F.2d 337, 341 (Fed. Cir. 1990) (*Timken*).

[10] *See Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

[11] *See Final Results.*

[12] *See Second Remand Results* at 4–5.

Notification to Interested Parties

This notice is issued and published in accordance with section 516A(e)(1), 781(d), and 777(i)(1) of the Act.

Dated: June 15, 2020.

Jeffrey I. Kessler,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2020–13266 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA155]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Chevron Richmond Refinery Long Wharf Maintenance and Efficiency Project in San Francisco Bay, California

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; issuance of renewal incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA), as amended, notification is hereby given that NMFS has issued a Renewal incidental harassment authorization (IHA) to Chevron Products Company (Chevron) to incidentally harass marine mammals incidental to the Long Wharf Maintenance and Efficiency Project (LWMEP) in San Francisco Bay, California.

DATES: This Renewal IHA is valid from June 15, 2020 through May 31, 2021.

FOR FURTHER INFORMATION CONTACT: Bonnie DeJoseph, Office of Protected Resources, NMFS, (301) 427–8401. Electronic copies of the original application, Renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: *https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act.* In case of problems accessing these documents, please call the contact listed above.

SUPPLEMENTARY INFORMATION:

Background

The Marine Mammal Protection Act (MMPA) prohibits the ''take'' of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed incidental take authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other ''means of effecting the least practicable adverse impact'' on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as ''mitigation measures''). Monitoring and reporting of such takings are also required. The meaning of key terms such as ''take,'' ''harassment,'' and ''negligible impact'' can be found in section 3 of the MMPA (16 U.S.C. 1362) and the agency's regulations at 50 CFR 216.103.

NMFS' regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed one year for each reauthorization. In the notice of proposed IHA for the initial authorization, NMFS described the circumstances under which we would consider issuing a Renewal for this activity, and requested public comment on a potential Renewal under those circumstances. Specifically, on a case-by-case basis, NMFS may issue a one time one-year Renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical, activities as described in the *Description of the Specified Activities and Anticipated Impacts* section of this notice is planned or (2) the activities as described in the *Description of the Specified Activities and Anticipated Impacts* section of this notice would not be completed by the time the IHA expires and a Renewal would allow for completion of the activities beyond that described in the Dates and Duration section of the initial

notice, provided all of the following conditions are met:

• A request for renewal is received no later than 60 days prior to the needed Renewal IHA effective date (recognizing that the Renewal IHA expiration date cannot extend beyond one year from expiration of the initial IHA).

• The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested Renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.,* reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take).

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for Renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed Renewal. A description of the Renewal process may be found on our website at: *www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals.*

The NDAA (Pub. L. 108–136) removed the ''small numbers'' and ''specified geographical region'' limitations indicated above and amended the definition of ''harassment'' as it applies to a ''military readiness activity.''

History of Request

On June 19, 2019, NMFS issued an IHA to Chevron to take marine mammals incidental to Chevron Richmond Refinery Long Wharf Maintenance and Efficiency Project (LWMEP) in in San Francisco Bay, California (84 FR 28474; June 19, 2019), effective from June 1, 2019 through May 31, 2020. On January 30, 2020, NMFS received an application for the Renewal of that initial IHA. As described in the application for Renewal, the activities for which incidental take is requested consist of activities that are covered by the initial 2019 IHA but will not be completed prior to its expiration. As required, the applicant also provided a preliminary monitoring report (available at *https://www.fisheries.noaa.gov/action/incidental-take-authorization-chevron-long-wharf-maintenance-and-efficiency-project-san-0*) which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted.

Description of the Specified Activities and Anticipated Impacts

Chevron will be unable to complete all of the planned work in the 2019 IHA at the Richmond Refinery Long Wharf (Long Wharf) before the expiration date of May 31, 2020 and, therefore, they have requested a Renewal IHA to authorize take of marine mammals for the subset of the initially planned work that could not be completed. These planned construction activities would allow Chevron to comply with Marine Oil Terminal Engineering and Maintenance Standards (MOTEMS) and to improve safety and efficiency at the Long Wharf. The work will be identical to a subset of the activities analyzed in the 2019 IHA and include both vibratory and impact pile driving for removal and installation of piles. Chevron installed 46 piles and removed 10 piles (of which 8 were temporary and removed shortly after installation) over approximately 18 construction days under the 2019 IHA, leaving 69 piles remaining to be installed and up to 109 piles to be removed in the June 1 to November 30, 2020 construction window. Similarly, the mitigation and monitoring will be identical to that included in the 2019 IHA. All documents associated with the 2019 IHA (*i.e.,* the IHA application, proposed IHA, final IHA, public comments, monitoring reports, *etc.*) can be found on NMFS's website, *https://www.fisheries.noaa.gov/action/incidental-take-authorization-chevron-long-wharf-maintenance-and-efficiency-project-san-0.* All documents associated with the 2018 IHA (which are sometimes referenced in the **Federal Register** notices supporting the 2019 IHA) can be found at: *https://www.fisheries.noaa.gov/action/incidental-take-authorization-chevron-long-wharf-maintenance-and-efficiency-project-san.*

Anticipated impacts, which will include both Level A and Level B harassment of marine mammals, will also be identical to those analyzed and authorized in the 2019 IHA (though fewer, since from a subset of activities). Species with the expected potential to be present during all or a portion of the in-water work window include the Gray whale (*Eschrichtius robustus*), Bottlenose dolphin (*Tursiops truncates*), harbor porpoise (*Phocoena phocoena*), California sea lion (*Zalophus californianus*), Northern fur seal (*Callorhinus ursinus*), Pacific harbor seal (*Phoca vitulina richardii*), and Northern elephant seal (*Mirounga angustirostris*). Monitoring results of the 2019 construction activities indicate that observed exposures above Level A and Level B harassment thresholds (see monitoring report) were below the amount authorized in association with the amount of work conducted; thus, the subset of Level A and Level B take remaining from that authorized under the 2019 IHA will be sufficient to cover the 2020 pile installation and removal activities.

Detailed Description of the Activity

A detailed description of the construction activities for which take is authorized here may be found in the notices of the proposed and final IHAs for the 2019 authorization. The work will be identical to a subset of the activities analyzed in the 2019 IHA and include both vibratory and impact pile driving for removal and installation of piles.

All piles for which take was authorized in the 2019 IHA were expected to be installed/removed during the 2019 in-water work window from June 1 to November 30, 2019. However, due to construction schedule delays, designated work was only conducted on 18 of the estimated 67 days of pile driving activity planned in the 2019 IHA. Table 1 shows the work completed in 2019 and the remaining subset of work covered under this Renewal. Identical to the 2019 IHA, pile driving activities will be timed to occur within the standard NMFS work windows for Endangered Species Act (ESA)- listed fish species (June 1 through November 30). This Renewal IHA is effective for a period of one year from the date of issuance.

TABLE 1—PILE INSTALLATIONS COMPLETED IN 2019 AND REMAINING SUBSET PLANNED FOR THE 2020 CONSTRUCTION WINDOW

Pile type	Pile driver type	Number of piles 2019 IHA	Number of piles completed in 2019	Number of piles requested in 2020 renewal application	Number installed/ removed per day 2020	Number of driving days 2020
60-inch steel pipe piles	Impact	8	0	8	1	8
36-inch steel template pile (Installation and removal).	Vibratory	8	8	0		0
20-inch steel template pile (Installation and removal).	Vibratory	8	8	0		0
22-inch concrete pile removal	Vibratory	5	2	3	5	1
24-inch square concrete	Impact	39	30	9	2	5
12-inch composite piles	Vibratory	52	0	52	5	11
Timber pile removal	Vibratory	106	0	106	12	9
Total		226	*48	178	NA	34

*46 piles were installed and 2 other piles were removed. Eight of the 46 piles were temporary and removed shortly after installation. Thus, a total of 48 piles were utilized in construction activities during 2019, in which 46 pile installations and 10 pile removals were monitored, as required by the initial IHA.

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which take is authorized here, including information on abundance, status, distribution, and hearing, may be found in the notices of the proposed and final IHAs for the 2019 authorization. NMFS has reviewed the monitoring data from the 2019 IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, and other scientific literature, and determined that neither this nor any other new information affects which species or stocks have the potential to be affected or the pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents for the 2019 IHA. The only change from the 2019 IHA is a reduction of the San Francisco-Russian River harbor porpoise and the U.S. California sea lion estimated stocks from 9,886 to 7,524 and 296,750 to 257,606, respectively (Carretta *et al.* 2019). NMFS determined that these updates do not change our findings.

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which take is authorized here may be found in the **Federal Register** notice of the issuance of the 2018 IHA for Chevron's Long Wharf Maintenance and Efficiency project (83 FR 27548; June 13, 2018) and the **Federal Register** notice of the proposed IHA (83 FR 18802; April 30, 2018). NMFS has reviewed the monitoring data from the 2019 IHA, recent draft Stock Assessment Reports, information on relevant Unusual Mortality Events, other scientific literature, and the public comments, and determined that neither this nor any other new information affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

As stated above in the *Description of the Specified Activities and Anticipated Impacts* section, the purpose of this Renewal IHA is to authorize take of marine mammals for the subset of the initially planned work that could not be completed before the expiration of the 2019 IHA, May 31, 2020. The subset of work completed in 2019 and that left to be completed during the 2020 construction window is listed in Table 1.

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the notices of the proposed and final IHAs for the 2019 authorization. Specifically, the source levels, in-water construction window, and marine mammal density data applicable to this authorization remain unchanged from the previously issued IHA, just the new, lesser, remaining levels of activity have been applied. Similarly, the stocks taken, methods of take, and types of take remain unchanged from the previously issued IHA.

TABLE 2—AUTHORIZED TAKE OF STOCKS, RENEWAL IHA 2020

Species	Stock	Authorized Level A take	Authorized Level B take
Harbor seal	California	*513	5,114
California sea lion	Eastern U.S.		302
Harbor porpoise	San Francisco–Russian River	*4	321
Northern elephant seal	California Breeding		11
Gray whale	Eastern North Pacific		2
Northern fur seal	California		10
Bottlenose Dolphin	California Coastal		17

*Level A take is associated with impact pile driving of 60-inch steel pipe, which was not conducted in 2019 as planned and is part of the subset of work to be completed in 2020.

Description of Mitigation, Monitoring and Reporting Measures

The authorized mitigation, monitoring, and reporting measures included as requirements in this authorization are identical to those included in the **Federal Register** notice announcing the issuance of the 2019 IHA, and the discussion of the least practicable adverse impact included in that document remains accurate. The following measures are proposed for this renewal:

Proposed Mitigation

Time Restrictions—For all in-water pile driving activities, Chevron must operate only during daylight hours (7 a.m. to 7 p.m.).

Attenuation Devices—Chevron must implement the use of bubble curtains during impact driving of 60-inch steel piles and 24-inch square concrete piles and operate it in a manner consistent with the following performance standards: (1) The bubble curtain must distribute air bubbles around 100 percent of the piling perimeter for the full depth of the water column. (2) The lowest bubble ring must be in contact with the mudline for the full circumference of the ring, and the weights attached to the bottom ring must ensure 100 percent mudline contact. No parts of the ring or other objects shall prevent full mudline contact. (3) Air flow to the bubblers must be balanced around the circumference of the pile.

Establishment of Shutdown Zone—For all pile driving and extraction activities Chevron must implement and monitor shutdown zones. See Table 3 for minimum radial distances required for shutdown zones.

TABLE 3—RADIAL DISTANCE TO SHUTDOWN ZONES

Project element requiring pile installation	Shutdown zones meters				
	Low-frequency cetaceans	Mid-frequency cetaceans	High-frequency Cetaceans	Phocid pinnipeds	Otariid pinnipeds
Attenuated Impact Driving (with bubble curtain)					
60-inch steel pipe	840	30	50	30	35
24-inch square concrete	20	10	50	15	10
Impact Pile Proofing (no bubble curtain)					
36-inch steel pipe pile	100	10	80	30	10
Vibratory Driving/Extraction					
12-inch Composite Barrier Pile	20	10	50	15	10
36-inch steel pipe pile	20	10	50	15	10
20-inch steel pipe pile	10	10	50	10	10
Wood and concrete pile extraction	10	10	50	10	10

Establishment of Monitoring Zones for Level A and Level B—Chevron must establish and monitor Level A harassment zones during impact driving for harbor seal extending to 450 meters (m) and for harbor porpoise extending to 990 m. Chevron must also establish and monitor Level B harassment zones as depicted in Table 4.

TABLE 4—RADIAL DISTANCES TO MONITORING ZONES

Pile type	Distance to threshold 160/120 dB RMS (Level B) in meters
Attenuated Impact Driving (with bubble curtain)	
60-inch steel pipe (1 per day)	740
24-inch square concrete (1–2 per day)	75
Impact Pile Proofing (no bubble curtain)	
36-inch steel pipe pile (2 total)	1,000
Vibratory Driving/Extraction	
12-Inch Composite Barrier Piles (5 per day)	15,850
36-inch steel pipe pile (4 per day)	21,545
20-inch steel pipe pile (4 per day)	7,360
Wood and concrete pile extraction (12 per day)	1,360

Soft Start—Chevron must use soft start techniques when impact pile driving. Chevron must provide an initial set of strikes at reduced energy, followed by a 30-second waiting period, then two subsequent reduced energy strike sets. Soft start must be implemented at the start of each day's impact pile driving and at any time

following cessation of impact pile driving for a period of 30 minutes or longer.

Pre-Activity Monitoring—Pre-activity monitoring must take place from 30 minutes prior to initiation of pile driving activity and post-activity monitoring must continue through 30 minutes post-completion of pile driving activity. Pile driving may commence at the end of the 30-minute pre-activity monitoring period, provided observers have determined that the shutdown zone is clear of marine mammals, which includes delaying start of pile driving activities if a marine mammal is sighted in the zone, as described below.

If a marine mammal approaches or enters the shutdown zone during activities or pre-activity monitoring, all pile driving activities at that location must be halted or delayed, respectively. If pile driving is halted or delayed due to the presence of a marine mammal, the activity may not resume or commence until either the animal has voluntarily left and been visually confirmed beyond the shutdown zone or 15 minutes have passed without re-detection of the animal. Pile driving activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than thirty minutes.

10-Meter Shutdown Zone—During the in-water operation of heavy machinery (*e.g.,* barge movements), a 10-m shutdown zone for all marine mammals must be implemented. If a marine mammal comes within 10 m, operations must cease and vessels must reduce speed to the minimum level required to maintain steerage and safe working conditions.

Non-authorized Take Prohibited—If a species for which authorization has not been granted or a species for which authorization has been granted but the authorized takes are met, is observed approaching or within the monitoring zone, pile driving and removal activities must shut down immediately using delay and shut-down procedures. Activities must not resume until the animal has been confirmed to have left the area or an observation time period of 15 minutes without re-sighting has elapsed.

Proposed Monitoring Measures

Visual Marine Mammal Observation—the following visual monitoring measures must be implemented:

Baseline biological monitoring must occur within one week before the project's start date.

Monitoring distances, in accordance with the identified shutdown zones, Level A and Level B zones, must be determined by using a range finder, scope, hand-held global positioning system (GPS) device or landmarks with known distances from the monitoring positions.

Monitoring locations must be established at locations offering best views of the monitoring zone. One protected species observer (PSO) must be stationed at the north end of the wharf monitoring the entire observable area with a special focus on the section between Castro Rocks and the wharf.

At least two PSOs must be actively scanning the monitoring zone during all pile driving activities.

Observers must record all incidents of marine mammal occurrence, regardless of distance from activity, and must document any behavioral reactions in concert with distance from piles being driven or removed.

Monitoring must be continuous unless the contractor takes a break longer than 2 hours from active pile and sheet pile driving, in which case monitoring must be required 30 minutes prior to restarting pile installation.

For in-water pile driving, under conditions of fog or poor visibility that might obscure the presence of a marine mammal within the shutdown zone or Level A zone, the pile in progress must be completed and then pile driving suspended until visibility conditions improve.

Monitoring of pile driving must be conducted by qualified PSOs, who must have no other assigned tasks during monitoring periods. Chevron must adhere to the following conditions when selecting observers: (1) Independent PSOs must be used (*i.e.,* not construction personnel); (2) At least one PSO must have prior experience working as a marine mammal observer during construction activities; (3) Other PSOs may substitute education (degree in biological science or related field) or training for experience; and (4) Chevron must submit PSO curriculum vitaes for approval by NMFS.

Chevron must ensure that observers have the following additional qualifications: (1) Ability to conduct field observations and collect data according to assigned protocols; (2) Experience or training in the field identification of marine mammals, including the identification of behaviors; (3) Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations; (4) Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and (5) Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Hydroacoustic Monitoring—Sound Source Verification (SSV) testing must be conducted as stipulated in the Hydroacoustic Monitoring Plan. Acoustic monitoring must be conducted on the following: (1) Acoustic monitoring for at least two timber piles (vibratory); (2) Acoustic monitoring for at least four 24-inch square concrete piles (impact); (3) Acoustic monitoring for at least two 20-inch steel piles (vibratory); (4) Acoustic monitoring for at least two 36-inch steel piles (vibratory); (5) Acoustic monitoring for at least two 60-inch steel piles (impact); and (6) Acoustic monitoring of two 12-inch composite piles (vibratory).

Testing must be conducted by an acoustical firm with prior experience conducting SSV testing. Final results must be sent to NMFS and may be used to establish shutdown and monitoring isopleths. Any alterations to the shutdown or monitoring zones based on testing data must be approved by NMFS.

Reporting

Marine Mammal Monitoring—A draft marine mammal monitoring report must be submitted to NMFS within 90 days after the completion of pile driving and removal activities or a minimum of 60 days prior to any subsequent IHAs. A final report must be prepared and submitted to NMFS within 30 days following receipt of comments on the draft report from NMFS.

The report must include an overall description of work completed, a narrative regarding marine mammal sightings, and associated marine mammal observation data sheets. Specifically, the report must include: (1) Dates and times (begin and end) of all marine mammal monitoring; (2) Construction activities occurring during each daily observation period, including how many and what type of piles were removed or driven and by what method (*i.e.,* impact, vibratory, drilling); (3) Weather parameters and water conditions during each monitoring period (*e.g.,* wind speed, percent cover, visibility, sea state); (4) The number of marine mammals observed, by species, relative to the pile location and if pile

removal or installation was occurring at time of sighting; (5) Age and sex class, if possible, of all marine mammals observed; (6) PSO locations during marine mammal monitoring; (7) Distances and bearings of each marine mammal observed to the pile being removed or driven for each sighting (if pile removal or installation was occurring at time of sighting); (8) Description of any marine mammal behavior patterns during observation, including direction of travel; (9) Number of individuals of each species (differentiated by month as appropriate) detected within the monitoring zone, and estimates of number of marine mammals taken, by species; (10) Detailed information about any implementation of any mitigation triggered (*e.g.,* shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal, if any; (11) Description of attempts to distinguish between the number of individual animals taken and the number of incidences of take, such as ability to track groups or individuals; and (12) Level B harassment exposures recorded by PSOs must be extrapolated based upon the number of observed takes and the percentage of the Level B harassment zone that was not visible.

Injury, Serious Injury, or Mortality—In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by the IHA, such as an injury, serious injury or mortality, Chevron would immediately cease the specified activities and report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS (301–427–8701), and the West Coast Regional Stranding Coordinator (562–980–3230). The report must include the following: (1) Description of the incident; (2) Environmental conditions (*e.g.,* Beaufort sea state, visibility); (3) Description of all marine mammal observations in the 24 hours preceding the incident; (4) Species identification or description of the animal(s) involved; (5) Fate of the animal(s); and (6) Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Chevron to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Chevron would not be able to resume their activities until notified by NMFS via letter, email, or telephone.

In the event that Chevron discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition as described in the next paragraph), Chevron would immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator. The report would include the same information identified in section above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Chevron to determine whether modifications in the activities are appropriate.

In the event that Chevron discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Chevron would report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, and the West Coast Regional Stranding Coordinator within 24 hours of the discovery. Chevron would provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network.

Public Comments

A notice of NMFS' proposal to issue a Renewal IHA to Chevron was published in the **Federal Register** on May 6, 2020 (85 FR 26962). That notice either described, or referenced descriptions of, the Chevron's activity, the marine mammal species that may be affected by the activity, the anticipated effects on marine mammals and their habitat, proposed amount and manner of take, and proposed mitigation, monitoring and reporting measures. NMFS received a comment letter from one entity, the Marine Mammal Commission (Commission). The comments and our responses are summarized below.

Comment 1: The Commission recommended that NMFS ensure that Chevron is aware that it must abide by requirement 5(a)(iii) in the final authorization, and ensures that the far-field observer is stationed at the north, not the south end of the wharf, focuses on the area between Castro Rocks and the wharf, and documents any reactions and takes of the seals hauled out at Castro Rocks.

Response: NMFS has clarified with Chevron that at least two PSOs are required to actively scan the shutdown and monitoring zones during all pile driving activities; one PSO is required to be stationed at the north end of the wharf monitoring the entire observable area with a special focus on the section between Castro Rocks and the wharf.

Comment 2: The Commission recommends that NMFS ensure that its internal acoustics expert reviews the hydroacoustic monitoring report and underlying data before the report is accepted as final and before any revised Level A or B harassment zones are used, including for enumerating takes in the annual monitoring report.

Response: NMFS will ensure that the hydroacoustic monitoring report is reviewed as needed prior to being accepted as final or being used as a basis for revising harassment zones. However, NMFS does not concur that Dr. Shane Guan must review every hydroacoustic report, as suggested by the Commission. It is not appropriate for the Commission to dictate the use of NMFS staff resources and NMFS will manage staff review of hydroacoustic report based on the content and complexity of the report, as well as the purpose of the review.

Comment 3: The Commission recommends that NMFS ensure that Chevron uses the appropriate extents of the various Level B harassment zones for extrapolation.

Response: NMFS will ensure that Chevron uses appropriate Level B harassment zones for the purposes of extrapolating estimated Level B harassment take in their final report.

Comment 4: The Commission recommends that NMFS ensure that Chevron reports those animals that were observed and considered taken based on when pile driving and removal is occurring and where the animals are located.

Response: NMFS has made clear to Chevron that only marine mammals observed during the monitoring period(s) defined in the Monitoring Measures section of the IHA should be used to record the estimated take, and that marine mammals observed in the vicinity of pile driving prior to or after active pile driving occurs should be included in the notes.

Comment 5: The Commission recommends that NMFS ensure that Chevron reports the distances only in meters.

Response: NMFS has confirmed that Chevron will provide their reporting data in meters.

Comment 6: The Commission recommends that NMFS ensure that Chevron extrapolates the number(s) of each species taken based on the

number(s) observed and the extent of the unobserved portion of the Level B harassment zone on each day and sums the daily extrapolated takes across the authorization period.

Response: Chevron will average their take across days and then apply the extrapolation factor to correct for the unobserved portion of the Level B zone. However, NMFS has confirmed that Chevron will differentiate their extrapolation of take calculations by pile driving type (*i.e.,* zone size) and then sum the extrapolated takes from the different types, which should alleviate the concerns raised by the Commission.

Comment 7: The Commission recommends that NMFS review all monitoring reports, including having its acoustic expert review all hydroacoustic monitoring reports, before accepting them as final to ensure that the action proponent has abided by the monitoring and reporting requirements under each incidental take authorization.

Response: NMFS acknowledges the need for a thorough review of all monitoring reports and will ensure that hydroacoustic monitoring reports are reviewed as needed prior to being accepted as final to ensure that the action proponent has abided by the monitoring and reporting requirements under each incidental take authorization.

Comment 8: The Commission recommends that NMFS refrain from issuing renewals for any authorization and instead use its abbreviated **Federal Register** notice process which is similarly expeditious and fulfills NMFS's intent to maximize efficiencies.

Response: NMFS does not agree with the Commission and, therefore, does not adopt the Commission's recommendation. NMFS will provide a detailed explanation of its decision within 120 days, as required by section 202(d) of the MMPA.

Comment 9: If NMFS continues to propose to issue renewals, the Commission recommends that it (1) stipulate that a renewal is a one-time opportunity (a) in all **Federal Register** notices requesting comments on the possibility of a renewal, (b) on its web page detailing the renewal process, and (c) in all draft and final authorizations that include a term and condition for a renewal and, (2) if NMFS declines to adopt this recommendation, explain fully its rationale for not doing so.

Response: NMFS agrees with the Commission's recommendation and has instituted this change.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our proposed action (*i.e.,* the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHA with no anticipated serious injury or mortality) of the Companion Manual for NOAA Administrative Order 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has determined that the issuance of the Renewal IHA qualifies to be categorically excluded from further NEPA review.

Determinations

The authorized action of this Renewal IHA, both vibratory and impact pile driving for removal and installation of piles, will be identical to a subset of the activities analyzed in the 2019 IHA, as listed in Table 2. Based on the analysis detailed in the notice of the final IHA for 2019 authorization, of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS found that the total marine mammal take from the activity will have a negligible impact on all affected marine mammal species or stocks.

NMFS has concluded that there is no new information suggesting that our analysis or findings should change from those reached for the 2019 IHA. This includes consideration of the estimated abundance of harbor porpoise and California sea lion stock decreasing slightly. Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) The required mitigation measures will affect the least practicable impact on marine mammal species or stocks and their habitat; (2) the authorized takes will have a negligible impact on the affected marine mammal species or stocks; (3) the authorized takes represent small numbers of marine mammals relative to the affected stock abundances; (4) Chevron's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action, and; (5) appropriate monitoring and reporting requirements are included.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA: 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is proposed for authorization or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

Renewal

NMFS has issued a Renewal IHA to Chevron for the take of marine mammals incidental to conducting vibratory and impact pile driving for removal and installation of piles at the Long Wharf in San Francisco Bay, California during the in-water construction window of June 1 through November 30, 2020.

Dated: June 12, 2020.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–13101 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA127]

Endangered and Threatened Species; Take of Anadromous Fish

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; receipt of one Incidental Take Permit application and one Enhancement of Survival Permit application; availability of a draft environmental assessment; request for comments.

SUMMARY: Notice is hereby given that NMFS has received one Incidental Take Permit application and one Enhancement of Survival Permit

application for Sierra Pacific Land & Timber Company's (SPL&T) Habitat Conservation Plan (HCP) and Safe Harbor Agreement (SHA). The HCP/SHA has been submitted pursuant to Section 10(a)(1)(B) and Section 10(a)(1)(A) of the Endangered Species Act (ESA) of 1973, as amended. NMFS has also prepared a draft environmental assessment (EA) under the National Environmental Policy Act (NEPA) describing the potential effects of NMFS' proposed issuance of the Permits associated with the submitted HCP/SHA.

SPL&T is the largest private forestland owner in the state of California, with ownership currently encompassing approximately 1.64 million acres of timberland throughout the northern and central portions of the state. Sierra Pacific Industries (SPI) is the authorized representative and manager of SPL&T lands. Rivers and streams on portions of SPL&T lands in the Trinity River and Sacramento River basins provide habitat for anadromous salmonids, including species listed under the ESA. NMFS is furnishing this notice in order to allow other agencies and the public an opportunity to review and comment on these documents. All comments and other information received will become part of the public record and will be available for review.

DATES: Comments or requests for a public hearing on the applications must be received at the appropriate address (see **ADDRESSES**) no later than 5 p.m. Pacific standard time on July 20, 2020.

ADDRESSES: Written comments on the submitted HCP/SHA and/or the draft NEPA EA should be addressed to the NMFS California Central Valley Office, Attn: Sierra Pacific Industries HCP/SHA, 650 Capitol Mall, Suite 5–100, Sacramento, CA 95814. Comments may also be submitted via email to *SierraPacificHCP.wcr@noaa.gov.* Include in the subject line of the email the following identifier: Comments on Sierra Pacific Industries HCP/SHA. Please specify whether the comments provided are associated with the HCP/SHA or the draft NEPA EA. When commenting, please refer to the specific page number and the subject of your comment. The documents are available on the internet at: *https://www.fisheries.noaa.gov/action/habitat-conservation-plan-and-safe-harbor-agreement-sierra-pacific-industries-forestland.*

FOR FURTHER INFORMATION CONTACT: Amanda Cranford, Sacramento, CA, at phone number: (916) 930–3706, or via email: *Amanda.Cranford@noaa.gov.*

SUPPLEMENTARY INFORMATION:

ESA-Listed Species Covered in This Notice

Chinook salmon (*Oncorhynchus tshawytscha*), (Evolutionary Significant Units (ESU)): Central Valley (CV) spring-run ESU and Sacramento River (SR) winter-run ESU.

Coho salmon (*O. kisutch*), (ESU): Southern Oregon/Northern California Coast (SONCC) ESU.

Steelhead (*O. mykiss*), (Distinct Population Segments (DPS)): California Central Valley (CCV) DPS.

Background

SPI has prepared a joint HCP/SHA to address effects of forest land management in the Sacramento River and Trinity River basins on salmonids listed under the ESA. The HCP addresses potential impacts resulting from SPI's timber harvest activities in watersheds with watercourses accessible to anadromous salmonids or upstream of those watercourses where potential effects from covered activities have the potential to extend to occupied habitat. Section 10(a)(1)(B) of the ESA authorizes NMFS to issue an Incidental Take Permit to non-Federal parties for the potential incidental taking of endangered and threatened species. In support of an Incidental Take Permit, SPI has prepared a HCP that provides an assessment of impacts; measures to monitor, minimize, and mitigate for those impacts; and procedures to account for unforeseen or extraordinary circumstances.

The SHA addresses potential impacts resulting from SPI's timber harvest activities on SPL&T lands in the Sacramento and Trinity River basins upstream of currently impassable dams where NMFS is proposing to reintroduce populations of ESA-listed *salmonids.* The purpose of the SHA is to provide incentives for non-Federal property owners to voluntarily conduct beneficial activities that either support or attract ESA-listed species. The SHA ensures that new restrictions are not placed on the future use of the property during the permit term, as long as the participating non-Federal property owners meet the terms of the SHA. The SHA identifies the Covered Species, boundaries of the enrolled property, the conservation benefits, the extent of incidental take, and the SHA Assurances. The incidental taking identified in the SHA is authorized under a Section 10(a)(1)(A) Enhancement of Survival Permit. The SHA prepared by SPI is reasonably expected to meet the regulatory standard of producing a net conservation benefit for ESA-listed salmonids to be reintroduced onto SPL&T lands.

Authority

Section 9 of the ESA and Federal regulations prohibit the taking of a species listed as endangered or threatened. The ESA defines ''take'' to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct. NMFS may issue permits, under limited circumstances to take listed species incidental to, and not the purpose of, otherwise lawful activities. Section 10(a)(1)(B) of the ESA and implementing regulations (50 CFR 222.307) provide for authorizing incidental take of listed species.

Enhancement of Survival permits are issued in accordance with Section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR 222.308). NMFS issues permits based on findings that such permits: (1) Are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of Section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

NEPA requires Federal agencies to conduct an environmental analysis of their proposed actions to determine if the actions may affect the human environment. Therefore, NMFS is seeking public input on the scope of the required NEPA analysis in the EA, including the range of reasonable alternatives and associated impacts of any alternatives.

This notice is provided pursuant to section 10(c) of the ESA. NMFS will evaluate the applications, associated documents, and comments submitted to determine whether the applications meet the requirements of section 10(a) of the ESA and Federal regulations. The final permit decisions will not be made until after the end of the 30-day comment period. NMFS will publish notice of its final action in the **Federal Register**.

Dated: June 15, 2020.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2020–13264 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XX060]

Atlantic Coastal Fisheries Cooperative Management Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, NMFS, has made a preliminary determination that an Exempted Fishing Permit application from the University of Connecticut contains all of the required information and warrants further consideration. This Exempted Fishing Permit would allow participating vessels to collect undersized and egg-bearing lobsters to conduct an endocrine disruption study. Regulations under the Magnuson-Stevens Fishery Conservation and Management Act and the Atlantic Coastal Fisheries Cooperative Management Act require publication of this notice to provide interested parties the opportunity to comment on applications for proposed Exempted Fishing Permits.

DATES: Comments must be received on or before July 6, 2020.

ADDRESSES: You may submit written comments by any of the following methods:

- *Email: NMFS.GAR.EFP@noaa.gov.* Include in the subject line ''Comments on UConn Lobster Study.'' If you are unable to submit your comment through *NMFS.GAR.EFP@noaa.gov,* please contact Laura Hansen, Fishery Mangagement Specialist, *Laura.Hansen@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, 978–281–9225, *Laura.Hansen@noaa.gov.*

SUPPLEMENTARY INFORMATION: The University of Connecticut submitted a complete exempted fishing permit (EFP) application on April 21, 2020. This project would collect egg bearing lobsters to examine the impact of endocrine disrupting chemicals on larvae development.

If the EFP is approved, this study would take place from June through September 2020. The EFP would authorize participating vessels to collect up to 18 undersized and 20 egg-bearing lobsters from Lobster Conservation Management Areas 2 and 3. The lobsters collected for this study would range in weight from 1.5–4.5 lb (0.68–2.41 kg). Fishermen would send the lobsters to a researcher at the Marine Biological Laboratory in Woods Hole, MA. The researcher would transfer the lobsters to a holding tank to conduct further analysis of blood samples for the presence of endocrine disruptors and monitor larval development. The researcher will return surviving lobsters to the ocean following the experiments.

If approved, the applicant may request minor modifications and extensions to the EFP throughout the study period. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 15, 2020.

Hélène M.N. Scalliet,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–13214 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XA239]

Mid-Atlantic Fishery Management Council (MAFMC); Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (Council) Atlantic Mackerel, Squid, and Butterfish (MSB) Advisory Panel will hold a meeting.

DATES: The meeting will be held on Monday, July 6, 2020, from 1 p.m. to 4 p.m. For agenda details, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The meeting will be held via webinar with a telephone-only audio connection. See the Council's website calendar at *www.mafmc.org,* for details.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331 or on their website at *www.mafmc.org.*

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore, Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The purposes of the meeting are to gather Advisory Panel input related to MSB quotas and specifications, and to create Fishery Performance Reports for Atlantic mackerel, longfin squid, and butterfish.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aid should be directed to M. Jan Saunders, (302) 526–5251, at least 5 days prior to any meeting date.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 16, 2020.

Tracey L. Thompson,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–13250 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XX059]

Atlantic Coastal Fisheries Cooperative Management Act Provisions; General Provisions for Domestic Fisheries; Application for Exempted Fishing Permits

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; request for comments.

SUMMARY: The NMFS Assistant Regional Administrator for Sustainable Fisheries, Greater Atlantic Region, has made a preliminary determination that an Exempted Fishing Permit application contains all of the required information and warrants further consideration. This Exempted Fishing Permit would allow six commercial lobster vessels to participate in a lobster growth and abundance study, under the direction of Massachusetts Division of Marine Fisheries.

Regulations under the Magnuson-Stevens Fishery Conservation and Management Act and the Atlantic Coastal Fisheries Cooperative Management Act require publication of this notice to provide interested parties

the opportunity to comment on Exempted Fishing Permit applications.

DATES: Comments must be received on or before July 6, 2020.

ADDRESSES: You may submit written comments by any of the following methods:

• *Email: NMFS.GAR.EFP@noaa.gov.* Include in the subject line ''Comments on MA DMF Lobster Study EFP.'' If you are unable to submit your comments to *NMFS.GAR.EFP@noaa.gov,* please contact Laura Hansen, Fishery Management Specialist, *Laura.Hansen@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Laura Hansen, Fishery Management Specialist, 978–281–9225.

SUPPLEMENTARY INFORMATION: The Massachusetts Division of Marine Fisheries (MA DMF) submitted a complete renewal application for an Exempted Fishing Permit (EFP) to conduct a lobster abundance survey that Federal regulations would otherwise restrict. The purpose of this study is to provide fishery-independent data on lobster growth and abundance in Massachusetts state waters of statistical areas 514 and 538.

This survey has occurred annually since 2006 in Massachusetts state waters. On average, 15,604 lobsters per year were sampled from 2007–2016. The EFP would authorize the six participating vessels to deploy three standard and three ventless traps per six-pot trawl. Stations would be sampled twice per month from June through October 2020. Sampling trips would occur after a soak time of 3 to 5 days and at least one MA DMF scientist would be on board for the sampling trips. MA DMF personnel would not be on board when traps are baited and deployed. All gear would be Atlantic Large Whale Take Reduction Plan compliant. Survey traps will be separate from each vessel's commercial lobster traps and would be tagged as, ''MADMF Research Traps.''

All catch during sampling trips would be retained temporarily to collect biological data. MA DMF staff may collect lobster and/or Jonah crab, including undersized, oversized, v-notched, and egg-bearing lobsters. Collected samples would be used for research projects on growth and maturity. No catch from the experimental trips would be landed for sale.

If approved, MA DMF may request minor modifications and extensions to the EFP throughout the study. EFP modifications and extensions may be granted without further notice if they are deemed essential to facilitate completion of the proposed research and have minimal impacts that do not change the scope or impact of the initially approved EFP request. Any fishing activity conducted outside the scope of the exempted fishing activity would be prohibited.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 15, 2020.

Hélène M.N. Scalliet,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2020–13221 Filed 6–18–20; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from the Procurement List.

SUMMARY: The Committee is proposing to add products and services to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products previously furnished by such agencies.

DATES: Comments must be received on or before: July 19, 2020.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia, 22202–4149.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products and services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

NSN(s)—Product Name(s):
MR 16500—Glasses, Readers, 1.25 Diopter
MR 16501—Glasses, Readers, 1.50 Diopter
MR 16502—Glasses, Readers, 1.75 Diopter
MR 16503—Glasses, Readers, 2.00 Diopter
MR 16504—Glasses, Readers, 2.50 Diopter
MR 16505—Glasses, Readers, 2.75 Diopter
Mandatory Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Military Resale-Defense Commissary Agency

Services

Service Type: Grounds Maintenance
Mandatory for: FAA, Charlotte Air Traffic Control Tower, Charlotte, NC
Mandatory Source of Supply: The Charles Lea Center, Inc., Spartanburg, SC
Contracting Activity: FEDERAL AVIATION ADMINISTRATION, 697DCK REGIONAL ACQUISITIONS SVCS

Deletions

The following product is proposed for deletion from the Procurement List:

Product

NSN(s)—Product Name(s):
7930–01–555–2897—Degreaser, Bio-renewable, Industrial Strength, 5 gl.
Mandatory Source of Supply: VisionCorps, Lancaster, PA
Contracting Activity: GSA/FSS GREATER SOUTHWEST ACQUISITI, FORT WORTH, TX

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2020–13229 Filed 6–18–20; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Additions and Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Additions to and deletions from the Procurement List.

SUMMARY: This action adds products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and deletes products and services from the Procurement List previously furnished by such agencies.

DATES: *Date added to and deleted from the Procurement List:* July 19, 2020.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Michael R. Jurkowski, Telephone: (703)

603–2117, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Additions

On May 8, 2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed additions to the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the products and impact of the additions on the current or most recent contractors, the Committee has determined that the products listed below are suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products to the Government.
2. The action will result in authorizing small entities to furnish the products to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products proposed for addition to the Procurement List.

End of Certification

Accordingly, the following products are added to the Procurement List:

Product

NSN(s)—Product Name(s): MR 13064—Set, Pan, Spring Form, 3 Piece
Mandatory Source of Supply: Winston-Salem Industries for the Blind, Inc., Winston-Salem, NC
Contracting Activity: Military Resale-Defense Commissary Agency

Deletions

On May 8, 2020, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the products listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.
2. The action may result in authorizing small entities to furnish the products to the Government.
3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the products deleted from the Procurement List.

End of Certification

Accordingly, the following products and service are deleted from the Procurement List:

Products

NSN(s)—Product Name(s):
7510–01–545–3777—DAYMAX System, 2019 Calendar Pad, Type I
7510–01–545–3732—DAYMAX System, 2019, Calendar Pad, Type II
Mandatory Source of Supply: Anthony Wayne Rehabilitation Ctr for Handicapped and Blind, Inc., Fort Wayne, IN
Contracting Activity: GSA/FAS ADMIN SVCS ACQUISITION BR (2, NEW YORK, NY

Service

Service Type: Grounds Maintenance, Janitorial
Mandatory for: Customs and Border Protection, El Centro Sector, 1111 N Imperial Avenue, El Centro, CA
Mandatory Source of Supply: ARC-Imperial Valley, El Centro, CA
Contracting Activity: U.S. CUSTOMS AND BORDER PROTECTION, BORDER ENFORCEMENT CTR DIV

Michael R. Jurkowski,

Deputy Director, Business & PL Operations.

[FR Doc. 2020–13230 Filed 6–18–20; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees

AGENCY: Department of Defense.

ACTION: Renewal of Federal Advisory Committee.

SUMMARY: The Department of Defense (DoD) is publishing this notice to announce that it is renewing the charter for the Education for Seapower Advisory Board (''the Board'').

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–692–5952.

SUPPLEMENTARY INFORMATION: The Board's charter is being renewed in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C., Appendix) and 41 CFR 102–3.50(d). The charter and contact information for the Board's Designated Federal Officer (DFO) are found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The Board shall provide the Secretary of Defense and the Deputy Secretary of Defense, through the Secretary of the Navy, with independent advice and recommendations on matters relating to the Naval University System, and specifically, the Naval Postgraduate School and the Naval War College. The Board shall: (a) Provide advice on naval education strategy and implementation thereof, (b) Provide advice on organizational management, curricula and methods of instruction, facilities, other issues of accreditation, and other matters of interest.

The Board shall be composed of no more than 15 members appointed in accordance with DoD policies and procedures, who are imminent authorities in the fields of academia, business, national defense and security, the defense industry, and research and analysis. Not less than 50 percent of Board members shall be eminent authorities in the field of academia. The Deputy Chief of Naval Operations for Manpower, Personnel, Training and Education, the Deputy Chief of Naval Operations for Warfighting Development, and the Commanding General, U.S Marine Corps Training and Education Command shall serve as ex-officio members of the Board, having voting rights and counting toward the Board's total membership.

Board members who are not full-time or permanent part-time Federal civilian officers, employees, or active duty members of the Armed Forces will be appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. Board members who are full-time or permanent part-time Federal civilian officers, employees, or active duty members of the Armed Forces will be appointed pursuant to 41 CFR 102–3.130(a), to serve as regular government employee members.

All members of the Board are appointed to provide advice on the basis of their best judgment without representing any particular point of view and in a manner that is free from conflict of interest. Except for reimbursement of official Board-related travel and per diem, members serve without compensation.

The public or interested organizations may submit written statements to the Board membership about the Board's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the Board. All written statements shall be submitted to the DFO for the Board, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: June 16, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–13256 Filed 6–18–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army, US Army Corps of Engineers

Notice of Intent To Prepare an Integrated Feasibility Report and Environmental Impact Statement for the St. Tammany Parish, Louisiana Feasibility Study

AGENCY: U.S. Army Corps of Engineers, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the National Environmental Policy Act (NEPA), the U.S. Army Corps of Engineers, New Orleans District (CEMVN) intends to prepare an Integrated Feasibility Report and Environmental Impact Statement (IFR–EIS) to evaluate potential coastal storm risk management measures and flood risk management measures in St. Tammany Parish as part of the St. Tammany Parish, Louisiana Feasibility Study. The IFR–EIS will evaluate reasonable alternatives and anticipated social, economic, and environmental impacts associated with those alternatives, as well as potential mitigation measures if adverse impacts are identified. The IFR–EIS will document the existing condition of significant resources in and around areas considered for construction and potential impacts to those resources as a result of implementing the alternatives and any mitigation measures.

DATES: A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the study website, *https://www.mvn.usace.army.mil/Media/Public-Meetings/* and published in the local newspapers no later than 15 days prior to the meeting dates.

ADDRESSES: U.S. Army Corps of Engineers, New Orleans District, Attn: Mrs. Amy Dixon, Project Manager, Room 335, CEMVN–PMR–C, 7400 Leake Avenue, New Orleans, LA 70118. *StTammanyFS@usace.army.mil.*

FOR FURTHER INFORMATION CONTACT: Questions or comments about the proposed action and requests to be added to the mailing list should be directed to: Mrs. Amy Dixon, U.S. Army Corps of Engineers, New Orleans District, Attn: CEMVN–PMR–C, 7400 Leake Avenue, New Orleans, LA 70118; by phone at: (504) 862–1798; or by email at *StTammanyFS@usace.army.mil.* For additional information, please visit *https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/St-Tammany/.*

SUPPLEMENTARY INFORMATION: The lead agency for this proposed action is the U.S. Army Corps of Engineers (USACE). The Louisiana Coastal Protection and Restoration Authority Board is the non-Federal sponsor.

1. *Authority:* Sections 1201 and 1207 of the Water Infrastructure Improvements Act of 2016 authorize the St. Tammany Parish, Louisiana Study for water resource development and conservation that include determining the feasibility of implementing projects for multiple purposes, including but not limited to, flood risk management as set forth in the 2015 and 2016 Reports to Congress on Future Water Resources Development. The St. Tammany Parish Louisiana Feasibility Study was authorized for inclusion as a funded study in the Bipartisan Budget Act of 2018 (Pub. L. 115–123), Division B, Subdivision 1, Title IV (BBA 2018) in a Memorandum from the Office of the Deputy Commanding General for Civil and Emergency Operations. The Memorandum provided that plan formulation will be limited to Coastal Storm Risk Management and Flood Risk Management in accordance with BBA 2018. The Government is authorized by BBA 2018 to conduct the Study at full Federal expense to the extent that appropriations provided under the Investigations heading of the BBA 2018 are available and used for such purpose.

2. *Background:* The study area is comprised of the entirety of St. Tammany Parish, with a focus on the areas impacted by flooding from rainfall and riverine bank overtopping, waves, and storm surge. The study area is located along the border with the state of Mississippi, with the Pearl River along the eastern boundary of the Parish. Lake Pontchartrain serves as the southern border, and is one of the largest estuaries in the United States, with the site of the Southeastern Louisiana National Wildlife Refuge Complex Headquarters in Lacombe. Tangipahoa Parish is located along the western boundary, and Washington Parish is located to the north. The majority of the Parish's population resides in communities along the edge of Lake Pontchartrain, and many residents commute into New Orleans.

Increased resiliency to flood events is the primary identified need for the affected communities within the study area. In addition, the study area's topography, low elevation, and proximity to the Gulf of Mexico are all contributing factors causing flooding and erosion, and degradation of wetland systems within the Parish. Without additional coastal storm and flood risk management measures, the people, economy, environment, and cultural heritage of St. Tammany Parish are at risk from reoccurring flooding.

The scoping, public involvement, and interagency coordination processes will help identify and define the range of the areas within the Parish that experience repetitive flood events, the types of damages caused by such events, and suggested alternatives to reduce the risk of flooding caused by such events. Important resources and issues evaluated in IFR–EIS could include, but are not limited to, the direct, indirect, and cumulative effects on socioeconomics, navigation, wetlands, uplands, aquatic and biological resources, prime and unique farmlands, essential fish habitat, waterfowl, wildlife resources, geology and soils agricultural land and prime and unique farmland; hydrology and hydraulics, threatened and endangered species and their critical habitat, wildlife resources, and other protected species of concern, cultural resources, recreation, aesthetics and visual resources, hazardous, toxic and radioactive waste, environmental justice, soils, air quality, and water quality. USACE will also consider issues identified and comments made throughout scoping, public involvement, and interagency coordination.

3. *Alternatives:* The USACE will evaluate a range of reasonable alternatives to reduce coastal storm and flood risks including structural and

nonstructural measures. For the reasonable and practicable alternatives, the USACE will fully evaluate them, including the no action alternative. Alternatives could include avoidance and minimization and mitigation measures to reduce or offset any impacts.

4. *Public Involvment:* Public involvement, an essential part of the NEPA process, is integral to assessing the environmental consequences of the proposed action and improving the quality of the agency decision-making. The public includes affected and interested Federal, state, and local agencies, Indian tribes, concerned citizens, stakeholders, and other interested parties. Public participation in the NEPA process is strongly encouraged, both formally and informally, to enhance the probability of a more technically accurate, economically feasible, socially acceptable, and environmentally sound IFR–EIS. Public involvement will include, but is not limited to: Information dissemination; identification of problems, needs and opportunities; idea generation; public education; problem solving; providing feedback on proposals; evaluation of alternatives; conflict resolution; public and scoping notices and meetings; public, stakeholder and advisory groups consultation and meetings; and making the IFR–EIS and supporting information readily available in conveniently located places, such as libraries and on the internet.

5. *Scoping:* Scoping, an early and open process for identifying the scope of significant issues related to the proposed action to be addressed in the IFR–EIS, will be used to: (a) Identify the affected public and agency concerns; (b) facilitate an efficient IFR–EIS preparation process; (c) define the issues and alternatives that will be examined in detail in the IFR–EIS; and (d) save time in the overall process by helping to ensure that the IFR–EIS adequately addresses relevant issues. A Scoping Meeting Notice announcing the locations, dates and times for scoping meetings is anticipated to be posted on the study website, *https://www.mvn.usace.army.mil/About/Projects/BBA-2018/studies/* and published in the local newspapers no later than 15 days prior to the meeting dates.

6. *Coordination:* The USACE will serve as the lead Federal agency in the preparation of the IFR–EIS. Other federal and/or state agencies may participate as cooperating and/or commenting agencies throughout the IFR–EIS process.

In accordance with Executive Order, 1307, referred to as One Federal Decision (OFD), the USACE and other agencies with environmental review, authorization, or consultation responsibilities for major infrastructure projects should develop a single EIS, sign a single Record of Decision (ROD) and issue all necessary authorizations within 90 days thereafter, subject to limited exceptions. An essential element of the OFD framework is the development of a schedule, referred to as the ''Permitting Timetable,'' including key milestones critical to completion of the environmental review and issuance of a ROD. Cooperating agencies required by law to develop schedules for environmental review or authorization processes should transmit a summary of such schedules to the lead agency for integration into the Permitting Timetable.

To ensure timely completion of the environmental review and issuance of necessary authorizations, OMB and CEQ recommend the Permitting Timetable for major infrastructure projects provide for environmental review according to the following schedule:

a. Formal scoping and preparation of a Draft EIS (DEIS) within 14 months, beginning on the date of publication of the NOI to publish an EIS and ending on the date of the Notice of Availability of the DEIS;

b. Completion of the formal public comment period and development of the Final EIS (FEIS) within eight months of the date of the Notice of Availability of the DEIS; and

c. Publication of the final ROD within two months of the publication of the Notice of Availability of the FEIS.

While the actual schedule for any given project may vary based upon the circumstances of the study and applicable law, agencies should endeavor to meet the two-year goal established in E.O. 13807.

The U.S. Fish and Wildlife Service (Service) will assist in documenting existing conditions and assessing effects of project alternatives through the Fish and Wildlife Coordination Act consultation procedures. Other environmental review and consultation requirements for the proposed project include the need for Louisiana Department of Environmental Quality Clean Water Act Section 401 water quality certification. In addition, because the proposed project may affect federally listed species, the USACE will consult with the Service and the National Marine Fisheries Service (NMFS) in accordance with Endangered Species Act, Section 7. The NMFS will be consulted regarding the effects of this proposed project on Essential Fish Habitat per the Magnuson-Stevens Act. The USACE will also consult with the State Historic Preservation Officer under Section 106 of the National Historic Preservation Act concerning properties listed, or potentially eligible for listing on the National Historic Register. The USACE will also coordinate with the Louisiana Department of Natural Resources for Coastal Zone Management Consistency per the Coastal Zone Management Act.

7. *Availability:* The Draft IFR–EIS is expected to be available for public comment and review no sooner than December 2020. At that time, a 45-day public review period will be provided for individuals and agencies to review and comment on the DEIS. All interested parties are encouraged to respond to this notice and provide a current mailing or email address if they wish to be notified of the Draft IFR–EIS circulation.

James A. Bodron,

Regional Business Director, Mississippi Valley Division.

[FR Doc. 2020–13239 Filed 6–18–20; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Army, Army Corps of Engineers

Notice of Solicitation of Applications for Stakeholder Representative Members of the Missouri River Recovery Implementation Committee

AGENCY: Department of the Army, U.S. Army Corps of Engineers, DoD.

ACTION: Notice.

SUMMARY: The Commander of the Northwestern Division of the U.S. Army Corps of Engineers (Corps) is soliciting applications to fill vacant stakeholder representative member positions on the Missouri River Recovery Implementation Committee (MRRIC). Members are sought to fill vacancies on a committee to represent various categories of interests within the Missouri River basin. The MRRIC was formed to advise the Corps on a study of the Missouri River and its tributaries and to provide guidance to the Corps with respect to the Missouri River recovery and mitigation activities currently underway. The Corps established the MRRIC as required by the U.S. Congress through the Water Resources Development Act of 2007 (WRDA), Section 5018.

DATES: The agency must receive completed applications and

endorsement letters no later than July 24, 2020.

ADDRESSES: Mail completed applications and endorsement letters to U.S. Army Corps of Engineers, Kansas City District (Attn: MRRIC), 601 E 12th Street, Kansas City, MO 64106 or email completed applications to *mrric@usace.army.mil.* Please put ''MRRIC'' in the subject line.

FOR FURTHER INFORMATION CONTACT: Lisa Rabbe, 816–389–3837.

SUPPLEMENTARY INFORMATION: The operation of the MRRIC is in the public interest and provides support to the Corps in performing its duties and responsibilities under the Endangered Species Act, 16 U.S.C. 1531 *et seq.;* Sec. 601(a) of the Water Resources Development Act (WRDA) of 1986, Public Law 99–662; Sec. 334(a) of WRDA 1999, Public Law 106–53, and Sec. 5018 of WRDA 2007, Public Law 110–114. The Federal Advisory Committee Act, 5 U.S.C. App. 2, does not apply to the MRRIC.

A Charter for the MRRIC has been developed and should be reviewed prior to applying for a stakeholder representative membership position on the Committee. The Charter, operating procedures, and stakeholder application forms are available electronically at *www.MRRIC.org.*

Purpose and Scope of the Committee.

1. The primary purpose of the MRRIC is to provide guidance to the Corps and U.S. Fish and Wildlife Service with respect to the Missouri River recovery and mitigation plan currently in existence, including recommendations relating to changes to the implementation strategy from the use of adaptive management; coordination of the development of consistent policies, strategies, plans, programs, projects, activities, and priorities for the Missouri River recovery and mitigation plan. Information about the Missouri River Recovery Program is available at *www.MoRiverRecovery.org.*

2. Other duties of MRRIC include exchange of information regarding programs, projects, and activities of the agencies and entities represented on the Committee to promote the goals of the Missouri River recovery and mitigation plan; establishment of such working groups as the Committee determines to be necessary to assist in carrying out the duties of the Committee, including duties relating to public policy and scientific issues; facilitating the resolution of interagency and intergovernmental conflicts between entities represented on the Committee associated with the Missouri River recovery and mitigation plan; coordination of scientific and other research associated with the Missouri River recovery and mitigation plan; and annual preparation of a work plan and associated budget requests.

Administrative Support. To the extent authorized by law and subject to the availability of appropriations, the Corps provides funding and administrative support for the Committee.

Committee Membership. Federal agencies with programs affecting the Missouri River may be members of the MRRIC through a separate process with the Corps. States and federally recognized Native American Indian tribes, as described in the Charter, are eligible for Committee membership through an appointment process. Interested State and Tribal government representatives should contact the Corps for information about the appointment process.

This Notice is for individuals interested in serving as a stakeholder member on the Committee. Members and their alternates must be able to demonstrate that they meet the definition of ''stakeholder'' found in the Charter of the MRRIC. Applications are currently being accepted for representation in the stakeholder interest categories listed below:

a. Agriculture;
b. Conservation Districts;
c. Fish & Wildlife;
d. Flood Control;
e. Irrigation;
f. Navigation;
g. Recreation;
h. Water Supply;
i. Waterway Industries; and
j. At Large.

Terms of stakeholder representative members of the MRRIC are three years. There is no limit to the number of terms a member may serve. Incumbent Committee members seeking reappointment do not need to re-submit an application. However, renewal requests are not guaranteed re-selection and they must submit a renewal request letter and related materials as outlined in the ''Streamlined Process for Existing Members'' portion of the document *Process for Filling MRRIC Stakeholder Vacancies* (*www.MRRIC.org*).

Members and alternates of the Committee will not receive any compensation from the Federal Government for carrying out the duties of the MRRIC. Travel expenses incurred by members of the Committee are not currently reimbursed by the Federal Government.

Application for Stakeholder Membership. Persons who believe that they are or will be affected by the Missouri River recovery and mitigation activities may apply for stakeholder membership on the MRRIC. Committee members are obligated to avoid and disclose any individual ethical, legal, financial, or other conflicts of interest they may have involving MRRIC. Applicants must disclose on their application if they are directly employed by a government agency or program (the term ''government'' encompasses state, tribal, and Federal agencies and/or programs).

Applications for stakeholder membership may be obtained electronically at *www.MRRIC.org.* Applications may be emailed or mailed to the location listed (see **ADDRESSES**). In order to be considered, each application must include:

1. The name of the applicant and the primary stakeholder interest category that person is qualified to represent;
2. A written statement describing the applicant's area of expertise and why the applicant believes he or she should be appointed to represent that area of expertise on the MRRIC;
3. A written statement describing how the applicant's participation as a Stakeholder Representative will fulfill the roles and responsibilities of MRRIC;
4. A written description of the applicant's past experience(s) working collaboratively with a group of individuals representing varied interests towards achieving a mutual goal, and the outcome of the effort(s);
5. A written description of the communication network that the applicant plans to use to inform his or her constituents and to gather their feedback, and
6. A written endorsement letter from an organization, local government body, or formal constituency, which demonstrates that the applicant represents an interest group(s) in the Missouri River basin.

To be considered, the application must be complete and received by the close of business on July 24 2020, at the location indicated (*see* **ADDRESSES**). Applications must include an endorsement letter to be considered complete. Full consideration will be given to all complete applications received by the specified due date.

Application Review Process. Committee stakeholder applications will be forwarded to the current members of the MRRIC. The MRRIC will provide membership recommendations to the Corps as described in Attachment A of the *Process for Filling MRRIC Stakeholder Vacancies* document (*www.MRRIC.org*). The Corps is responsible for appointing stakeholder members. The Corps will consider applications using the following criteria:

- Ability to commit the time required.
- Commitment to make a good faith (as defined in the Charter) effort to seek balanced solutions that address multiple interests and concerns.
- Agreement to support and adhere to the approved MRRIC Charter and Operating Procedures.
- Demonstration of a formal designation or endorsement by an organization, local government, or constituency as its preferred representative.
- Demonstration of an established communication network to keep constituents informed and efficiently seek their input when needed.
- Agreement to participate in collaboration training as a condition of membership.

All applicants will be notified in writing as to the final decision about their application.

Certification. I hereby certify that the establishment of the MRRIC is necessary and in the public interest in connection with the performance of duties imposed on the Corps by the Endangered Species Act and other statutes.

D. Peter Helmlinger,

Brigadier General, US Army, Division Commander.

[FR Doc. 2020–13240 Filed 6–18–20; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0093]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Impact Aid Discretionary Construction Grant Program (1894–0001)

AGENCY: Department of Education (ED), Office of Elementary and Secondary Education (OESE).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 20, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Melissa Torchon-Duke, 202–260–0732.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Impact Aid Discretionary Construction Grant Program (1894–0001).

OMB Control Number: 1810–0657.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 40.

Total Estimated Number of Annual Burden Hours: 240.

Abstract: The Impact Aid Program, authorized by Title VII of the Elementary and Secondary Education Act (ESEA), as amended by the Every Student Succeeds Act (ESSA), provides financial assistance to Local Educational Agencies (LEAs) whose enrollment or revenues are adversely affected by Federal activities. The Impact Aid Discretionary Construction Program provides grants to eligible Impact Aid school districts to assist in addressing their school facility emergency and modernization needs. The eligible Impact Aid school districts have a limited ability to raise revenues for capital improvements because they have large areas of Federal land within their boundaries. As a result, these districts find it difficult to respond when their school facilities are in need of emergency repairs or modernization. This information collection request is an extension without change of the grant application for this program.

Dated: June 16, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division Office of Chief Data Officer.

[FR Doc. 2020–13237 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0059]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Family Educational Loan Program (FFEL)—Administrative Requirements for States, Not-For-Profit Lenders, and Eligible Lenders Trustees

AGENCY: Department of Education (ED), Federal Student Aid (FSA).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 20, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information

collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Family Educational Loan Program (FFEL)—Administrative Requirements for States, Not-For-Profit Lenders, and Eligible Lenders Trustees.

OMB Control Number: 1845–0085.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 43.

Total Estimated Number of Annual Burden Hours: 43.

Abstract: The regulations in 34 CFR 682.302(f) assure the Secretary that the integrity of the program is protected from fraud and misuse of funds. These regulations require a State, not-profit entity, or eligible lender trustee to provide to the Secretary a certification on the State or non-profit entity's letterhead, signed by the State or non-profit's Chief Executive Officer, which states the basis upon which the entity meets the regulations. The submission must include the name and lender identification number(s) for which the eligible designation is being certified. Once an entity is approved it must provide an annual recertification notice identifying the name and lender identification number(s) for which designation is being requested.

Dated: June 16, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division Office of Chief Data Officer.

[FR Doc. 2020–13251 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0100]

Agency Information Collection Activities; Comment Request; U.S. Department of Education Supplemental Information for the SF–424 Form

AGENCY: Office of the Secretary (OS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 18, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0100. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W–208B, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Alfreida Pettiford, 202–245–6110.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: U.S. Department of Education Supplemental Information for the SF–424 form.

OMB Control Number: 1894–0007.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 5,976.

Total Estimated Number of Annual Burden Hours: 1,972.

Abstract: The U.S. Department of Education Supplemental Information Form for the SF–424 is used together with the SF–424, Application for Federal Assistance. Several years ago ED made a decision to switch from its previously cleared form, the Application for Federal Education Assistance or ED 424 (1890–0017) collection (now 1894–0007). ED made a policy decision to switch to the SF–424 in keeping with Federal-wide forms standardization and streamlining efforts, especially with widespread agency use of *Grants.gov*.

There were several data elements/questions on the ED 424 that were required for ED applicants that were not included on the SF–424. Therefore, ED put these questions that were already cleared as part of the 1890–0017 collection (now 1894–0007) on a form entitled the, U.S. Department of Education Supplemental Information for the SF–424. The questions on this form deal with the following areas: Project Director identifying and contact information; New Potential Grantee or Novice Applicants; Qualified Opportunity Zones, and Human Subjects Research. The ED Supplemental Information Form could be used with any of the SF–424 forms

in the SF–424 forms family, as applicable.

Dated: June 16, 2020.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–13265 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0057]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; NCEE System Clearance for Design and Field Studies 2020–2023

AGENCY: Department of Education (ED), Institute of Education Sciences (IES).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before July 20, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Michael Fong, 202–245–8407.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: NCEE System Clearance for Design and Field Studies 2020–2023.

OMB Control Number: 1850–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 4,000.

Total Estimated Number of Annual Burden Hours: 2,000.

Abstract: This is a request for a 3-year generic clearance for the National Center for Education Evaluation (NCEE) that will allow it to collect preliminary or exploratory information to aid in study design. The procedures expected to be used include but are not limited to exploratory surveys and interviews, focus groups, cognitive laboratory activities, pilot testing versions of an intervention or data collection approach, small-scale experiments that explore questionnaire design, incentives, or mode, and usability testing.

Dated: June 16, 2020.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer Office of Planning, Evaluation and Policy Development.

[FR Doc. 2020–13263 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0033]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Measuring Educational Gain in the National Reporting System for Adult Education

AGENCY: Office of Career, Technical, and Adult Education (OCTAE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before July 20, 2020.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Braden Goetz, 202–245–7405.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Measuring Educational Gain in the National Reporting System for Adult Education.

OMB Control Number: 1830–0567.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 15.

Total Estimated Number of Annual Burden Hours: 600.

Abstract: Title 34 of the Code of Federal Regulations part 462 establishes procedures the Secretary uses to consider literacy tests for use in the National Reporting System (NRS) for adult education. This information is used by the Secretary to determine the suitability of published literacy tests to measure and report educational gain under the NRS.

Dated: June 16, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–13233 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0098]

Agency Information Collection Activities; Comment Request; Report of Children Receiving Early Intervention Services in Accordance With Part C; Report of Program Settings in Accordance With Part C; Report on Infants and Toddlers Exiting Part C

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 18, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0098. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Amy Bae, 202–245–8272.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Report of Children Receiving Early Intervention Services in Accordance With Part C; Report of Program Settings in Accordance with Part C; Report on Infants and Toddlers Exiting Part C.

OMB Control Number: 1820–0557.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 56.

Total Estimated Number of Annual Burden Hours: 5,311.

Abstract: Section 618 of the Individuals with Disabilities Education Act (IDEA), Public Law 108–446, directs the Secretary of Education to obtain data on the number and percentage of infants and toddlers with disabilities, by race, ethnicity, and gender, who are receiving early intervention services, the number and percentage of infants and toddlers, by race and ethnicity, who are at risk of having substantial developmental delays (as described in Section 632), and who are receiving early intervention services under Part C, and the number and percentage of children with disabilities, by race, ethnicity, and gender, who, from birth through age 2, stopped receiving early intervention services because of program completion or for other reasons. The specific legislative authority for these data collections may be found in Section 618(a)(1)(B), Section 618(a)(1)(C), Section 618(a)(2) and Section 618(a)(3). This package provides instructions and forms necessary for States to report the number of children receiving early intervention services under Part C of IDEA, the settings in which these children are provided services, and the reasons by which these children exit Part C of IDEA. The form satisfies reporting requirements and is used by OSEP to monitor State agencies and for Congressional and public reporting. No adjustments were made to this data collection therefore we anticipate no change in the response burden associated with this data collection. The Department of Education is interested in public comment addressing the COVID crisis. Specially, are there any considerations to these data collections due to the national emergency caused by the novel Coronavirus disease 2019 (COVID–19). Please note that written comments received in response to this notice will be considered public records.

Dated: June 15, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–13200 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0088]

Agency Information Collection Activities; Comment Request; Eligibility of Students at Institutions of Higher Education for Funds Under the CARES Act

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is

requesting the Office of Management and Budget (OMB) to conduct an emergency review of a new information collection.

DATES: Since an initial notice was published prematurely on June 9, 2020, ED is issuing this new emergency notice again, and approval by the OMB has been requested by June 17, 2020. A regular clearance process is also hereby being initiated. Interested persons are invited to submit comments on or before August 18, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0088. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Gaby Watts, 202–453–7195.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Eligibility of Students at Institutions of Higher Education for Funds under the CARES Act.

OMB Control Number: 1840–NEW.

Type of Review: A new information collection.

Respondents/Affected Public: Private Sector; State, Local, and Tribal Governments; Individuals or Households.

Total Estimated Number of Annual Responses: 1,553,009.

Total Estimated Number of Annual Burden Hours: 536,478.

Abstract: The U.S. Department of Education is requesting an emergency clearance of this information collection request to allow for immediate outreach to institutions of higher eduction (IHEs) to meet the requirements of the Coronavirus Aid, Relief, and Economic Security Act or the CARES Act, Public Law 116–136 (March 27, 2020). This will help to ensure that the distribution of the CARES Act funds is managed by IHEs in accordance with the clarification as discussed in the Interim Final Rule. The Department is requesting emergency clearance and OMB approval of our emergency and 60 day public comment period with this filing. The Department will publish a 30 **Federal Register** notice as required by 5 CFR 1320.8(d), soliciting comments on the information collection after the end of the 60 day notice.

Additional Information: An emergency clearance approval for the use of the system is described below due to the following conditions:

Section 18004 of the Act authorizes the Secretary of Education (''Secretary'') to allocate formula grant funds to participating institutions of higher educations (IHEs). It requires the IHEs to use no less than fifty percent of the funds received to provide emergency financial aid grants to students for expenses related to the disruption of campus operations due to coronavirus (including eligible expenses under a student's cost of attendance such as food, housing, course materials, technology, health care, and child care). ED is requesting an emergency clearance so that IHEs may appropriately determine which individuals attending their institution are eligible to receive emergency financial aid grants under the CARES Act.

Dated: June 16, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–13246 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2020–SCC–0099]

Agency Information Collection Activities; Comment Request; State Lead Agency Record Keeping and Reporting Requirements Under Part C of the Individuals With Disabilities Education Act

AGENCY: Office of Special Education and Rehabilitative Services (OSERS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension of an existing information collection.

DATES: Interested persons are invited to submit comments on or before August 18, 2020.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2020–SCC–0099. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW,

LBJ, Room 6W–208D, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Rebecca Walawender, 202–245–7399.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: State Lead Agency Record Keeping and Reporting Requirements under Part C of the Individuals with Disabilities Education Act.

OMB Control Number: 1820–0682.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 56.

Total Estimated Number of Annual Burden Hours: 4,268.

Abstract: This collection has been created to reflect the requirements under Part C of IDEA and the Part C regulations that require State lead agencies (LAs) to collect and maintain information or data and, in some cases, report information or data to other public agencies or to the public. However, such information or data are not required to be reported to the Secretary. These required collections are consolidated into 1820–0682.

Dated: June 15, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–13199 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice of Investigation and Record Requests

AGENCY: Office of the General Counsel, Department of Education.

ACTION: Notice.

SUMMARY: The Department publishes a letter, dated May 27, 2020, notifying Case Western Reserve University of an investigation related to Case Western Reserve University's reports of defined gifts and contracts, including restricted and conditional gifts or contracts, from or with a statutorily defined foreign source.

FOR FURTHER INFORMATION CONTACT: Patrick Shaheen, U.S. Department of Education, Office of the General Counsel, 400 Maryland Avenue SW, Room 6E300, Washington, DC 20202. Telephone: (202) 453–6339. Email: *Patrick.Shaheen@ed.gov.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service, toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Department publishes this letter, dated May 27, 2020, notifying Case Western Reserve University of an investigation related to Case Western Reserve University's reports of defined gifts and contracts, including restricted and conditional gifts or contracts, from or with a statutorily defined foreign source. The letter to Case Western Reserve University is in the Appendix of this notice.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) on request to the person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Reed D. Rubinstein,

Principal Deputy General Counsel delegated the authority to perform the functions and duties of the General Counsel.

Appendix—Letter to Case Western Reserve University

May 27, 2020

Barbara R. Snyder, President, Office of the President, Adelbert Hall 216, 10900 Euclid Avenue, Case Western Reserve University, Cleveland, OH 44106–7001

Re: Notice of 20 U.S.C. 1011f Investigation and Record Request/Case Western Reserve University

Dear President Snyder:

Section 117 of the Higher Education Act of 1965 (20 U.S.C. 1011f) requires institutions of higher education (IHEs), including Case Western Reserve University (CWRU), to report all gifts, contracts, and/or restricted and conditional gifts or contracts from or with a foreign source to the U.S. Department of Education (''Department''). These reports are posted at *https://studentaid.ed.gov/sa/about/data-center/school/foreign-gifts.*

CWRU is a significant recipient of American taxpayer dollars, including more than $412,201,774 in NIH awards from 2018–2020.[1] Notably, CWRU's School of Medicine is currently one of the top 20 U.S. medical school NIH grant recipients.[2] On May 13, 2020, Dr. Qing Wang was arrested and charged by federal criminal complaint with false claims and wire fraud relating to more than $3.6 million in federal grant funding that he and his research group at CWRU's Cleveland Clinic Foundation (CCF) received from the National Institutes of Health (NIH). First joining CCF in 1997, Dr. Wang was a prominent researcher (professor of molecular medicine) at CCF until a recent NIH and Department of Justice investigation [3] revealed his concurrent position as Dean of the College of Life Sciences and Technology at Huazhong University of Science and Technology (HUST) in the People's Republic of China (PRC) and his participation in the PRC's Thousand Talent's Program (TTP) (an ongoing subterfuge of the PRC to recruit individuals with access to foreign technology and intellectual property). *See https://www.justice.gov/opa/pr/former-cleveland-clinic-employee-and-chinese-thousand-talents-participant-arrested-wire-fraud.*

DOJ's investigation found that at the same time Dr. Wang was applying for and receiving NIH grants in his capacity as faculty at CCF, he also received undisclosed funding from the PRC's National Natural Science Foundation of China. *See https://www.healthleadersmedia.com/ex-cleveland-clinic-researcher-arrested-charged-wire-fraud.* In his TTP recruiting role, the PRC paid for Dr. Wang's travel to China and a three-bedroom apartment on the HUST campus while Dr. Wang secured PRC funds for ''recruits'' at Harvard Medical School, the University of California, and the University of Texas (pursuant to Dr. Wang's efforts on behalf of the PRC, those recruits received between $200,000 and $300,000 in financial compensation).[4]

CWRU has an ''Office of Global Strategy'' which has published a ''Plan for Internationalization'' which includes two phases for transitioning CWRU to a massive international presence and creating ''Major International Partnerships.'' [5] CWRU's plan for international operations appears to be well underway. In fact, CWRU published that it has ''200 international agreements in more than 40 different countries.'' See *https://case.edu/international/global-strategy/major-international-partnerships.* Some of CWRU's international efforts include recruiting students from the PRC and setting up partnerships in the PRC.[6] In an August 2018 interview with the PRC's state-run news agency, Xinhua, you indicated that CWRU has ''been very fortunate to have a lot of help as we forge partnerships in China.'' Xinhua reported that while ''CWRU does not have any immediate plans to open a campus in China . . . it has been working on many joint research projects, and faculty and student exchanges [sic] programs with some of the universities in China.'' *See http://en.people.cn/n3/2018/0827/c90000-9494467.html.* CWRU's School of Dental Medicine, ''in a move to expand its international presence and influence . . . signed a six-year agreement to train junior faculty from Qassim University'' in Saudi Arabia in 2016. *See https://thedaily.case.edu/dental-school-strikes-agreement-to-train-faculty-of-saudi-arabian-university/.* A similar agreement was also signed with an Egyptian university. *See https://case.edu/think/spring2016/dentalschool-international-impact.html#.XsWVqWi6OUk.* CWRU's School of Law, pursuant to an agreement with Saudi Arabia's Naif Arab University for Security Sciences (NAUSS), now offers a Master of Arts in Financial Integrity degree program in Riyadh, Saudi Arabia. *See https://case.edu/international/global-strategy/major-international-partnerships.*

Despite CWRU's very extensive entanglement with foreign sources here in the U.S. and abroad, a review of the Department's records reveals significant disclosure deficiencies. Until January 2020, CWRU failed to make a single foreign source disclosure to the Department over a more than 12-year period (since January 2, 2008). During the past five months, CWRU has retroactively filed disclosure reports indicating receipt of over $53 million in qualifying foreign source gifts and contracts for the period January 2013 through the present. CWRU now reports only one qualifying foreign source transaction during the entire period from January 1, 2008, through January 13, 2013. The Department views CWRU's reports as untimely and incomplete. The foreign source reporting obligation provides critical transparency to American taxpayers and policymakers. Failure to timely provide accurate disclosures could result in: (a) Unintentional transfers of critical research data with multiple applications to hostile foreign entities, (b) loss of public trust in university research enterprises, (c) diversions of proprietary and pre-publication research data to foreign entities, and (d) inaccurately informed decisions by policy makers about the use of taxpayer funding.

The PRC has been clear about its intent to acquire high-level scientific foreign talent and knowledge in furtherance of China's high-priority scientific development, national security, and economic prosperity through its ''Chinese Talent Programs'' (CTP) and other initiatives, both lawful and illicit. One such program, the TTP, involves the PRC and its agencies and agents offering salaries, research funding, laboratory space, honorary titles, and other incentives in exchange for the commitment of researchers in transmitting and sharing highly-specialized research and knowledge with the PRC. It is the TTP in which CWRU's Dr. Wang was a recruiter. Multiple federal agencies, including the NIH, Federal Bureau of Investigation (FBI), and Department of Energy (DOE), have publicly warned about the potential damage to American national security interests presented by CTPs.[7]

Section 117(f), 20 U.S.C. 1011f(f), provides that whenever it appears an institution has failed to comply with the law, the Secretary of Education may request the Attorney General commence an enforcement action to compel compliance and to recover the full costs to the United States of obtaining compliance, including all associated costs of investigation and enforcement. To meet the Department's statutory duty to verify compliance prior to any potential referral for enforcement action by the Attorney General, the Department is continuing its administrative investigation of CWRU and requests that you produce the following within forty-five (45) calendar days:

1. All CWRU records of, regarding, or referencing gifts, contracts, and/or restricted or conditional gifts or contracts from or with a foreign source or foreign sources to CWRU. This includes, but is not limited to, true copies of qualifying pledges, donations, contributions, contracts, and/or agreements. Our request includes all supporting and related communications and metadata regarding these records. The time frame for this request is January 1, 2008, through the present.

2. A list of all gifts, contracts, and/or restricted or conditional gifts or contracts

[1] *See https://www.report.nih.gov/award/index.cfm?ot=MS&fy=2020&state=&ic=&fm=&orgid=218601&distr=&rfa=&om=n&pid=&view=state, https://www.report.nih.gov/award/index.cfm?ot=MS&fy=2019&state=&ic=&fm=&orgid=218601&distr=&rfa=&om=n&pid=&view=state, https://www.report.nih.gov/award/index.cfm?ot=MS&fy=2018&state=&ic=&fm=&orgid=218601&distr=&rfa=&om=n&pid=&view=state.*

[2] *See https://case.edu/medicine/about/newsroom/our-latest-news/school-medicine-soars-top-20-ranking-nih-funding-2019.*

[3] Dr. Wang, while a faculty member at CCF, is alleged to have engaged in a pervasive pattern of fraud by deliberately failing to disclose his PRC funding and positions which overlapped with disclosure obligations to the NIH as part of the grant application process. *See https://www.washingtonexaminer.com/news/doj-escalates-chinese-thousand-talents-crackdown-with-arrest-of-cleveland-clinic-researcher.*

[4] *See id.*

[5] *See https://case.edu/international/global-strategy/major-international-partnerships.*

[6] *See* ''The China-to-Case Western Reserve University Pipeline is Flowing at Full Speed.'' *https://www.crainscleveland.com/scott-suttell-blog/china-case-western-reserve-university-pipeline-flowing-full-speed.*

[7] NIH has clearly and repeatedly warned of the insidious threat of TTP to American research institutions, including colleges and universities. *See https://nihrecord.nih.gov/2019/10/04/nih-investigates-foreign-influence-us-grantee-institutions*, and *https://www.sciencemag.org/news/2018/08/nih-investigating-whether-us-scientists-are-sharing-ideas-foreign-governments.* The NIH also informed NIH grantees, of which CWRU is one, of the ongoing threat to biomedical research from foreign sources and the obligation of universities to timely report funding by foreign entities. The FBI has, likewise, warned of the TTP's threat to American security interests through research developed by taxpayer-funded American universities. *See https://www.fbi.gov/news/testimony/securing-the-us-research-enterprise-from-chinas-talent-recruitment-plans-111919; https://www.hsgac.senate.gov/imo/media/doc/Brown%20Testimony.pdf.* The Department of Energy, similarly, has warned of and acted to block TTP-based efforts to access technology critical to the security of the United States. *See https://www.directives.doe.gov/directives-documents/400-series/0486.1-border/@@images/file*; *https://phys.org/news/2019-06-energy-dept-blocks-china-thousand.html.*

from or with a foreign source that were not contemporaneously reported to the Department by CWRU between January 1, 2008 and the present. For each such gift, contract, and/or restricted or conditional gift or contract, please (a) list the name and address of the foreign source; (b) list the CWRU person(s) who solicited, negotiated, or benefited from each such gift, contract, and/or conditional gift or contract; and (c) explain in a detailed narrative why CWRU failed to lawfully disclose the gift, contract, and/or conditional gift or contract.

3. All records of, regarding, or referencing gifts, contracts, and/or restricted or conditional gifts or contracts from or with: (i) The government of the PRC and/or its agencies, departments, agents, employees and instrumentalities (whether domiciled in China, the United States, or elsewhere); the Central Committee of the Communist Party of China and/or its agents, employees, and instrumentalities (whether domiciled in China, the United States, or elsewhere); the People's Liberation Army and/or its agents, employees, and instrumentalities (whether domiciled in China, the United States, or elsewhere); Huawei Technologies Co. Ltd., Huawei Technologies USA, Inc., ZTE Corp and/or their agents, employees, subsidiaries, and instrumentalities (whether domiciled in China, the United States, or elsewhere); and any China-based university or educational entity, and/or their agents, employees, and instrumentalities (whether domiciled in China, the United States, or elsewhere). (ii) The government of Saudi Arabia and/or its agents, employees, and instrumentalities (whether domiciled in Saudi Arabia, the United States, or elsewhere); and any Saudi Arabian university or educational entity and/or its agents, employees, and instrumentalities (whether domiciled in Saudi Arabia, the United States, or elsewhere). (iii) The government of Egypt, its agents, employees, and instrumentalities (whether domiciled in Egypt, the United States, or elsewhere); and any Egyptian university or educational entity and/or its agents, employees, and instrumentalities (whether domiciled in Egypt, the United States, or elsewhere). (iv) The government of the Islamic Republic of Iran, and/or its agents, employees, and instrumentalities (whether domiciled in Iran, the United States, or elsewhere); the Islamic Revolutionary Guard Corps and/or its agents, employees, and instrumentalities (whether domiciled in Iran, the United States, or elsewhere); any Iranian foundation (*e.g.* the ''Foundation for the Oppressed''), corporation, or legal entity and/or its agents, employees, subsidiaries, and instrumentalities (whether domiciled in Iran, the United States, or elsewhere); and any Iranian university or educational entity and/or its agents, employees, and instrumentalities (whether domiciled in Iran, the United States, or elsewhere). For each such gift, contract, and/or restricted or conditional gift or contract, specify all CWRU person(s) (*e.g.* principal investigator, student, faculty member, employee, foundation, department) who were the object or beneficiaries thereof. The time frame for this request is January 1, 2008, through the present.

4. A complete list of any current or former CWRU faculty and staff, whether paid or unpaid, (including full and part time employees and contractors) involved in Chinese talent-recruitment and related programs (including TTP) from January 1, 2008, through the present. Provided contact information should include names, position(s) held, email addresses, mailing addresses, and phone numbers.

5. Identification of CWRU administrators or other personnel with responsibility for and/or oversight of faculty and staff involved in Chinese talent-recruitment programs (including TTP) from January 1, 2008, through the present. Provided contact information should include names, specific responsibilities, position(s) held, email addresses, mailing addresses, and phone numbers.

6. Identification of all known talent recruitment agencies, agents, and/or representatives who facilitated and/or supervised CWRU faculty and/or staff who were engaged in Chinese talent-recruitment programs (including TTP) from January 1, 2008, through the present. Provided contact information should include names, titles, apparent functions, email addresses, mailing addresses, and phone numbers.

7. All records of, regarding, or referencing communications concerning Chinese talent-recruitment programs (including TTP) and/or the involvement of CWRU faculty, staff, and students in Chinese talent-recruitment programs, from January 1, 2008, through the present.

8. All documents, including all written records, agreements, contracts, and modifications of contracts, evidencing agreements or consideration of agreements between CWRU, its faculty, staff, and administrators, and Chinese talent-recruitment program (including TTP) agencies or agents.

9. All records of CWRU's compliance with U.S. government requirements under Executive Order 13224 and related legal authorities, and under all relevant U.S. Department of the Treasury Office of Foreign Assets Control (OFAC) laws, regulations, and guidance related, *inter alia,* to Iran.

The Department requests that CWRU's production of records in response to this request utilize the following procedures:

- Searches for records in electronic form should include searches of all relevant mobile devices, hard drives, network drives, offline electronic folders, thumb drives, removable drives, records stored in the cloud, and archive files, including, but not limited to, backup tapes. Do not time stamp or modify the content, the create date, or the last date modified of any record and do not scrub any metadata.
- All email searches should be conducted by the agency's information technology department, or its equivalent, and not by the individuals whose records are being searched. Please provide the name and contact information of the individual(s) who conducted the search, as well as an explanation of how the search was conducted.
- To the extent practicable, please produce all records in a searchable electronic format and not hardcopies. Electronic records should be produced in native format. For emails, please place responses in one .pst file per employee. All other loose electronic files should be produced in their native format. To the extent practicable, all files should be produced in a manner that facilitates quick and accurate custodial assignment. Should CWRU have any questions about the method or format of production please contact the undersigned.

As used in this Notice of Investigation and Information Request:

''Agencies'' include any organizations or entities providing services or performing functions or tasks on behalf of another organization, entity, or individual.

''Agent'' has its plain and ordinary meaning, indicating that a person, organization, or entity, is acting on behalf of another person, organization, or entity, whether that agency is disclosed or undisclosed.

''Contract'' has the meaning given at 20 U.S.C. 1011f(h)(1).

''Faculty'' refers to all teaching positions at the university (including professors of all ranks, teachers, lecturers, and/or researchers whether in a classroom, laboratory, or other educational environment—whether physically or electronically present).

''Foreign source'' has the meaning given at 20 U.S.C. 1011f(h)(2).

''Gift'' has the meaning given at 20 U.S.C. 1011f(h)(3).

''Institution'' has the meaning given at 20 U.S.C. 1011f(h)(4) and for the purposes of this request includes CWRU, its employees, tenured faculty, non-tenured faculty and lecturers, researchers, fellows, graduate students, and all affiliated entities operating substantially under its control or for its benefit (*e.g.,* centers, schools, boards, foundations, research facilities, laboratories, branches, partnerships, or non-profit organizations).

''Record'' means all recorded information, regardless of form or characteristics, made or received, and including metadata, such as email and other electronic communication, word processing documents, PDF documents, animations (including PowerPoint™ and other similar programs) spreadsheets, databases, calendars, telephone logs, contact manager information, internet usage files, network access information, writings, drawings, graphs, charts, photographs, sound recordings, images, financial statements, checks, wire transfers, accounts, ledgers, facsimiles, texts, animations, voicemail files, data generated by calendaring, task management and personal information management (PIM) software (such as Microsoft Outlook), data created with the use of personal data assistants (PDAs), data created with the use of document management software, data created with the use of paper and electronic mail logging and routing software, and other data or data compilations, stored in any medium from which information can be obtained either directly or, if necessary, after translation by the responding party into a reasonably usable form. The term ''recorded information'' also includes all traditional forms of records, regardless of physical form or characteristics.

''Restricted or conditional gift or contract'' has the meaning given at 20 U.S.C. 1011f(h)(5).

''Staff'' refers to all members of the university involved in administration of the university and its obligations and commitments (including deans of all ranks, administration officials, and support personnel).

If CWRU asserts attorney-client or attorney-work product privilege for a given record, then it must prepare and submit a privilege log expressly identifying each such record and describing it so the Department may assess the claim's validity. Please note that no other privileges apply here. CWRU's record and data preservation obligations are outlined at Exhibit A.

The Department recognizes that the impact of the Coronavirus on all IHE operations is profound and ongoing. Nonetheless, the possible national security implications of undisclosed gifts, contracts, and/or restricted and conditional gifts or contracts from or with foreign sources is a critical matter and CWRU's statutory reporting obligation is long-standing. Therefore, your timely response to this Notice of Investigation and Record Request is essential.

This investigation is being directed by the Department's Office of General Counsel with investigative support from Federal Student Aid. To arrange for the transmission of the requested information or should you have any other questions, please contact: Paul R. Moore, Esq., Office of the General Counsel, U.S. Department of Education, 400 Maryland Ave. SW, Room 6E304, Washington, DC 20202, *Paul.Moore@ed.gov.*

Sincerely yours,

Reed D. Rubinstein,
Principal Deputy General Counsel, delegated the Authorities and Duties of the General Counsel

Enclosure (Exhibit A)

[FR Doc. 2020–13195 Filed 6–18–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–483]

Application to Export Electric Energy; Fuel Market LP

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Fuel Market LP (Applicant or Fuel Market LP) has applied for authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before July 20, 2020.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (16 U.S.C. 824a(e)).

On June 9, 2020, Fuel Market LP filed an application with DOE (Application or App.) to transmit electric energy from the United States to Mexico for a term of five years. Fuel Market LP states that it ''is a Texas corporation, with its principal place of business in Houston [Texas].'' App. at 1. Fuel Market LP adds that it ''does not own or control any electric power generation or transmission facilities and does not have a franchised electric power service area.'' *Id.* at 2.

Fuel Market LP further states that it ''will purchase surplus electric energy from electric utilities and other suppliers within the United States and will export this energy to Mexico over the international electric transmission facilities . . . listed in Exhibit C.'' App. at 3. Fuel Market LP contends that ''[b]ecause this electric energy will be purchased from other voluntarily, it will be surplus to the needs of the selling entities [and, therefore, the proposed] export of power will not impair the sufficiency of electric power supply in the U.S.'' *Id.*

Fuel Market LP also ''agrees to abide by the export limits of [approved] transmission facilities'' and states that ''[t]he controls that are inherent in any transaction that compiles with all [reliability] requirements and the export limits imposed by DOE on the references transmission facilities are sufficient to ensure that export by Fuel Market LP will not impede or tend to impede the coordinated use of transmission facilities'' under the Federal Power Act. App. at 4.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning Fuel Market LP's application to export electric energy to Mexico should be clearly marked with OE Docket No. EA–483. Additional copies are to be provided directly to Genaro Gomez, 4545 Post Oak Place Drive, Suite 217, Houston, Texas 77027; *genaro@gfint.com.*

A final decision will be made on this Application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE determines that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Matthew Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on June 15, 2020.

Christopher Lawrence,

Management and Program Analyst, Transmission Permitting and Technical Assistance, Office of Electricity.

[FR Doc. 2020–13234 Filed 6–18–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

DOE Response to Defense Nuclear Facilities Safety Board Recommendation 2020–1, Nuclear Safety Requirements

AGENCY: Office of Environment, Health, Safety and Security, Department of Energy.

ACTION: Notice.

SUMMARY: On February 21, 2020, the Defense Nuclear Facilities Safety Board issued Recommendation 2020–1, *Nuclear Safety Requirements,* to the Department of Energy. In accordance with the Atomic Energy Act of 1954, the Secretary of Energy's response to the Recommendation is provided in this notice.

DATES: Comments, data, views, or arguments concerning the Secretary's response are due on or before July 20, 2020.

ADDRESSES: Please send to: Defense Nuclear Facilities Safety Board, 625

Indiana Avenue NW, Suite 700, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Do, Office of the Departmental Representative to the Defense Nuclear Facilities Safety Board, Office of Environment, Health, Safety and Security, U.S. Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, or telephone number (301) 903–6460, or email *Mark.Do@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: On February 21, 2020, the Defense Nuclear Facilities Safety Board issued Recommendation 2020–1, *Nuclear Safety Requirements,* to the Department of Energy. Recommendation 2020–1 was published in the **Federal Register** on March 13, 2020 (85 FR 14658). In accordance with section 315(c) of the Atomic Energy Act of 1954 (42 U.S.C. 2286d(c)), the Secretary of Energy's response to the Recommendation is printed in full at the conclusion of this notice.

Signing Authority

This document of the Department of Energy was signed on June 15, 2020, by Joe Olencz, Departmental Representative to the Defense Nuclear Facilities Safety Board, Office of Environment, Health, Safety and Security, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on June 16, 2020.

Treena V. Garrett,

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

June 11, 2020

The Honorable Bruce Hamilton
Defense Nuclear Facilities Safety Board
625 Indiana Avenue NW, Suite 700
Washington, DC 20004

Dear Chairman Hamilton:

The Department of Energy (DOE) acknowledges receipt of Defense Nuclear Facilities Safety Board (DNFSB or Board) Recommendation 2020–1, *Nuclear Safety Requirements,* dated February 21, 2020, and published in the **Federal Register** on March 13, 2020.

The Board stated that the Recommendation is ''intended to strengthen DOE's regulatory framework in its current form,'' and consists of actions which DOE understands are intended to improve its existing nuclear safety regulatory framework, rather than remedy Board-perceived flaws in such framework. DOE stated in its December 17, 2019, response to the Draft Recommendation 2020–1, that continuous improvement is a core value in maintaining a robust nuclear safety regulatory framework to ensure adequate protection of public and worker health and safety.

DOE's recent actions to improve the framework include proposing to modify and improve Title 10 Code of Federal Regulations (CFR) Part 830, *Nuclear Safety Management,* and associated DOE nuclear safety directives and technical standards.

These efforts underscore DOE's goal to continuously improve its nuclear safety regulatory framework, which has helped DOE achieve and maintain an outstanding record of safety performance in recent decades. DOE does not agree with the DNFSB's assertion that the revisions proposed in the August 8, 2018, Notice of Proposed Rulemaking for 10 CFR part 830 would erode DOE's nuclear safety regulatory framework. Rather, DOE believes that these proposed changes would improve the effectiveness and efficiency of that framework while continuing to ensure adequate protection of the public and worker health and safety across the DOE complex.

Following DOE's evaluation of Recommendation 2020–1, the Department partially accepts the Board's Recommendation as summarized below and detailed in the enclosure.

On June 9, 2020, DOE provided the Board staff with the draft Final Rule, which touches on certain sub-elements of Recommendation 2020–1. Because the Department continues to consider these topics as part of its current rulemaking process, DOE rejects sub-recommendations 2.a, 2.b, 3.a, 4.a, and 4.b.

In addition, DOE rejects sub-recommendations 3.b, 3.c, and 4.e, as currently written because these topics are outside of the scope of the current rulemaking process to amend 10 CFR part 830. However, DOE will perform a regulatory analysis to evaluate whether further changes to 10 CFR part 830 should be proposed in an additional rulemaking.

As explained further in the enclosure to this letter, DOE partially accepts subrecommendations 1.a, 4.c, and 4.d, and will develop an Implementation Plan to address these elements. We appreciate the Board's advice and will continue working closely with the Board to improve the Department's regulatory framework at DOE defense nuclear facilities in a manner that meets our shared objectives to ensure the continued safe, effective, and efficient execution of our mission. We look forward to working with the Board and its staff as we prepare the Implementation Plan.

If you have any questions, please contact Mr. Matthew Moury, Associate Under Secretary for Environment, Health, Safety and Security, at 202–586–1285.

Sincerely,

Dan Brouillette

Enclosure

Enclosure

Enclosure—Department of Energy Response to DNFSB Recommendation 2020–1, Nuclear Safety Requirements

The Department of Energy (DOE or Department) has evaluated Defense Nuclear Facilities Safety Board (DNFSB or Board) Recommendation 2020–1. The following discussion presents a detailed response for each DNFSB sub-recommendation, which reflects the Department's partial acceptance of Recommendation 2020–1 (Recommendation).

DOE disagrees with the DNFSB's assertion that the revisions proposed in the August 8, 2018, Notice of Proposed Rulemaking (NOPR) for 10 CFR part 830, *Nuclear Safety Management,* would erode DOE's nuclear safety regulatory framework. Rather, DOE believes that these proposed changes would improve the effectiveness and efficiency of the framework while continuing to ensure adequate protection of public and worker health and safety at DOE defense nuclear facilities.

The DNFSB's Recommendation includes specific sub-recommendations related to two of the proposed revision topics identified in the NOPR: Hazard categorization and the review and approval of safety documentation. Because the Department continues to consider these topics as part of its current rulemaking efforts, DOE rejects sub-recommendations 2.a, 2.b, 3.a, 4.a, and 4.b.

Following issuance of the Final Rule, DOE plans to evaluate affected directives and standards (primarily DOE–STD–1104–2016, *Review and Approval of Nuclear Facility Safety Basis and Safety Design Basis Documents,* and DOE G 424.1–1B, *Implementation Guide for Use in Addressing Unreviewed Safety Question Requirements*) for conformance with any new requirements and provide any necessary implementation guidance. There will be an opportunity for the Board to engage in these revisions. Further discussion regarding these two topics is provided below.

In addition, DOE rejects sub-recommendations 3.b, 3.c, and 4.e as written because these topics are outside of the scope of the current rulemaking to amend 10 CFR part 830. However, DOE will perform a regulatory analysis to evaluate whether changes to 10 CFR part 830 should be pursued through an additional rulemaking.

Sub-Recommendation 1: Aging Infrastructure

Sub-Recommendation 1.a. *Develop and implement an approach including requirements to aging management that includes a formal process for identifying and performing infrastructure upgrades that are necessary to ensure facilities and structures, systems, and components can perform their safety functions.*

DOE partially accepts this sub-recommendation. DOE believes its nuclear safety regulatory framework has requirements in place to ensure facilities and safety structures, systems, and components (SSCs), both active and passive, perform their safety

function. In the Department's December 17, 2019, response to the Draft Recommendation, we included extensive discussion regarding DOE's expectations for the performance of safety SSCs within DOE's policy documents. At the highest level, compliance with 10 CFR part 830, including the requirement in § 830.204(b)(4) to ''. . . demonstrate the adequacy of these [hazard] controls to eliminate, limit, or mitigate identified hazards . . .'', is required for all Hazard Category (HC) 1, 2, and 3 nuclear facilities, and applies to new and aging facilities.

In responding to this sub-recommendation, however, DOE will ensure that nuclear safety is appropriately considered within existing organizations and committees in the Department who are charged with establishing Department-wide priorities and providing recommendations regarding infrastructure.

DOE has also been involved in the development of ANS–3.14–202x, *Process for Aging Management and Life Extension of Nonreactor Nuclear Facilities,* and will continue to support this effort to develop a consensus standard that is intended to guide the review and management of aging degradation mechanisms.

Sub-Recommendation 2: Hazard Categorizies

Sub-Recommendation 2.a. *Retain qualitative definitions of hazard categories in 10 CFR 830.*

DOE rejects this sub-recommendation because DOE is considering this matter in the current rulemaking. The August 8, 2018 NOPR proposed to remove Table 1 of Appendix A, which provides a qualitative concept of hazard categories, and replace that table with a formal definition in § 830.3 for ''Hazard Category 1, 2, and 3 DOE nuclear facilities'' that references DOE–STD–1027–92 Change Notice 1.

The NOPR notes that the removal of Table 1 would allow for a clearer link between the HC determination and the methodology in DOE–STD–1027–92 Change Notice 1 (as required in 10 CFR 830.202(b)(3)). As proposed, the qualitative ordering in which HC 1 would have higher potential consequences and HC 3 would have lower potential consequences remains unchanged from the current method. However, the determination of hazard categorization has always required the use of a quantitative methodology consistent with DOE–STD–1027–92, Change Notice 1, not on the guidance related to the qualitative concept provided in Table 1 of Appendix A to 10 CFR part 830, subpart B.

Sub-Recommendation 2.b. *Revise 10 CFR 830 to mandate use of a single version of Standard 1027 when performing facility hazard categorization.*

DOE rejects this sub-recommendation because DOE is considering this matter in the current rulemaking. It is worth noting that DOE's current approach is as follows: Section 830.202(b)(3) mandates that each facility be categorized ''consistent with DOE–STD–1027–92 (''Hazard Categorization and Accident Analysis Techniques for compliance with DOE Order 5480.23, Nuclear Safety Analysis Reports,'' Change Notice 1, September 1997).'' DOE has allowed updates to the Standard, as in DOE–STD–1027–2018, that retain the same methodology as in DOE–STD–1027–92. The Recommendation states that ''the words 'consistent with' introduce flexibility in implementation to not actually follow the requirements in DOE–STD–1027.'' DOE disagrees with this point. The rule *requires* that hazard categorization be conducted in a manner that is consistent with the methodology in DOE–STD–1027–92.

DOE provided the Board staff with a draft Final Rule on June 9, 2020. In the future, if DOE were to propose a new methodology for categorization, DOE would need to undertake a new rulemaking that would include the revised methodology for public comment and reference the new standard that includes the methodology.

Sub-Recommendation 3: DOE Approvals

Sub-Recommendation 3.a. *Conduct a root cause analysis to identify the underlying issues prohibiting the current safety basis approval process from working efficiently and use the findings to improve DOE's approval process.*

DOE rejects this sub-recommendation because DOE is considering this matter in the current rulemaking. The Recommendation identifies a number of concerns with the NOPR regarding the deletion of the requirement for review and approval of the annual updates to the documented safety analysis (DSA). Sub-recommendations 3.a. and 4.a. recommend conducting a root cause analysis to identify underlying issues in the DSA annual submittal and approval process.

Prior to issuing the NOPR, DOE carefully considered the proposed changes. DOE is the approval authority of safety bases and can approve changes to safety bases outside of the annual update process. DOE does not believe that the proposed change to delete the requirement for review and approval of the annual updates ''complicates DOE's ability to ensure the configuration of the facility, the processes, and the documentation'' on the safety of DOE facilities, as asserted in the Recommendation. The following discussion provides an explanation of DOE's proposal in the NOPR to remove this requirement, and why DOE believes this would be an effective path forward.

In § 830.203, *Unreviewed Safety Question Process,* DOE currently requires the contractor to obtain DOE approval prior to taking any action determined to involve an unreviewed safety question (USQ). DOE–STD–1104–2016 explains that ''[s]ince a ''positive'' [USQD determination (USQD)] indicates a situation that is not within the current DOE-approved safety envelope (*i.e.,* a USQ), that situation or action(s) is required to be evaluated in accordance with 10 CFR part 830 and approved by DOE.''

Additionally, § 830.202, *Safety Basis,* requires the contractor to annually submit to DOE either the updated DSA for approval or a letter stating that there have been no changes in the DSA since the prior submission. This effectively requires the contractor to submit changes to the DSA, for DOE approval, twice.

The requirement in § 830.201 that a contractor must perform work in accordance with the safety basis remains unchanged. The NOPR proposes a change to clarify that work must be performed in accordance with ''the DOE-approved safety basis'' for a facility. This has always been the expectation as described in § 830.207, *DOE approval of safety basis;* however, this change is proposed in the NOPR to further clarify the point.

In the NOPR, the language in § 830.207(b) has also been proposed for revision and would be strengthened to say: ''Pending issuance of a safety evaluation report in which DOE approves *an updated or amended* safety basis for *an existing* Hazard Category 1, 2, or 3 DOE nuclear facility, the contractor responsible for the facility must continue to perform work in accordance with the *DOE-approved* safety basis for the facility and maintain the existing safety basis consistent with the requirements of this Subpart'' (emphasis added).

The NOPR's proposed change to eliminate the requirement for DOE to approve the annual update would rely on an effectively implemented process for USQs. This proposed change would allow the USQ process to be the primary mechanism by which DOE's approval for changes to the DSA, where appropriate, would be obtained. If new changes or planned DSA updates are proposed (which have not been approved by DOE through the USQ process), DOE would review and approve those changes as required by § 830.207. The NOPR proposes to amend 10 CFR part 830, Appendix A to Subpart B, Section F.3, to include revised text to clarify this process.

Sub-Recommendation 3.b. *Add language to the rule to explain that DOE's review of safety basis updates should consider the cumulative effect of changes to the safety basis.*

DOE rejects this sub-recommendation because this topic is outside of the scope of the current rulemaking to amend 10 CFR part 830. However, DOE will perform a regulatory analysis to evaluate whether any changes to 10 CFR part 830 should be proposed through an additional rulemaking.

Sub-Recommendation 3.c. *Revise the body of 10 CFR 830, Subpart B, to include formal DOE approval of justifications for continued operation and evaluations of the safety of a situation.*

DOE rejects this sub-recommendation because this topic is outside of the scope of the current rulemaking to amend 10 CFR part 830. However, DOE will perform a regulatory analysis to evaluate whether any changes to 10 CFR part 830 should be proposed through an additional rulemaking.

Sub-Recommendation 4: Safety Basis Process and Requirements

Sub-Recommendation 4.a. *Conduct a root cause analysis to identify the underlying issues prohibiting contractors from developing and submitting a documented safety analysis on an annual schedule for DOE approval and use the findings to improve the submission process.*

DOE rejects this sub-recommendation because DOE is considering this matter in the

current rulemaking. See discussion under sub-recommendation 3.a. for the basis for rejection of 4.a.

Sub-Recommendation 4.b. *While conducting the analyses in 3.a. and 4.a. above, retain the requirement for contractors to submit a documented safety analysis on an annual schedule for DOE approval.*

DOE rejects this sub-recommendation because DOE is considering this matter in the current rulemaking. See discussion under sub-recommendation 3.a for the basis for rejection of 4.b.

Sub-Recommendation 4.c. *Specify what safety basis documentation a contractor must submit when seeking approval for an action involving a USQ (proposed 10 CFR 830.203(d)).*

DOE partially accepts this sub-recommendation and will evaluate DOE's nuclear safety management framework (*i.e.,* DOE directives and technical standards) to determine whether improvements are necessary. DOE's understanding is that the Board staff is also in the process of reviewing DOE's implementation of USQ requirements for defense nuclear facilities. DOE looks forward to considering the results of this review, once complete, to inform DOE's path forward in this area. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 4.d. *Establish requirements for USQs and TSRs in 10 CFR 830 and/or orders, by elevating key guidance on USQs and TSRs to clearly identified requirements.*

DOE partially accepts this sub-recommendation and will evaluate DOE's nuclear safety management framework (*i.e.,* DOE directives and technical standards) to determine whether improvements are necessary. DOE's understanding is that the Board staff is also in the process of reviewing DOE's implementation of USQ and technical safety requirements (TSR) for defense nuclear facilities. DOE looks forward to considering the results of these reviews, once complete, to inform DOE's path forward in this area. The Implementation Plan will further describe the steps that will be taken to address this sub-recommendation.

Sub-Recommendation 4.e. *Establish requirements for and incorporate the concept of defense-in-depth and SACs and add a discussion of defense-in-depth and SACs to 10 CFR 830 under safety structures, systems, and components.*

DOE rejects this sub-recommendation because this topic is outside of the scope of the current rulemaking to amend 10 CFR part 830. However, DOE will perform a regulatory analysis to evaluate whether any changes to 10 CFR part 830 should be proposed through an additional rulemaking.

[FR Doc. 2020–13238 Filed 6–18–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[OE Docket No. EA–375–B]

Application To Export Electric Energy; Rainbow Energy Marketing Corporation

AGENCY: Office of Electricity, Department of Energy.

ACTION: Notice of application.

SUMMARY: Rainbow Energy Marketing Corporation (Applicant or Rainbow) has applied to renew its authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before July 20, 2020.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to *Electricity.Exports@hq.doe.gov,* or by facsimile to (202) 586–8008.

SUPPLEMENTARY INFORMATION: The Department of Energy (DOE) regulates exports of electricity from the United States to a foreign country, pursuant to sections 301(b) and 402(f) of the Department of Energy Organization Act (42 U.S.C. 7151(b) and 42 U.S.C. 7172(f)). Such exports require authorization under section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)).

On December 3, 2015, DOE issued Order No. EA–375–A, which authorized Rainbow to transmit electric energy from the United States to Mexico as a power marketer for a five-year term using existing international transmission facilities appropriate for open access. This authorization expires on December 14, 2020. On June 5, 2020, Rainbow filed an application (Application or App.) with DOE for renewal of the export authorization contained in Order No. EA–375–A.

Rainbow states that its principal place of business is in Bismarck, North Dakota, and that it ''is a privately owned U.S. corporation, which is partially owned by United Energy Corporation.'' App. at 1–2. Rainbow adds that it ''does not own or control any electric power generation or transmission facilities and does not have a franchised electric power service area.'' *Id.* at 2.

Rainbow further states that it ''will purchase the power to be exported from electric utilities and federal power marketing agencies as those terms are defined in the FPA.'' App. at 3–4. Rainbow contends that its proposed exports ''would not impede or tend to impede the coordinated use of transmission facilities within the meaning of FPA Section 202(e).'' *Id* at 5.

The existing international transmission facilities to be utilized by the Applicant have previously been authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the address provided above. Protests should be filed in accordance with Rule 211 of the Federal Energy Regulatory Commission's (FERC) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the above address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning Rainbow's Application should be clearly marked with OE Docket No. EA–375–B. Additional copies are to be provided directly to Joseph A. Wolfe, Kirkwood Office Tower, 919 South 7th Street, Suite 405, Bismarck, ND 58504, *j.wolfe@rainbowenergy.com;* and Steven A. Weiler, 1401 New York Avenue NW, Suite 900, Washington, DC 20005–2102, *weiler.steve@dorsey.com.*

A final decision will be made on this Application after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE determines that the proposed action will not have an adverse impact on the sufficiency of supply or reliability of the U.S. electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at *http://energy.gov/node/11845,* or by emailing Matthew Aronoff at *matthew.aronoff@hq.doe.gov.*

Signed in Washington, DC, on June 15, 2020.

Christopher Lawrence,

Management and Program Analyst, Transmission Permitting and Technical Assistance, Office of Electricity.

[FR Doc. 2020–13236 Filed 6–18–20; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2048–000]

Ellwood Power, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Ellwood Power, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 6, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: June 15, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–13243 Filed 6–18–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER20–2047–000]

Ormond Beach Power, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Ormond Beach Power, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is July 6, 2020.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: June 15, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–13241 Filed 6–18–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG20–186–000.
Applicants: Ellwood Power, LLC.
Description: Self-Certification of EWG of Ellwood Power, LLC.
Filed Date: 6/12/20.
Accession Number: 20200612–5226.
Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: EG20–187–000.
Applicants: Ormond Beach Power, LLC.
Description: Self-Certification of EWG of Ormond Beach Power, LLC.
Filed Date: 6/12/20.
Accession Number: 20200612–5227.
Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: EG20–188–000.
Applicants: Fern Solar LLC.

Description: Fern Solar LLC Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 6/12/20.

Accession Number: 20200612–5229.

Comments Due: 5 p.m. ET 7/6/20.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER20–1107–002.

Applicants: Midcontinent Independent System Operator, Inc., ITC Midwest LLC.

Description: Tariff Amendment: 2020–06–15_SA 2945 ITC–IPL Sub 1st Rev FSA (J233 J514) Unpopulated Template to be effective 2/28/2020.

Filed Date: 6/15/20.

Accession Number: 20200615–5142.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2050–000.

Applicants: Tri-State Generation and Transmission Association, Inc.

Description: § 205(d) Rate Filing: Amendment to Service Agreement No. 207 to be effective 2/25/2020.

Filed Date: 6/12/20.

Accession Number: 20200612–5192.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2051–000.

Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.

Description: Compliance filing: Niagara Mohawk—Order No. 864 compliance re: transmission service charge to be effective 1/27/2020.

Filed Date: 6/15/20.

Accession Number: 20200615–5017.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2052–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ICSA, SA No. 5247; Queue Position Z2–107 to be effective 6/21/2019.

Filed Date: 6/15/20.

Accession Number: 20200615–5106.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2053–000.

Applicants: Republic Transmission, LLC.

Description: Tariff Cancellation: Republic Transmission LLC Cancellation of Formula Rates Tariff to be effective 6/15/2020.

Filed Date: 6/15/20.

Accession Number: 20200615–5130.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2055–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: Amended GIA & DSA Kaweah River Power Authority SA Nos. 1100–1101 Terminus Dam to be effective 8/15/2020.

Filed Date: 6/15/20.

Accession Number: 20200615–5165.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2056–000.

Applicants: Northern Indiana Public Service Company.

Description: § 205(d) Rate Filing: Filing of a CIAC Agreement to be effective 6/10/2020.

Filed Date: 6/15/20.

Accession Number: 20200615–5198.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2057–000.

Applicants: El Paso Electric Company.

Description: § 205(d) Rate Filing: Service Agreement No. 335, Nonconforming EPE and EDFR Solar LGIA to be effective 5/29/2020.

Filed Date: 6/15/20.

Accession Number: 20200615–5220.

Comments Due: 5 p.m. ET 7/6/20.

Docket Numbers: ER20–2058–000.

Applicants: El Paso Electric Company.

Description: § 205(d) Rate Filing: Service Agreement No. 336, Nonconforming EPE and NextEra LGIA to be effective 5/20/2020.

Filed Date: 6/15/20.

Accession Number: 20200615–5240.

Comments Due: 5 p.m. ET 7/6/20.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES20–43–000.

Applicants: Consolidated Edison Company of New York, Inc.

Description: Application Under Section 204 of the Federal Power Act for Authorization to Issue Securities of Consolidated Edison Company of New York, Inc.

Filed Date: 6/12/20.

Accession Number: 20200612–5242.

Comments Due: 5 p.m. ET 7/6/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 15, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–13245 Filed 6–18–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Docket Numbers: RP19–581–003.

Applicants: Rager Mountain Storage Company LLC.

Description: Compliance filing Order No. 587–Y—Request for Additional Extension of Time.

Filed Date: 6/12/20.

Accession Number: 20200612–5103.

Comments Due: 5 p.m. ET 6/24/20.

Docket Numbers: RP19–582–003.

Applicants: Equitrans, L.P.

Description: Compliance filing Order No. 587–Y—Request for Additional Extension of Time.

Filed Date: 6/12/20.

Accession Number: 20200612–5157.

Comments Due: 5 p.m. ET 6/24/20.

Docket Numbers: RP20–955–000.

Applicants: Gas Transmission Northwest LLC.

Description: § 4(d) Rate Filing: Negotiated Rate Agreement—Seven Generations to be effective 6/1/2020.

Filed Date: 6/12/20.

Accession Number: 20200612–5208.

Comments Due: 5 p.m. ET 6/24/20.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: June 15, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–13244 Filed 6–18–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Effectiveness of Exempt Wholesale Generator Status

	Docket Nos.
Frontier Windpower II, LLC	EG20–88–000
Coyote Wind, LLC	EG20–89–000
Roundhouse Renewable Energy, LLC.	EG20–90–000
Oliver Wind II, LLC	EG20–91–000
Anson Solar Center, LLC	EG20–92–000
Bluestone Farm Solar, LLC	EG20–93–000
Whitehorn Solar LLC	EG20–94–000
Las Majadas Wind Farm, LLC	EG20–95–000
Milligan 1 Wind LLC	EG20–96–000
King Plains Wind Project, LLC	EG20–97–000
Johanna Energy Center, LLC	EG20–98–000
Dakota Range III, LLC	EG20–99–000
Triple H Wind Project, LLC	EG20–100–000
Las Lomas Wind Project, LLC	EG20–101–000
Prairie Hill Wind Project, LLC	EG20–102–000
Mechanicsville Solar, LLC	EG20–103–000
Albemarle Beach Solar, LLC	EG20–104–000
RE Mustang Two Barbaro, LLC	EG20–105–000
RE Mustang Two Whirlaway, LLC.	EG20–106–000
LA3 West Baton Rouge, LLC	EG20–107–000
Yards Creek Energy, LLC	EG20–108–000
Inter-Power/AhlCon Partners, L.P.	EG20–109–000
Northern Colorado Wind Energy Center, LLC.	EG20–110–000

Take notice that during the month of May 2020, the status of the above-captioned entities as Exempt Wholesale Generators became effective by operation of the Commission's regulations. 18 CFR 366.7(a) (2019).

Dated: June 15, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–13242 Filed 6–18–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Southeastern Power Administration

Revision to Power Marketing Policy Kerr-Philpott System of Projects

AGENCY: Southeastern Power Administration, DOE.

ACTION: Notice of proposed revision to power marketing policy.

SUMMARY: Pursuant to its Procedure for Public Participation in the Formulation of Marketing Policy, published in the **Federal Register** of July 6, 1978, Southeastern Power Administration (Southeastern or SEPA) published on November 15, 2019, a notice of intent to revise its power marketing policy to include provisions regarding renewable energy certificates (RECs) from its Kerr-Philpott System of Projects (Kerr-Philpott System). The current power marketing policy was published on July 29, 1985, for the Kerr-Philpott System and is reflected in contracts for the sale of system power, which are maintained in Southeastern's headquarters office. The following is the proposed revision to the Kerr-Philpott System Power Marketing Policy to include a procedure for distribution of RECs to Preference Customers. Southeastern solicits written comments in formulating the final marketing policy revision.

DATES: A public information and comment forum will be held in Boydton, Virginia, at 1:00 p.m. on August 18, 2020. Persons desiring to attend the forum should notify Southeastern by August 10, 2020, so that a list of forum participants can be prepared. Persons desiring to speak at the forum should specify this in their notification to Southeastern; others may speak if time permits. Written comments are due September 2, 2020, fifteen (15) days after the scheduled comment forum.

ADDRESSES: Five copies of written comments should be submitted to: Herbert R. Nadler, Acting Administrator, Southeastern Power Administration, Department of Energy, 1166 Athens Tech Road, Elberton, Georgia 30635–6711, and emailed to *Comments@sepa.doe.gov.* The public information and comment forum for the revision of the Kerr-Philpott System power marketing policy to include provisions for renewable energy certificates will be at the U.S. Army Corps of Engineers, J. H. Kerr Reservoir Visitor Assistance Center, 1930 Mays Chapel Road, Boydton, Virginia 23917, Phone: (434) 738–6143. If travel restrictions occur due to the COVID–19 pandemic on August 18, 2020, the comment forum will be held as a webinar on the same date and time. Please register your intent to attend, including name, address, phone number, and email address, with Southeastern's Legal Assistant at *judith.worley@sepa.doe.gov,* to receive updates on the meeting status of the comment forum. Registered attendees will be contacted on August 11, 2020, regarding meeting updates and call-in information, if held by webinar.

FOR FURTHER INFORMATION CONTACT: Leon Jourolmon IV, General Counsel, Southeastern Power Administration, 1166 Athens Tech Road, Elberton, GA 30635, (706) 213–3800, *leon.jourolmon@sepa.doe.gov.*

SUPPLEMENTARY INFORMATION: *Background:* Pursuant to its Procedure for ''Public Participation in Formulation of Marketing Policy'' published in the **Federal Register** on July 6, 1978, 43 FR 29186, Southeastern published a ''Notice of Issuance of Final Power Marketing Policy, Kerr-Philpott System of Projects'' in the **Federal Register** on July 29, 1985, 50 FR 30751. The policy establishes the marketing area for system power and addresses the utilization of area utility systems for essential purposes. The policy also addresses wholesale rates, resale rates, and conservation measures, but does not address renewable energy certificates. Under Section 5 of the Flood Control Act of 1944 (16 U.S.C. 825s), Southeastern is responsible for the transmission and disposition of electric power and energy from reservoir projects operated by the Department of the Army. Furthermore, Southeastern must transmit and dispose of such power and energy in such manner as to encourage the most widespread use at the lowest possible rates to consumers consistent with sound business principles. Rate schedules shall be drawn to recover all costs associated with producing and transmitting the power in accordance with repayment criteria

All documents introduced at the public information and comment forum, and all comments, questions and answers will be available for inspection and copying in accordance with the Freedom of Information Act (5 U.S.C. 552).

Public Notice and Comment

On November 15, 2019, Southeastern published in the **Federal Register**, 84 FR 62519, a ''Notice of Intention to begin a public process'' to revise its marketing policy by including provisions regarding renewable energy certificates from its Kerr-Philpott System. The notice requested that written comments and proposals be submitted on or before January 14, 2020. All comments received are summarized and answered in the following section.

Staff Review of Comments

Written comments were received from one source, Southeastern Federal Power Customers, Inc. (SeFPC), and are summarized below. Southeastern's response follows each comment.

Comment 1: Precedential Effect

At the outset, the SeFPC recognizes that SEPA is only revising the marketing policy for the Kerr-Philpott system of

projects. However, the precedent set by these revisions may apply to other marketing areas which requires due care to ensure that the approach adopted by SEPA can be adopted and modified as appropriate for other marketing areas. Moreover, SEPA should explain that the development of a REC policy and allocation of RECs to existing customers does not change the Administrator's prior determinations on power allocations within the marketing area.

Response 1: Southeastern's proposal addresses only changes to the Kerr-Philpott System marketing policy. Revisions to other marketing policies would involve a similar public process to allow comments from interested parties. The revision would not change the Administrator's prior determinations regarding power allocations within the marketing area. Southeastern recognizes that policy decisions within the Kerr-Philpott System may be taken into account in Southeastern's development of subsequent proposals. Southeastern believes that many of the principles used may be used in other systems; however, as Renewable Energy Certificates are defined on a state-by-state basis with a variety of generation requirements and reporting systems, a uniform policy is not possible.

Comment 2: Eligible Customers

The RECs which will be made available under this new policy should be offered to all eligible customers. Here, we suggest that SEPA clarify that eligible recipients of RECs are limited to existing power customers with an allocation in that specific marketing area.

Response 2: The Renewable Energy Certificates for the Kerr-Philpott System would be distributed to Kerr-Philpott preference customers based upon the amount of energy sold to each customer during a quarterly period.

Comment 3: Flexibility and Optionality

The REC policy adopted by SEPA must incorporate flexibility to allow for customers to utilize RECs to the maximum benefit for each customer. As a starting premise, SEPA should offer RECs to each available customer to determine how to utilize the RECs for optimum benefit. If a customer declines to take possession of its REC entitlement, SEPA should offer to sell the RECs on behalf of that customer and credit the customer's bill accordingly. Additionally, SeFPC suggests SEPA offer individual customers the option to transfer RECs to wholesale power providers that meet the definition of a preference customer but are not the counterparty to the power supply contract with SEPA.

Response 3: The proposal would allow for flexibility while limiting the transactional costs for Southeastern. Customers would be able to accept RECs directly or designate third-parties to receive the REC distributions. Southeastern does not propose to sell any RECs at this time. Southeastern reserves the right to distribute RECs that have been declined at a later date.

Comment 4: Relationship to Laws and Regulations

SEPA must ensure the revised Kerr-Philpott System power marketing policy adheres to current SEPA regulations and contracts, as well as current state, federal, and local laws. Such a practice will support consistency and clarity within SEPA's marketing areas. Additionally, SeFPC suggests SEPA work with individual customers to ensure that RECs sourced from a particular balancing/marketing area will be eligible to qualify under state programs.

Response 4: Southeastern will adhere to all applicable statutes, regulations, and contracts. Southeastern will assist Kerr-Philpott System customers in gaining value from REC distributions through state renewable energy programs by providing data for the registration of the generating resources with state programs where applicable.

Comment 5: Term

The REC policy and availability of RECs should track the term of the power supply agreements in place with a power customer. In particular, RECs should be available for the duration of the agreement and subject to recall by SEPA only in the event that the power customer ceases to buy capacity and energy from SEPA.

Response 5: The proposal is for a distribution to preference customers based upon energy sales during the prior quarter.

Comment 6: Billing and Costs

Because SEPA will incur no direct expense in allocating available RECs, the policy should clarify that RECs are provided at no cost to requesting customers. To the extent that a customer declines to take possession of a REC and relies on SEPA to sell the REC, a separate line item should be included on that customer's bill setting forth the benefit received and the costs directly attributable to sale of RECs for that particular customer.

Response 6: The administrative costs to maintain the PJM–GATS membership and fees for creation and distribution of the certificates would be allocated over the entire Kerr-Philpott System. Southeastern would not establish any rate schedules for RECs. Southeastern would not sell any RECs.

Comment 7: Further Review and Comment

The recommendations set forth above provide a general framework for SEPA to consider in drafting the policy. As the policy is prepared in a more detailed format, the SeFPC reserves the right to provide additional comments and clarifications to the points raised above.

Response 7: Southeastern will accept comments from interested parties including SeFPC and its members until 15 days after the announced Public Information and Comment Forum. Written comments must be submitted on or before September 2, 2020.

Proposed Revision to the Power Marketing Policy

Kerr-Philpott System: The Kerr-Philpott System consists of two projects, the John H. Kerr Project (Kerr) and the Philpott Project (Philpott). The power from the projects is currently marketed to Preference Customers located in the service areas of Dominion Energy, Duke Energy Progress, American Municipal Power and American Electric Power. Both projects are located within the current PJM Interconnection, L.L.C. (PJM) footprint. Southeastern owns no transmission assets and is reliant on PJM transmission resources to deliver power and energy from the projects. As such, Southeastern became a PJM market participant member in 2005.

Southeastern proposes to revise the Power Marketing Policy for the Kerr-Philpott System to include the following additional provisions for RECs associated with hydroelectric generation:

Renewable Energy Certificates: The Generation Attribute Tracking System (GATS) of PJM Environmental Information Services, Inc. (PJM–EIS) creates and tracks certificates reporting generation attributes, by generating unit, for each megawatt-hour (MWh) of energy produced by registered generators. PJM–EIS is a wholly-owned subsidiary of PJM Connext, L.L.C., itself a subsidiary of PJM. Both the Kerr and Philpott projects are registered generators within GATS. The RECs potentially satisfy Renewable Portfolio Standards, state policies, and other regulatory or voluntary clean energy standards in a number of states. Southeastern has subscribed to GATS and has an account in which RECs are collected and tracked for each MWh of energy produced from Kerr and

Philpott. Within GATS, certificates can be transferred to other GATS subscribers or to a third-party tracking system.

As defined by the PJM–GATS Terms, ''Certificates'' refers to a GATS electronic record of generation data representing all of the Attributes from one MWh of electricity generation from a Generating Unit registered with the GATS tracking system. The GATS will create exactly one Certificate per MWh of generation. These certificates may be used by electricity suppliers and other energy market participants to comply with relevant state policies and regulatory programs and to support voluntary ''green'' electricity markets.

Southeastern proposes distribution of the GATS-created REC to Preference Customers with allocations of power from the Kerr-Philpott System.

REC Distribution: Southeastern shall maintain an account with GATS and collect RECs from the generation at the Kerr and Philpott projects. Southeastern will verify the total amount of RECs each month. Preference Customers with an allocation of power from the Kerr-Philpott System are eligible to receive RECs by transfer from Southeastern's GATS account to their GATS account or that of their agent. GATS (or a successor application) will be the transfer mechanism for all RECs related to the Kerr-Philpott System. Any further transfer, sale, use, or trade transaction would be the sole responsibility of a Preference Customer. Southeastern will summarize RECs by month for calendar year, quarterly distribution to customers through GATS. Southeastern will determine a total number of RECs to transfer to each customer based on the customer's monthly invoices during the same three-month period. RECs will be project-specific based on the customer's applicable contractual arrangements. Thus, customers receiving energy from Philpott will receive equivalent RECs from Philpott, and customers receiving energy from Kerr will receive equivalent RECs from Kerr.

All RECs distributed by Southeastern shall be transferred within thirty days of the end of the calendar year quarter (quarterly distribution month). Each customer must submit to Southeastern, by the tenth day of a quarterly distribution month, the name, contact information, and identification number of the GATS account to which the RECs are to be transferred initially and for any quarterly distribution month in which the account for transfer changes. The account may be held by a third party. If the customer fails to designate an account by the tenth day of the quarterly distribution month, those RECs shall not be distributed until the following quarter. Any RECs that were not transferred because a transfer account was not provided to Southeastern will be forfeited if they become non-transferable in the GATS Terms of Use procedures, policies, or definitions of Reporting and Trading Periods, or any subsequent rules and procedures for transfers as established.

The initial transfer process in GATS will be accomplished by the thirtieth day after the end of the first completed calendar year quarter subsequent to publication of the final policy revision. Any balance of RECs that exist in Southeastern's GATS account, other than the first quarter after policy revision publication, may also be transferred to Preference Customers according to the customer's invoiced energy at the time of the REC creation.

Rates: No rates shall be established by Southeastern for RECs transferred to Preference Customers. Any cost to Southeastern, such as the GATS subscription, will be incorporated into marketing costs and included in recovery through the energy and capacity rates of the Kerr-Philpott System.

Signing Authority

This document of the Department of Energy was signed on June 11, 2020, by Herbert R. Nadler, Acting Administrator, Southeastern Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register.**

Signed in Washington, DC, on June 12, 2020.

Treena V. Garrett,

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

[FR Doc. 2020–13106 Filed 6–18–20; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0052; FRL–10010–85]

Pesticide Product Registration; Receipt of Applications for New Uses (May 2020)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before July 20, 2020.

ADDRESSES: Submit your comments, identified by the docket identification (ID) number and the File Symbol of the EPA registration number of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), main telephone number: (703) 305–7090, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC

20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each application summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register new uses for pesticide products containing currently registered active ingredients. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications.

Notice of Receipts—New Uses

1. *EPA Registration Numbers:* 100–791, 100–1202 and 100–1614. *Docket ID number:* EPA–HQ–OPP–2019–0346. *Applicant:* Syngenta Crop Protection, LLC. P.O. Box 18300, Greensboro, NC 27419. *Active ingredient:* Mefenoxam. *Product type:* Fungicide. *Proposed use:* Tree nut Crop Group 14–12. Contact: RD

2. *EPA Registration Numbers:* 7969–312 and 7969–310. *Docket ID number:* EPA–HQ–OPP–2020–0228. *Applicant:* BASF Corporation, Agricultural Products P.O. Box 13528, 26 Davis Drive, Research Triangle Park, NC 27709. *Product name:* Xemium Fungicide Technical and Merivon Xemium Brand Fungicide. *Active ingredient:* Fluxapyroxad at 99.5% (Xemium Fungicide Technical); Fluxapyroxad at 21.26% and Pyraclostrobin at 21.26% (Merivon Xemium Brand Fungicide). *Proposed use(s):* Pomegranate; Vegetable, fruiting, group 8–10; Fruit, pome, group 11–10; Cottonseed subgroup 20C. Contact: RD.

3. *EPA Registration Numbers:* 7969–446 and 7969–444. *Docket ID number:* EPA–HQ–OPP–2020–0267. *Applicant:* BASF corporation, 26 David Drive, P.O. Box 13528, RTP, NC 27709. *Product name:* Glufosinate-Ammonium Technical and Finale Herbicide. *Active ingredient:* Glufosinate at 95% (Glufosinate-Ammonium Technical) and 11.33% (Finale Herbicide). *Proposed use(s):* Turfgrass Use Pattern to Include All Turf Scenarios, Including Residential, Golf, and Sod farms. Contact: RD.

4. *EPA File Symbol:* 89459–RRT. *Docket ID number:* EPA–HQ–OPP–2020–0269. *Applicant:* Central Garden & Pet, 1501 E Woodfield Rd., Suite 200W, Schaumburg, IL 60173. *Active ingredients:* Acetamiprid and Etofenprox. *Product type:* Insecticide. *Proposed use:* Non-food indoor use on horses. Contact: RD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 12, 2020.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2020–13272 Filed 6–18–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–9051–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information 202–564–5632 or *https://www.epa.gov/nepa.*

Weekly receipt of Environmental Impact Statements (EIS)

Filed June 8, 2020, 10 a.m. EST Through June 15, 2020 10 a.m. EST

Pursuant to 40 CFR 1506.9.

Section 309(a) of the Clean Air Act requires that EPA make public its comments on EISs issued by other Federal agencies. EPA's comment letters on EISs are available at: *https://cdxnodengn.epa.gov/cdx-enepa-public/action/eis/search.*

EIS No. 20200124, Final, APHIS, NAT, Southern Gardens Citrus Nursery, LLC Permit to Release Genetically Engineered Citrus tristeza virus, *Review Period Ends:* 07/20/2020, *Contact:* Cindy Eck 301–851–3892.

EIS No. 20200125, Draft, USAF, FL, F–35A Wing Beddown at Tyndall AFB and MQ–9 Wing Beddown at Tyndall AFB or Vandenberg AFB, *Comment Period Ends:* 08/03/2020, *Contact:* Nolan Swick 210–925–3392.

EIS No. 20200126, Final Supplement, USFS, MT, Greater Red Lodge Area Vegetation and Habitat Management Project, *Review Period Ends:* 08/03/2020, *Contact:* Victoria Regula 406–848–7375.

EIS No. 20200127, Final, DHS, SC, Adoption—Navy Base Intermodal Container Transfer Facility, *Review Period Ends:* 07/20/2020, *Contact:* Jennifer DeHart Hass 202–834–4346.

The Department of Homeland Security (DHS) has adopted the U.S. Army Corps of Engineers Final EIS No. 20180148, filed 06/22/2018 with EPA. DHS was not a cooperating agency on this project. Therefore, recirculation of the document is necessary under Section 1506.3(b) of the CEQ Regulations.

EIS No. 20200128, Draft, FHWA, WI, South Bridge Connector, Brown County, Wisconsin, Tier 1 DEIS, *Comment Period Ends:* 08/03/2020, *Contact:* Ian Chidister 608–829–7503.

EIS No. 20200129, Revised Final, USFS, ID, Little Boulder, *Review Period Ends:* 07/20/2020, *Contact:* Amy Boykin 208–476–8205.

Amended Notice

EIS No. 20200054, Draft, BIA, BLM, NM, Farmington Mancos-Gallup Resource Management Plan Amendment and

Environmental Impact Statement, *Comment Period Ends:* 09/25/2020, *Contact:* Jillian Aragon 505–564–7722. Revision to FR Notice Published 2/28/2020; Extending the Comment Period from 5/28/2020 to 9/25/2020.

EIS No. 20200060, Draft, FHWA, VA, Route 220 Martinsville Southern Connector, *Comment Period Ends:* 07/24/2020, *Contact:* Mack A Frost 804–775–3352. Revision to FR Notice Published 5/15/2020; Extending the Comment Period from 6/19/2020 to 7/24/2020.

Dated: June 16, 2020.

Cindy S. Barger,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2020–13252 Filed 6–18–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2020–0049; FRL–10010–84]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before July 20, 2020.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the File Symbol of interest as shown in the body of this document, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), main telephone number: (703) 305–7090, email address: *BPPDFRNotices@epa.gov.* The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation website for additional information on this process (*http://www2.epa.gov/pesticide-registration/public-participation-process-registration-actions*).

A. Notice of Receipt—New Active Ingredients

1. *File Symbol:* 71771–RG. *Docket ID number:* EPA–HQ–OPP–2020–0285. *Applicant:* Plant Health Care Inc., 2626 Glenwood Avenue, Suite 350, Raleigh, NC 27608. *Product name:* PHC 25279. *Active ingredient:* Fungicide; PDHP 25279 at 1%. *Proposed classification/Use:* Biochemical, food and non-food crops. *Contact:* BPPD.

2. *File Symbol:* 73049–LRA. *Docket ID number:* EPA–HQ–OPP–2019–0516. *Applicant:* Valent BioSciences LLC. *Product name:* ACC Technical Powder Plant Growth Regulator. *Active ingredient:* Plant Growth Regulator; 1-Aminocyclopropanecarboxylic Acid (ACC) at 98.56%. *Proposed classification/use:* Manufacturing Use Product. *Contact:* BPPD.

3. *File Symbol:* 73049–LRT. *Docket ID number:* EPA–HQ–OPP–2019–0516. *Applicant:* Valent BioSciences LLC. *Product name:* VBC–30445 Plant Growth Regulator Liquid Concentrate. *Active ingredient:* Plant Growth Regulator; 1-Aminocyclopropanecarboxylic Acid (ACC) at 10.0%. *Proposed classification/Use:* End Use Product. *Contact:* BPPD.

4. *File Symbol:* 89186–E. *Docket ID number:* EPA–HQ–OPP–2020–0252. *Applicant:* ConidioTec LLC, 2440 Earlystown Road, Suite 600 Centre Hall, PA 16828 (c/o Lewis & Harrison, 2461

South Clark Street, Suite 710, Arlington, VA 22202). *Product name:* Aprehend RTU. *Active ingredient:* Insecticide; *Beauveria bassiana* Strain l93–825 at 2%. *Proposed classification/Use:* For use to control and prevent bed bug infestations in indoor environments. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: June 10, 2020.

Delores Barber,

Director, Information Technology and Resources Management Division, Office of Pesticide Programs.

[FR Doc. 2020–13275 Filed 6–18–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[GN Docket No. 18–122; DA 20–599; FRS 16864]

Wireless Telecommunications Bureau Announces Relocation Payment Clearinghouse Request for Proposal, Selection Criteria, and Application Deadlines in 3.7–4.2 GHz Band Transition

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Federal Communications Commission (Commission) announces that that it has received a Request for Proposal, which contains the selection criteria and filing instructions for proposals for the position of Relocation Payment Clearinghouse (Clearinghouse) in the 3.7–4.2 GHz band (C-band) transition.

DATES: Entities must file proposals electronically with the search committee, according to the filing instructions contained in the Request for Proposal, by June 29, 2020.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Susan Mort of the Wireless Telecommunications Bureau, at (202) 418–2429 or *Susan.Mort@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Public Notice* in GN Docket No. 18–122, DA 20–599 released June 8, 2020. The full text of the *Public Notice* is available for inspection and copying during normal business hours in the FCC Reference Center, 445 12th Street SW, Room CY–A257, Washington, DC 20554, or by downloading the text from the Commission's website at *https://ecfsapi.fcc.gov/file/06082630229367/DA-20-599A1.pdf* and *https://ecfsapi.fcc.gov/file/06082630229367/DA-20-599A2.pdf.* Alternative formats are available for people with disabilities (Braille, large print, electronic files, audio format), by sending an email to *FCC504@fcc.gov* or calling the Consumer and Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (TTY).

Synopsis

With this Public Notice, the Wireless Telecommunications Bureau (the Bureau) announces that it has received a Request for Proposal, which contains the selection criteria and filing instructions for proposals for the position of Clearinghouse in the C-band transition. In the *3.7 GHz Band Report and Order,* the Commission adopted rules to make 280 megahertz of mid-band spectrum available for flexible use, plus a 20 megahertz guard band, throughout the contiguous United States by transitioning existing services out of the lower portion of the band and into the upper 200 megahertz of the C-band. The *3.7 GHz Band Report and Order* provided for the creation of a neutral, independent Clearinghouse to oversee the cost-related aspects of the transition, including collecting relocation payments from new 3.7 GHz Service licensees and disbursing those payments to incumbents. In the *3.7 GHz Band Report and Order,* the Commission invited a committee of stakeholders in the C-band to establish detailed selection criteria and to select the Clearinghouse. The *3.7 GHz Band Report and Order* directed the Bureau to issue a Public Notice that: (1) Notified the public that the search committee had published criteria for the selection of the Clearinghouse; (2) outlined the submission requirements; and (3) provided the closing dates for the selection of the Clearinghouse. The search committee submitted the Request for Proposal to the Commission on June 1, 2020.

The search committee's Request for Proposal, attached to this Public Notice, details the selection criteria and instructions for filing proposals for the Clearinghouse position. Entities must file proposals electronically with the search committee, according to the filing instructions contained in the Request for Proposal, by June 29, 2020.

People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Government Affairs Bureau at 202–418–0530 (voice, 202–418–0432 (tty).

Federal Communications Commission.

Amy Brett,

Associate Division Chief, Competition and Infrastructure Policy Division, Wireless Telecommunications Bureau.

[FR Doc. 2020–13213 Filed 6–18–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[GN Docket No. 19–329; FRS 16867]

Federal Advisory Committee Act; Task Force for Reviewing the Connectivity and Technology Needs of Precision Agriculture in the United States

AGENCY: Federal Communications Commission.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's Task Force for Reviewing the Connectivity and Technology Needs of Precision Agriculture in the United States (Task Force) will hold its third meeting via live internet link.

DATES: July 22, 2020. The meeting will come to order at 9:30 a.m.

ADDRESSES: The meeting will be held via conference call and available to the public via live feed from the FCC's web page at *www.fcc.gov/live.*

FOR FURTHER INFORMATION CONTACT: Jesse Jachman, Designated Federal Officer, Federal Communications Commission, Wireline Competition Bureau, (202) 418–2668, or email: *Jesse.Jachman@fcc.gov;* Erin Boone, Deputy Designated Federal Officer, Federal Communications Commission, Wireless Telecommunications Bureau, (202) 418–0736, or email: *Erin.Boone@fcc.gov;* or Celia Lewis, Deputy Designated Federal Officer, Federal Communications Commission, Wireline Competition Bureau, (202) 418–7456, or email *Celia.Lewis@fcc.gov.*

SUPPLEMENTARY INFORMATION: The meeting will be held on July 22, 2020, at 9:30 a.m. EDT and may be viewed live, by the public, at *http://www.fcc.gov/live.* Any questions that arise during the meeting should be sent to *PrecisionAgTF@fcc.gov* and will be answered at a later date. Members of the public may submit comments to the Task Force in the FCC's Electronic Comment Filing System, ECFS, at *www.fcc.gov/ecfs.* Comments to the Task Force should be filed in GN Docket No. 19–329.

Open captioning will be provided for this event. Other reasonable

accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to *fcc504@fcc.gov* or by calling the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice), (202) 418–0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute requests will be accepted but may be impossible to fill.

Proposed Agenda: At this meeting, the Working Group leadership will update to the Task Force on their progress. This agenda may be modified at the discretion of the Task Force Chair and the Designated Federal Officer.

Federal Communications Commission.

Cecilia Sigmund,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2020–13261 Filed 6–18–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[PS Docket Nos. 15–80, 13–75, 11–60; DA 20–453; FRS 16750]

911 Reliability

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: In this document, the Federal Communication Commission's (FCC or Commission) Public Safety and Homeland Security Bureau (Bureau) seeks comment on the implementation of new data fields for covered 911 service providers that it will add to the Network Outage Reporting System (NORS) and 911 Reliability Certification System to improve the Bureau's situational awareness regarding 911 reliability. The effective date for the implementation of these changes will be announced in a future Public Notice.

DATES: Submit comments on or before July 20, 2020.

ADDRESSES: You may submit comments, identified by PS Docket Nos. 15–80, 13–75, 11–60; DA 20–453, by any of the following methods:

- *Federal Communications Commission's website: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. See the **SUPPLEMENTARY INFORMATION** section for more instructions.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432. For detailed instructions for submitting comments see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For general questions, contact Kenneth Mallory, Attorney Advisor, Cybersecurity and Communications Reliability Division, Public Safety and Homeland Security Bureau, at (202) 418–7785 or *kenneth.mallory@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the *Modifications to Network Outage Reporting and 911 Reliability Certifications for Covered 911 Service Providers Public Notice,* PS Docket Nos. 15–80, 13–75, 11–60; DA 20–453, released April 27, 2020.

The complete text of the *Modifications to Network Outage Reporting and 911 Reliability Certifications for Covered 911 Service Providers Public Notice* is also available electronically at: *https://www.fcc.gov/document/pshsb-seeks-comment-nors-911-reliability-certification-changes.*

I. Introduction and Background

The Bureau seeks comment on the implementation of new NORS and 911 Reliability Certification System data fields for covered 911 service providers. These new fields will improve the Bureau's ability to assess 911 reliability by aiding the Commission in identifying 911 special facilities (such as public safety answering points (PSAPs)) affected by service outages, determining whether alternative measures to circuit diversity are effective in maintaining network reliability, recognizing year-to-year improvements in 911 reliability, and ensuring compliance with existing network reliability requirements. The Bureau intends to make these modifications pursuant to its delegated authority. Specifically, the Commission has delegated authority to the Bureau to administer its ''communications disruption reporting requirements,'' and ''revise the filing system and template used for the submission of such communications disruption reports,'' 47 CFR 0.392(i), 0.191(g). The Commission has also delegated authority to the Bureau, ''consistent with the requirements of the Administrative Procedure Act and relevant portions of the Communications Act,'' to develop ''forms and procedures as may be required to collect and process [911] certifications, and . . . periodically update those forms and procedures as necessary'' and ''order appropriate remedial action on a case-by-case basis where 911 reliability certifications indicate such actions are necessary to protect public safety,'' 79 FR 3123, 3129 (Jan. 17, 2014) (*911 Reliability Report and Order*). While these systems have distinct and independent reporting requirements, the Bureau believes that modifications to NORS will supply more insight into the representations covered 911 service providers make with respect to 911 reliability certifications. Specifically, supplementing NORS outage reports with information available to covered 911 service providers from their most recent 911 reliability certifications can help to confirm the extent to which any alternative measures they use to ensure circuit diversity are effective.

II. Modifications to NORS Reporting Forms

911 Special Facilities Impacted by Outages. Information about which 911 special facilities are affected by outages, and whether 911 special facilities were notified of outages, facilitates the Bureau's efforts to better ascertain and analyze the effect of outages required to be reported under the Commission's part 4 rules, and to enforce those aspects of the rules requiring covered 911 service providers to submit notifications to the Bureau regarding outages that potentially affect 911 special facilities. The part 4 rules require that ''all pertinent information on the outage, including any information that was not contained in, or that has changed from that provided in, the Initial report.'' In the Bureau's experience, it has often been required to follow up with covered 911 service providers to determine whether 911 special facilities were affected and whether the relevant PSAPs were appropriately notified. We believe a more efficient approach would be to receive this information in the reports from covered 911 service providers at the outset. In these regards, the Bureau proposes to modify the specificity of the information requested of covered 911 service providers on NORS notification, initial and final reports submission forms. These forms will be revised to include a checkbox that will enable filers to check ''yes'' or ''no'' to indicate whether they are a covered 911 service provider. If the filer indicates that it is a covered 911 service provider, the filer will be prompted to identify which 911 special facilities are affected by an outage, whether they were notified and, if so, how they were

notified. Specifically, fields will be added to NORS submission forms for covered 911 service providers to type in appropriate 911 special facility names. As these filers type in a 911 special facility name, a list of matching names will be displayed for filers to select the appropriate response. To reduce burdens on covered 911 service providers and ensure consistency in the information that is reported, the Bureau will offer filers a list of 911 special facility names generated from the list of PSAPs that the Commission receives from covered 911 service providers' submissions to the 911 Reliability Certification System. If the names of the affected 911 special facilities are not shown on the list, covered 911 service providers can enter additional facility names in the field. For each affected 911 special facility, the form will provide a drop-down option (*i.e.,* yes/no) for filers to indicate whether the PSAP has been notified. A field will also be added to NORS to enable covered 911 service providers to specify how they notified the affected PSAP (*e.g.,* by phone, by email). By providing these fields, the Bureau believes the revised forms will be a more effective and minimally burdensome way of enforcing the obligation in the rules to notify PSAPs of outages potentially affecting 911 special facilities, records of which in light of this obligation we anticipate that covered 911 service providers already keep. Service providers that do not serve as covered 911 service providers for the affected 911 special facilities will not be required to complete these fields.

Alternative Measures for Circuit Diversity. The Bureau has also had to follow up with covered 911 service providers about alternative measures they use for circuit diversity when there has been an outage. It would improve the Bureau's situational awareness if this information were available in NORS reports rather than only pursuant to follow up requests. Collecting this information will improve the Bureau's ability to evaluate the effectiveness of alternative measures in lieu of certification to physical circuit diversity. Accordingly, the Bureau proposes to require NORS filers indicating on NORS final report submission forms that they are covered 911 service providers to identify, in a new data field that will be added to NORS final report submission forms, whether alternative measures to circuit diversity were in place for affected 911 special facilities. For each affected 911 special facility, there will be a dropdown option in NORS (*i.e.,* yes/no/Not Applicable) for filers to indicate whether an alternate measure was taken for the affected PSAP. If the response is ''yes,'' filers will be prompted to specify the alternate measure taken in a new free text field. Service providers that do not serve as covered 911 service providers for the affected 911 special facilities will not be required to complete these fields. The Bureau believes that requiring covered 911 service providers to disclose whether outages occur on network segments that use alternative measures for circuit diversity will impose a minimal burden on covered 911 service providers as they would need only relate information they already prepare for submission to the Commission's 911 Reliability Certification System to specific outages they report in NORS. All service providers, including covered 911 service providers, will still be required to complete the existing NORS fields that collect information on whether an outage could have been prevented or mitigated if physical diversity had been implemented in their network.

The Bureau seeks comment on whether the implementations proposed are the most effective and efficient ways for the Commission to collect the information sought from covered 911 service providers in NORS. Are there any alternative approaches to collecting this information that would reduce burdens on covered 911 service providers that are required to file in NORS while achieving the Bureau's objectives of obtaining accurate and robust data on 911 reliability and ensuring compliance with the Commission's rules?

III. Modifications to 911 Certification Forms

Applicability of 911 Certifications. The Commission's rules require covered 911 service providers to certify whether elements of the 911 reliability certifications are not applicable to their networks, 47 CFR 9.19(c)(1)(ii). Some certifications submitted to the Commission are ambiguous as to the reasons why their filers believe those elements are not applicable. For example, some covered 911 service providers certify that certification elements regarding critical 911 circuits are not applicable to them because they do not operate selective routers. However, even if these providers do not operate selective routers, the rules may nonetheless be applicable to these providers if they operate a functional equivalent of a selective router or offer other capabilities such as automatic location information or automatic number information to a PSAP, statewide default answering point, or appropriate local emergency authority. The Bureau must then seek information on a case-by-case basis to assess whether covered 911 service providers are complying with the existing rules and to follow up as appropriate. To ensure that the Bureau can more efficiently evaluate whether covered 911 service providers are in compliance with the Commission's 911 reliability certification rules, the Bureau proposes to make necessary updates to the 911 Reliability Certification System to reduce ambiguity in certifications. The Bureau will modify the 911 Reliability Certification System to prompt covered 911 service providers to explain with greater specificity how the certification elements apply to their network. Specifically, the Bureau will add drop-down fields to 911 reliability certifications that will require covered 911 service providers to indicate whether they provide the following services: (1) 911, E911 or NG911 call routing through a selective router or its functional equivalent; (2) automatic location information or automatic number information database lookup capability or its functional equivalent; and (3) direct service to a PSAP by one or more central offices it operates, including administrative lines to a PSAP, statewide default answering point, or appropriate local emergency authority. The Bureau believes that this information will assist in corroborating certifications that certain elements are not applicable, which will save time and resources of covered 911 service providers by reducing the number of questions they receive from Bureau staff about their certifications.

911 Network Upgrades. Additionally, the Bureau recognizes that some covered 911 service providers continue to make improvements to their networks that improve the reliability of 911 but are not currently captured in the 911 Reliability Certification System. Collecting information about these improvements will help the Bureau's efforts to assess the extent and scope of providers' initiatives to enhance 911 service nationwide and identify industry practices and standards that will help inform the Bureau's recommendations to the Commission for future Commission action consistent with its rules. To allow covered 911 service providers an opportunity to update the Commission as to their efforts on 911 reliability, the Bureau proposes to revise 911 reliability certifications to include a data field that enables covered 911 service providers to highlight network upgrades completed within the past year that have resulted

in improvements to 911 reliability and/or performance. To implement this change, a new text field will be added to the 911 Reliability Certification System for filers to provide a summary of major network upgrades and improvements they completed within the past year. This data field would be optional and therefore would not impose burdens on covered 911 service providers who choose not to use the field.

The Bureau seeks comment on whether the implementations proposed are the most effective and efficient way to validate the certifications that indicate that one or more elements are inapplicable to their networks and capture additional information on yearly 911 improvements. Are there any alternative approaches to collecting this information that would reduce burdens on covered 911 service providers while achieving the Bureau's objectives of obtaining accurate and robust data on 911 reliability and ensuring compliance with the Commission's rules?

IV. Implementation

Following the receipt of comments on these modifications, the Bureau will release a Public Notice to specify the changes that will be implemented in the Network Outage Reporting System (NORS) and 911 Reliability Certification System and address issues and alternative approaches raised by commenters. To the extent necessary, these changes may be made without prior notice-and-comment under the Administrative Procedure Act as ''rules of agency organization, procedure, or practice,'' 5 U.S.C. 553(b)(A). The Bureau will then seek Office of Management and Budget (OMB) approval of the modifications to the extent required under the Paperwork Reduction Act. Upon receipt of OMB approval, and the Bureau's completion of all necessary changes to the systems, the Bureau will announce that the modifications are effective. Moreover, the Bureau understands that NORS filers may need the Bureau's technical assistance to ensure that their existing systems are compatible with any resulting modifications to the NORS Application Programming Interface (API). Therefore, the Bureau will work with system filers prior to the effective date of these new modifications to ensure that no API issues impede their compliance.

Paperwork Reduction Act. This document contains proposed modified information collection requirements. The Commission, as part of its continuing effort to reduce paperwork burdens, invites the general public and the OMB to comment on the information collection requirements contained in this document, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), we seek specific comment on how we might further reduce the information collection burden for small business concerns with fewer than 25 employees.

V. Procedural Matters

Interested parties may file comments in response to this *Public Notice* on or before the date indicated on the first page of this document. See *Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998). Comments may be filed using the Commission's Electronic Comment Filing System (ECFS).

- *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing.
- Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.
- Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9050 Junction Drive, Annapolis Junction, MD 20701.
- U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW, Washington, DC 20554.
- Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. See *FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy,* Public Notice, DA 20–304 (March 19, 2020).
- During the time the Commission's building is closed to the general public and until further notice, if more than one docket or rulemaking number appears in the caption of a proceeding, paper filers need not submit two additional copies for each additional docket or rulemaking number; an original and one copy are sufficient.
- *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

This proceeding has been designated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. See 47 CFR 1.1200(a), 1.1206. Persons making *ex parte* presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral *ex parte* presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the *ex parte* presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during *ex parte* meetings are deemed to be written *ex parte* presentations and must be filed consistent with rule 1.1206(b). In proceedings governed by rule 1.49(f) or for which the Commission has made available a method of electronic filing, written *ex parte* presentations and memoranda summarizing oral *ex parte* presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (*e.g.,* .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Federal Communications Commission.

Lisa Fowlkes,

Chief, Public Safety and Homeland Security Bureau.

[FR Doc. 2020–13189 Filed 6–18–20; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2020–0046; NIOSH–233–C]

Hazardous Drugs: Draft NIOSH List of Hazardous Drugs in Healthcare Settings, 2020; Procedures; and Risk Management Information; Extension of Comment Period

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Extension of comment period.

SUMMARY: On May 1, 2020, the National Institute for Occupational Safety and Health (NIOSH), within the Center for Disease Control and Prevention (CDC), opened a docket to obtain public input on the following draft documents: (1) *NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings (Procedures);* (2) *NIOSH List of Hazardous Drugs in Healthcare Settings, 2020 (List)*, and (3) *Managing Hazardous Drug Exposures: Information for Healthcare Settings.* Comments were to be received by June 30, 2020. NIOSH is extending the comment period to close on July 30, 2020, to allow stakeholders and other interested parties additional time to respond.

DATES: The comment period for the document published on May 1, 2020 (85 FR 25439), is extended. Comments must be received by July 30, 2020.

ADDRESSES: You may submit written comments, identified by docket numbers CDC–2020–0046 and NIOSH–233–C, by either of the following two methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, Ohio 45226–1998.

Instructions: All information received in response to this notice must include the agency name and docket number [CDC–2020–0046; NIOSH–233–C]. All relevant comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Barbara MacKenzie, NIOSH, Robert A. Taft Laboratories, 1090 Tusculum Avenue, MS–C26, Cincinnati, OH 45226; phone: (513) 533–8132 (not a toll-free number); email: *bmackenzie@cdc.gov.*

SUPPLEMENTARY INFORMATION: NIOSH published a notice and request for comment in the **Federal Register** on May 1, 2020 (85 FR 25439) regarding the development of the *NIOSH List of Hazardous Drugs in Healthcare Settings* and related risk management information for healthcare settings. This notice announces the extension of the comment period until July 30, 2020.

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2020–13278 Filed 6–18–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meetings Announcement for the Physician-Focused Payment Model Technical Advisory Committee Required by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA); Correction

ACTION: Notice of public meetings; correction.

SUMMARY: The Department of Health and Human Services published a document in the **Federal Register** of November 29, 2019 detailing the 2020 PTAC meeting dates and the link that connects to the meeting registration website. The March meeting date was postponed until June due to the public health emergency. The June meeting date has been shortened to a one day meeting that will be taking place from 10:00 a.m. to 3:00 p.m. ET virtually.

FOR FURTHER INFORMATION CONTACT: Audrey McDowell, Designated Federal Official, at the Office of Health Policy, Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, 200 Independence Ave. SW, Washington, DC 20201, (202) 690–6870.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of November 29, 2019, in FR Doc. 2019–25898, on page 65828, in the first column, correct the ''**DATES**'' caption to read:

DATES: The 2020 PTAC meetings will occur on the following dates:

- Monday, June 22, 2020, from 10:00 a.m. to 3:00 p.m. ET
- Tuesday–Wednesday, September 15–16, 2020, from 9:00 a.m. to 5:00 p.m. ET
- Monday–Tuesday, December 7–8, 2020, from 9:00 a.m. to 5:00 p.m. ET

Please note that times are subject to change. If the times change, registrants will be notified directly via email.

Correction

In the **Federal Register** of November 29, 2019, in FR Doc. 2019–25898, on page 65828, in the first column, correct the ''**ADDRESS**'' caption to read:

ADDRESSES: All 2020 PTAC meetings will be held in the Great Hall of the Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201 or virtually.

Correction

In the **Federal Register** of November 29, 2019, in FR Doc. 2019–25898, on page 65828, in the first column, correct the **FOR FURTHER INFORMATION CONTACT** caption to read:

FOR FURTHER INFORMATION CONTACT: Audrey McDowell, Designated Federal Officer, (202) 690–6870.

Correction

In the **Federal Register** of November 29, 2019, in FR Doc. 2019–25898, on page 65828, beginning in the first column and continuing to the second column, correct the ''Meeting Attendance'' caption to read:

Meeting Attendance. These meetings are open to the public. For meetings that are held in the Great Hall of the Hubert Humphrey Building, the public may attend in person, via conference call, or view the meeting via livestream at *www.hhs.gov/live.* The conference call dial-in information will be sent to registrants prior to the meeting. Space may be limited, and registration is preferred. For meetings that are held virtually, the public may by attend via virtual meeting WebEx link (including a dial-in only option), or view the meeting via livestream at *www.hhs.gov/live.* Registration may be completed online at *http://www.cvent.com/d/gbq2tg.* Name, organization name, and email address are submitted when registering. Registrants will receive a confirmation email shortly after completing the registration process.

Dated: June 10, 2020.

Brenda Destro,

Deputy Assistant Secretary for Planning and Evaluation (HSP).

[FR Doc. 2020–13186 Filed 6–16–20; 4:15 pm]

BILLING CODE 4150–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel, NIAAA Review Subcommittee Member Conflict Panel.

Date: July 8, 2020.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Luis Espinoza, Ph.D., Scientific Review Officer, Extramural Project Review Branch, Office of Extramural Activities, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Room 2109, Bethesda, MD 20892, (301) 443–8599, *espinozala@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research and Research Support Awards., National Institutes of Health, HHS)

Dated: June 15, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–13197 Filed 6–18–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; Tissue Chips Database Center.

Date: June 26, 2020.

Time: 3:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1073, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Christine A. Livingston, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1073, Bethesda, MD 20892, (301) 435–1348, *livingsc@mail.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: June 15, 2020.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–13196 Filed 6–18–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0004; OMB No. 1660–0107]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; FEMA Public Assistance Customer Satisfaction Surveys

AGENCY: Federal Emergency Management Agency, Department of Homeland Security (DHS).

ACTION: 30 Day notice and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission will describe the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort and resources used by respondents to respond) and cost, and the actual data collection instruments FEMA will use.

DATES: Comments must be submitted on or before July 20, 2020.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Kristin Brooks, Statistician, Customer Survey Analysis Section, Reporting and Analytics Division, Recovery Directorate, at (940) 891–8579 or *kristin.brooks@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on January 30, 2020 at 85 FR 5461 with a 60-day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the

information collection abstracted below to the Office of Management and Budget for review and clearance. The only changes made were to the average hourly wage rates based on updated U.S. Department of Labor information.

Collection of Information

Title: FEMA Public Assistance Customer Satisfaction Surveys.

Type of information collection: Revision of a currently approved information collection.

OMB Number: 1660–0107.

Form Titles and Numbers: FEMA Form 519–0–32, Public Assistance Initial Customer Satisfaction Survey (Telephone); FEMA Form 519–0–33, Public Assistance Initial Customer Satisfaction Survey (internet); FEMA Form 519–0–34, Public Assistance Assessment Customer Satisfaction Survey (Telephone); FEMA Form 519–0–35, Public Assistance Assessment Customer Satisfaction Survey (internet).

Abstract: Federal agencies are required to survey their customers to determine the kind and quality of services customers want and their level of satisfaction with those services. FEMA managers use the survey results to measure performance against standards for performance and customer service, measure achievement of strategic planning objectives, and generally gauge and make improvements to disaster service that increase customer satisfaction.

Affected Public: Not-for-profit institutions, State, local, or Tribal government.

Estimated Number of Respondents: 4,034.

Estimated Number of Responses: 4,034.

Estimated Total Annual Burden Hours: 1,902.

Estimated Total Annual Respondent Cost: $110,629.

Estimated Respondents' Operation and Maintenance Costs: $12,420.

Estimated Respondents' Capital and Start-Up Costs: N/A.

Estimated Total Annual Cost to the Federal Government: $803,624.

Comments: Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Maile Arthur,

Acting Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2020–13274 Filed 6–18–20; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2020–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security (DHS).

ACTION: Notice; withdrawal.

SUMMARY: The Federal Emergency Management Agency (FEMA) is withdrawing its final notice concerning the flood hazard determinations for Barnstable County, Massachusetts (All Jurisdictions); Norfolk County, Massachusetts (All Jurisdictions); Newport County, Rhode Island (All Jurisdictions).

DATES: The final notice of the flood hazard determinations for Barnstable County, Massachusetts (All Jurisdictions), Norfolk County, Massachusetts (All Jurisdictions), and Newport County, Rhode Island (All Jurisdictions), which published on March 17, 2020 (85 FR 15215), is withdrawn as of June 19, 2020.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: On March 17, 2020, FEMA published a notice at 85 FR 15216, containing final flood hazard determinations for Barnstable County, Massachusetts (All Jurisdictions); Norfolk County, Massachusetts (All Jurisdictions); and 85 FR 15218 for Newport County, Rhode Island (All Jurisdictions). Communities within the Cape Cod Watershed study experienced difficulties during the adoption and compliance period resulting in the inability to adopt the FIS and FIRM and thereby comply with the National Flood Insurance Program (NFIP) regulations. The final flood hazard determinations is hereby rescinded, and ordinances must revert to the previously adopted FIS Report and FIRM. FEMA is withdrawing the notice for the affected communities.

Authority: 42 U.S.C. 4104; 44 CFR 67.4.

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2020–13281 Filed 6–18–20; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7024–N–23]

30-Day Notice of Proposed Information Collection: Application for Healthy Homes and Lead Hazard Control Grant Programs and Quality Assurance Plans—OMB Control No. #2539–0015

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 30 days of public comment.

DATES: *Comments Due Date:* June 19, 2020.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax:202–395–5806, Email: *OIRA Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email her at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. This is not a toll-free number. Person with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on April 9, 2020.

A. Overview of Information Collection

Title of Information Collection: HOME Investment Partnerships Program.

OMB Approval Number: 2539–0015.

Type of Request: Revision of approved collection.

Form Number: SF 424; HUD–424CBW; HUD–27061; HUD–2991; HUD–96008; SF–LLL.

Description of the need for the information and proposed use: Receive applications for funding in response to NOFAs issued by HUD OLHCHH, including: Lead Hazard Control; Lead Hazard Reduction Demonstration; Lead Technical Studies; Healthy Homes Technical Studies; and others. Receive Quality Assurance Plans from successful applicants.

Information collection	Number of respondents	Frequency of response p.a.	Responses p.a.	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Pre-Application Preparation	380.00	1.00	380.00	24.00	9,120.00	$49.54	$451,805.00
Full Application Preparation	300.00	1.00	300.00	60.00	18,000.00	49.54	891,720.00
Finalizing the Grant Award	147.00	1.00	147.00	16.00	2,352.00	49.54	116,518.00
Quality Assurance Plans	47.00	1.00	47.00	24.00	1,128.00	49.54	55,881.00
Totals or Averages	380.00	1.00	874.00	35.01	30,600.00	49.54	1,515,924.00

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Anna P. Guido,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2020–13249 Filed 6–18–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7027–N–21]

60-Day Notice of Proposed Information Collection: Multifamily Project Construction Contract, Building Loan Agreement, and Construction Change Request (Form HUD–92437) OMB Control Number: 2502–0011

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date: August 18, 2020.*

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Request for Construction on Project Mortgages.

OMB Approval Number: 2502–0011.

OMB Expiration Date: 1/31/20.

Type of Request: Revision of a currently approved collection.

Form Number: HUD–92437.

Description of the need for the information and proposed use: This is a revision of a currently approved collection. The previous OMB collection reflects an accurate assessment of the numbers submitted under this collection, which included two forms used by OMAPO, formally Contract Administration, CA (HUD–92442–CA, HUD-92442–A–CA). In addition, the specific forms, HUD–92441, HUD–92442, and HUD–92442–A have been deleted under this collection and placed under the Closing documents, OMB control number 2502–0598. The current numbers were based on the average of

three fiscal years of initial endorsements. Furthermore, the numbers under this collection reflect a healthy housing industry since 2010 in which credit markets stabilized and interest rates were low and Multifamily housing occupancy was very strong. HUD plays a vital part in the housing industry and the increased numbers reflect that strong demand.

This form HUD–92437 serves as the project's change order involving changes to contact work, contract price, or contract time. All on-site construction changes are submitted on this form. The contractor, architect, mortgagor, and mortgagee must approve the proposed changes before the request is submitted to HUD for approval. The form ensures that viable projects are developed.

Respondents: Individuals participating in HUD Multifamily mortgage insurance programs as principals of sponsors, mortgagors, and general contractors.

Estimated Number of Respondents: 1,174.

Estimated Number of Responses: 3,522.

Frequency of Response: 3.

Average Hours per Response: 2.

Total Estimated Burden: 7,044.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. 3507.

The Acting Assistant Secretary for Housing, Len Wolfson, having reviewed and approved this document, is delegating the authority to electronically sign this document to submitter, Nacheshia Foxx, who is the Federal Register Liaison for HUD, for purposes of publication in the **Federal Register**.

Dated: June 16, 2020.

Nacheshia Foxx,

Federal Register Liaison for the Department of Housing and Urban Development.

[FR Doc. 2020–13235 Filed 6–18–20; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2019–N150; FXES11140800000–201–FF08EVEN00]

Draft Environmental Assessment and Draft Coastal Region Conservation Program Multiple Species Habitat Conservation Plan; Central and Southern California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received an application for a permit for take of endangered and threatened species that is incidental to, and not the purpose of, carrying out otherwise lawful activities. With some exceptions, the Endangered Species Act and its implementing regulations as applicable to the species at issue prohibit take of endangered and threatened species unless a Federal permit allows such activity. We invite comments on this application which we will take into consideration before issuing a permit.

DATES: We will receive public comments on the draft Habitat Conservation Plan and draft Environmental Assessment until August 3, 2020.

ADDRESSES:

Obtaining Documents: You may download a copy of the draft Habitat Conservation Plan and draft Environmental Assessment at *http://www.fws.gov/ventura/* or you may request copies of the documents by U.S. mail (below) or by phone (see **FOR FURTHER INFORMATION CONTACT**).

Submitting Written Comments: Please send your written comments using one of the following methods:

- *U.S. mail:* Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.
- *Email: chris_dellith@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Chris Dellith, Senior Biologist, by phone at 805–677–3308, email (see **ADDRESSES**), or via the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: Southern California Gas Company (applicant) has applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit (ITP) under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicant is requesting an ITP with a 30-year term, for incidental take of 19 wildlife species likely to result from implementation of activities covered by the applicant's Habitat Conservation Plan, and seeking assurances for 22 plant species. The covered species are indicated in the table below. Pursuant to the National Environmental Policy Act of 1969, as amended (NEPA; 42 U.S.C. 4321 *et seq.*), we advise the public of the availability of the proposed Habitat Conservation Plan and our draft Environmental Assessment.

Common name	Scientific name	Federal status *	State status **
Invertebrates (3):			
Delhi sands flower-loving fly	*Rhaphiomidas terminatus abdominalis*	E	
El Segundo blue butterfly	*Euphilotes battoides allyni*	E	
Morro shoulderband (banded dune) snail	*Helminthoglypta walkeriana*	E	
Fish (1):			
Santa Ana sucker	*Catostomus santaanae*	T	
Amphibians (4):			
Arroyo toad	*Anaxyrus californicus*	E	SSC
California red-legged frog	*Rana draytonii*	T	SSC
California tiger salamander	*Ambystoma californiense*	E	T
Mountain yellow-legged frog	*Rana muscosa*	E	E

Common name	Scientific name	Federal status *	State status **
Reptiles (2):			
Southern rubber boa	*Charina bottae umbratical*		T
Southwestern pond turtle	*Emys marmorata pallida*		SSC
Birds (6):			
Belding's savannah sparrow	*Passerculus sandwichensis beldingi*		E
Burrowing owl	*Athene cunicularia*	BCC	SSC
Coastal California gnatcatcher	*Polioptila californica californica*	T	SSC
Least Bell's vireo	*Vireo bellii pusillus*	E	E
Southwestern willow flycatcher	*Empidonax traillii extimus*	E	E
Western yellow-billed cuckoo	*Coccyzus americanus occidentalis*	T/BCC	E
Mammals (3):			
San Bernardino kangaroo rat	*Dipodomys merriami parvus*	E	SSC
San Joaquin kit fox	*Vulpes macrotis mutica*	E	T
Stephens' kangaroo rat	*Dipodomys stephensi*	E	T
Plants (22):			
Braunton's milk-vetch	*Astragalus brauntonii*	E	
California seablite	*Suaeda californica*	E	
Chorro Creek bog thistle	*Cirsium fontinale* var. *obispoense*	E	E
Conejo dudleya	*Dudleya abramsii* spp. *parva*	T	
Gambel's water cress	*Nasturtium gambelii*	E	T
Gaviota tarplant	*Deinandra increscens* ssp. *villosa*	E	E
Indian Knob mountainbalm	*Eriodictyon altissimum*	E	E
Lompoc yerba santa	*Eriodictyon capitatum*	E	R
Lyon's pentachaeta	*Pentachaeta lyonia*	E	E
Marcescent dudleya	*Dudleya cymosa* ssp. *marcescens*	T	R
Morro manzanita	*Arctostaphylos morroensis*	T	
Nevin's barberry	*Berberis nevinii*	E	E
Nipomo Mesa lupine	*Lupinus nipomensis*	E	E
Pismo clarkia	*Clarkia speciosa* ssp. *immaculata*	E	R
San Fernando Valley spineflower	*Chorizanthe parryi* var. *Fernandina*		E
Santa Ana River woollystar	*Eriastrum densifolium* ssp. *sanctorum*	E	E
Santa Monica Mountains dudleya	*Dudleya cymosa* ssp. *ovatifolia*	T	
Seaside bird's beak	*Cordylanthus rigidus* ssp. *littoralis*		E
Slender-horned spineflower	*Dodecahema leptoceras*	E	E
Vandenberg monkey flower	*Diplacus vandenbergensis*	E	
Ventura Marsh milk-vetch	*Astragalus pycnostachyus* var. *lanosissimus*	E	E
Verity's dudleya	*Dudleya verity*	T	

* Federal Status: Endangered (E); Threatened (T); Bird of Conservation Concern (BCC).
*** State Status:* Species of Special Concern (SSC); Threatened (T); Endangered (E); Rare (R).
**** Critical Habitat:* Not applicable (N/A); No Critical Habitat Designated or Proposed (NCH).

Background

Section 9 of the ESA prohibits take of fish and wildlife species listed as endangered (16 U.S.C. 1538). By regulation, this take prohibition also applies to certain species listed as threatened. (50 CFR 17.31(a)). Under section 10(a)(1)(B) of the ESA (16 U.S.C. 1539(a)(1)(B)), we may issue permits to authorize take of listed fish and wildlife species that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing permits for listed fish and wildlife species are set forth in 50 CFR parts 17.22 and 17.32.

The National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) requires Federal agencies to analyze their proposed actions to determine whether the actions may significantly affect the human environment. In these NEPA analyses, the Federal agency will identify direct, indirect, and cumulative effects, as well as possible mitigation for effects on environmental resources that could occur with implementation of the proposed action and alternatives.

Public Review

If you wish to comment on the draft HCP and draft EA, you may submit comments by one of the methods in **ADDRESSES**.

Any comments we receive will become part of the decision record associated with this action. Before including your address, phone number, email address, or other personal identifying information in your comment, please be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority

We issue this notice pursuant to section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22 and 17.32), and the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6 and 43 CFR 46.305).

Stephen Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2020–13191 Filed 6–18–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2020–NXXX; FXES11140800000–201–FF08EVEN00]

Draft Habitat Conservation Plan and Draft Categorical Exclusion for 12 Rancho San Carlos (Ocho West) Project, Monterey County, California

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft Habitat Conservation Plan (HCP) and draft categorical exclusion for activities associated with an application for an incidental take permit (ITP) under the Endangered Species Act of 1973, as amended. The ITP would authorize take of listed species incidental to construction of a single-family residence at 12 Rancho San Carlos (Ocho West). The Applicant developed the draft HCP as part of their application for an ITP. The Service prepared a draft categorical exclusion in accordance with the National Environmental Policy Act to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to the Applicant. We invite public comment on these documents.

DATES: Written comments should be received on or before July 20, 2020.

ADDRESSES:

To obtain documents: You may download a copy of the draft HCP and categorical exclusion screening form at *http://www.fws.gov/ventura/,* or you may request copies of the documents by sending U.S. mail to our Ventura office, or by phone (see **FOR FURTHER INFORMATION CONTACT**).

To submit written comments: Please send us your written comments using one of the following methods:

- *U.S. mail:* Send your comments to: Stephen P. Henry, Field Supervisor, Ventura Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2493 Portola Road, Suite B, Ventura, CA 93003.
- *Email: danielle_fagre@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Danielle Fagre, Biologist, by phone at 805–677–3339, or via the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), announce the availability of a draft Habitat Conservation Plan (HCP) and the associated draft categorical exclusion with an application for an incidental take permit by Andris Upitis (Applicant). The permit would authorize take of the federally threatened Central Distinct Population Segment (DPS) of the California tiger salamander (*Ambystoma californiense*) and the federally threatened California red-legged frog (*Rana draytonii*) incidental to activities associated with the construction of a single-family residence at 12 Rancho San Carlos (Ocho West). The Applicant developed the draft HCP as part of his application for an ITP under section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The Service prepared a draft categorical exclusion in accordance with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to the Applicant. We invite public comment on these documents.

Background

The Service listed the Central DPS of the California tiger salamander as threatened on August 4, 2004 (69 FR 47212). The Service listed the California red-legged frog as threatened on May 23, 1996 (61 FR 25813), and critical habitat was designated on March 10, 2010 (75 FR 12816). Federal regulation pursuant to section 4(d) of the ESA prohibits the ''take'' of certain fish or wildlife species listed as threatened, including the Central DPS of the California tiger salamander and the California red-legged frog, with exceptions for certain ranching activities on private and tribal lands as described in 50 CFR 17.43(c)(3)(i)–(xi) and 50 CFR 17.43(d)(3)(i)–(xi). ''Take'' is defined under the ESA to include the following activities: ''[T]o harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532); however, under section 10(a)(1)(B) of the ESA, we may issue permits to authorize incidental take of listed species. Incidental take is take that is incidental to, and not the purpose of, carrying out of an otherwise lawful activity. Regulations governing incidental take permits for threatened species are in the Code of Federal Regulations (CFR) at 50 CFR 17.32. Issuance of an incidental take permit also must not jeopardize the existence of federally listed fish, wildlife, or plant species. The permittee would receive assurances under our ''No Surprises'' regulations (50 CFR 17.22(b)(5) and 17.32(b)(5)).

Applicant's Proposed Activities

The Applicant has applied for a permit for incidental take of the Central DPS of the California tiger salamander and California red-legged frog. The potential take would occur in association with activities necessary for the construction of a single-family home and accessory dwelling unit, improvement of the existing driveway, revegetation of temporarily disturbed areas, and invasive species management on 5.9 acres of habitat occupied by the covered species. The development would result in impacts to 7.5 acres of California tiger salamander upland habitat. It would result in impacts to 7.6 acres of California red-legged frog habitat, all of which are in California red-legged frog Critical Habitat Unit MNT–2. The 7.5 acres of California tiger salamander habitat overlaps entirely with the 7.6 acres of California red-legged frog habitat.

The HCP includes avoidance and minimization measures for the covered species and mitigation for unavoidable loss of occupied upland and dispersal habitat. The Applicant will provide mitigation either by securing 5.9 acres of otherwise developable habitat in a conservation easement, protected in perpetuity, or through a Service-approved conservation bank or in-lieu fee program.

Public Comments

If you wish to comment on the permit application, draft HCP, and associated documents, you may submit comments by one of the methods in **ADDRESSES**.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10 of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA regulations (40 CFR 1506.6).

Stephen Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2020–13190 Filed 6–18–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLMT926000–20X–L14400000.BJ0000; MO#4500143878]

Notice of Proposed Filing of Plats of Survey; Montana

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Notice of proposed official filing.

SUMMARY: The plats of survey for the lands described in this notice are scheduled to be officially filed 30

calendar days after the date of this publication in the BLM Montana State Office, Billings, Montana. The surveys, which were executed at the request of the National Park Service (NPS), Glacier National Park (GNP), West Glacier, Montana, are necessary for the management of these lands.

DATES: A person or party who wishes to protest this decision must file a notice of protest in time for it to be received in the BLM Montana State Office no later than 30 days after the date of this publication.

ADDRESSES: A copy of the plats may be obtained from the Public Room at the BLM Montana State Office, 5001 Southgate Drive, Billings, Montana 59101, upon required payment. The plat may be viewed at this location at no cost.

FOR FURTHER INFORMATION CONTACT: Joshua F. Alexander, BLM Chief Cadastral Surveyor for Montana; telephone: (406) 896–5123; email: *jalexand@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at (800) 877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The lands surveyed are:

Principal Meridian, Montana

T. 33 N., R. 18 W.
Secs. 11 and 15.

A person or party who wishes to protest an official filing of a plat of survey identified above must file a written notice of protest with the BLM Chief Cadastral Surveyor for Montana at the address listed in the **ADDRESSES** section of this notice. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. The notice of protest must be received in the BLM Montana State Office no later than the scheduled date of the proposed official filing for the plat(s) of survey being protested; if received after regular business hours, a notice of protest will be considered filed the next business day. A written statement of reasons in support of the protest, if not filed with the notice of protest, must be filed with the BLM Chief Cadastral Surveyor for Montana within 30 calendar days after the notice of protest is received.

If a notice of protest of the plat(s) of survey is received prior to the scheduled date of official filing or during the 10 calendar day grace period provided in 43 CFR 4.401(a) and the delay in filing is waived, the official filing of the plat(s) of survey identified in the notice of protest will be stayed pending consideration of the protest. A plat of survey will not be officially filed until the next business day after all timely protests have been dismissed or otherwise resolved.

If a notice of protest is received after the scheduled date of official filing and the 10 calendar day grace period provided in 43 CFR 4.401(a), the notice of protest will be untimely, may not be considered, and may be dismissed.

Before including your address, phone number, email address, or other personal identifying information in a notice of protest or statement of reasons, you should be aware that the documents you submit—including your personal identifying information—may be made publicly available in their entirety at any time. While you can ask us to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chapter 3.

Joshua F. Alexander,

Chief Cadastral Surveyor for Montana.

[FR Doc. 2020–13277 Filed 6–18–20; 8:45 am]

BILLING CODE 4310–DN–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–512 and 731–TA–1248 (Review)]

Carbon and Certain Alloy Steel Wire Rod From China

Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping and countervailing duty orders on carbon and certain alloy steel wire rod (''wire rod'') from China would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on December 2, 2019 (84 FR 66007) and determined on March 6, 2020 that it would conduct expedited reviews (85 FR 29483, May 15, 2020).

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on June 15, 2020. The views of the Commission are contained in USITC Publication 5064 (June 2020), entitled *Carbon and Certain Alloy Steel Wire Rod from China: Investigation Nos. 701–TA–512 and 731–TA–1248 (Review).*

By order of the Commission.

Issued: June 15, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–13223 Filed 6–18–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–624–625 and 731–TA–1450–1451 (Final)]

Quartz Surface Products From India and Turkey; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of quartz surface products from India and Turkey, provided for in subheading 6810.99.00 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''), and to be subsidized by the governments of India and Turkey.[2]

Background

The Commission instituted these investigations effective May 14, 2019, following receipt of petitions filed with the Commission and Commerce by Cambria Company LLC, Eden Prairie, Minnesota. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of quartz surface products from India and Turkey were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C.

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] The Commission also finds that imports subject to Commerce's affirmative critical circumstances determination are not likely to undermine seriously the remedial effect of the countervailing and antidumping duty orders on quartz surface products from India and Turkey.

1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the revised notice in the **Federal Register** on February 11, 2020 (85 FR 7782). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, and in accordance with 19 U.S.C. 1677c(a)(1), the Commission did not cancel its hearing scheduled for April 29, 2020, but conducted its hearing through a series of written questions, submissions of written testimony, written responses to questions, posthearing briefs and closing remarks through teleconferencing; all persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to sections 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on June 15, 2020. The views of the Commission are contained in USITC Publication 5061 (June 2020), entitled *Quartz Surface Products from India and Turkey: Investigation Nos. 701–TA–624–625 and 731–TA–1450–1451 (Final).*

By order of the Commission.

Issued: June 15, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–13224 Filed 6–18–20; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–631 and 731–TA–1463–1464 (Final)]

Forged Steel Fittings From India and Korea; Scheduling of the Final Phase of Countervailing Duty and Anti-Dumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of the final phase of antidumping and countervailing duty investigation Nos. 701–TA–631 and 731–TA–1463–1464 (Final) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of forged steel fittings from India and Korea, provided for in subheadings 7307.92.30, 7307.92.90, 7307.93.30, 7307.93.60, 7307.93.90, 7307.99.10, 7307.99.30, and 7307.99.50 of the Harmonized Tariff Schedule of the United States, preliminarily determined by the Department of Commerce (''Commerce'') to be subsidized and sold at less-than-fair-value.

DATES: May 28, 2020.

FOR FURTHER INFORMATION CONTACT: Keysha Martinez (202–205–2136), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Scope.—For purposes of these investigations, Commerce has defined the subject merchandise as ''carbon and alloy forged steel fittings, whether unfinished (commonly known as blanks or rough forgings) or finished. Such fittings are made in a variety of shapes including, but not limited to, elbows, tees, crosses, laterals, couplings, reducers, caps, plugs, bushings, unions (including hammer unions), and outlets. Forged steel fittings are covered regardless of end finish, whether threaded, socket-weld or other end connections. The scope includes integrally reinforced forged branch outlet fittings, regardless of whether they have one or more ends that is a socket welding, threaded, butt welding end, or other end connections.

While these fittings are generally manufactured to specifications ASME B16.11, MSS SP–79, MSS SP–83, MSS–SP–97, ASTM A105, ASTM A350, and ASTM A182, the scope is not limited to fittings made to these specifications.

The term forged is an industry term used to describe a class of products included in applicable standards, and it does not reference an exclusive manufacturing process. Forged steel fittings are not manufactured from casings. Pursuant to the applicable standards, fittings may also be machined from bar stock or machined from seamless pipe and tube.

All types of forged steel fittings are included in the scope regardless of nominal pipe size (which may or may not be expressed in inches of nominal pipe size), pressure class rating (expressed in pounds of pressure, *e.g.,* 2,000 or 2 M; 3,000 or 3 M; 6,000 or 6 M; 9,000 or 9 M), wall thickness, and whether or not heat treated.

Excluded from this scope are all fittings entirely made of stainless steel. Also excluded are flanges, nipples, and all fittings that have a maximum pressure rating of 300 pounds per square inch/PSI or less.

Also excluded from the scope are fittings certified or made to the following standards, so long as the fittings are not also manufactured to the specifications of ASME B16.11, MSS SP–79, MSS SP–83, MSS SP–97, ASTM A105, ASTM A350, and ASTM A182:

- American Petroleum Institute (API) 5CT, API 5L, or API11B;
- American Society of Mechanical Engineers (ASME) B16.9;
- Manufacturers Standardization Society (MSS) SP–75;
- Society of Automotive Engineering (SAE) J476, SAE J514, SAE J516, SAE J517, SAE J518, SAE J1026, SAEJ1231, SAE J1453, SAE J1926, J2044, or SAE AS 35411;
- Hydraulic hose fittings (*e.g.,* fittings used in high pressure water cleaning applications, in the manufacture of hydraulic engines, to connect rubber dispensing hoses to a dispensing nozzle or grease fitting) made to ISO 12151–1, 12151–2, 12151–3, 12151–4, 12151–5, or 12151–6;
- Underwriter's Laboratories (UL) certified electrical conduit fittings;
- ASTM A153, A536, A576, or A865;
- Casing Conductor Connectors made to proprietary specifications;
- Machined steel parts (*e.g.,* couplers) that are not certified to any specifications in this scope description and that are not for connecting steel pipes for distributing gas and liquids;
- Oil country tubular goods (OCTG) connectors (*e.g.,* forged steel tubular connectors for API 5L pipes or OCTG for offshore oil and gas drilling and extraction);
- Military Specification (MIL) MIL–C–4109F and MIL–F–3541; and
- International Organization for Standardization (ISO) ISO6150–B.

Also excluded from the scope are assembled or unassembled hammer unions that consist of a nut and two subs. To qualify for this exclusion, the hammer union must meet each of the following criteria: (1) The face of the nut

of the hammer union is permanently marked with one of the following markings: ''FIG 100,'' ''FIG 110,'' ''FIG 100C,'' ''FIG 200,'' ''FIG 200C,'' ''FIG 201,'' ''FIG 202,'' ''FIG 206,'' ''FIG 207,'' ''FIG 211,'' ''FIG 300,'' ''FIG 301,'' ''FIG 400,'' ''FIG 600,'' ''FIG 602,'' ''FIG 607,'' ''FIG 1002,'' ''FIG 1003,'' ''FIG 1502,'' ''FIG 1505,'' ''FIG 2002,'' or ''FIG 2202''; (2) the hammer union does not bear any of the following markings: ''Class 3000,'' ''Class 3M,'' ''Class 6000,'' ''Class 6M,'' ''Class 9000,'' or ''Class 9M''; and (3) the nut and both subs of the hammer union are painted.

Also excluded from the scope are component parts for hammer union assemblies, either subs or wingnuts, marked on the wingnut and subs with ''FIG 1002,'' ''FIG 1502,'' and ''FIG 2002,'' and with pressure rating of 10,000 PSI or greater. These parts are made from AISI/SAE 4130, 4140 or 4340 steel and are 100 percent magnetic particle inspected before shipment.

Also excluded from the scope are tee, elbow, cross, adapter (or ''crossover''), blast joint (or ''spacer''), blind sub, swivel joint and pup joint which have wing nut or not. To qualify for this exclusion, these products must meet each of the following criteria: (1) Manufacturing and Inspection standard is API 6A or API 16C; and, (2) body or wing nut is permanently marked with one of the following markings: ''FIG 2002,'' ''FIG 1502,'' ''FIG 1002,'' ''FIG 602,'' ''FIG 206,'' or ''FIG any other number'' or MTR (Material Test Report) shows these FIG numbers.

To be excluded from the scope, products must have the appropriate standard or pressure markings and/or be accompanied by documentation showing product compliance to the applicable standard or pressure, *e.g.,* ''API 5CT'' mark and/or a mill certification report.

Subject carbon and alloy forged steel fittings are normally entered under Harmonized Tariff Schedule of the United States (HTSUS) 7307.92.3010, 7307.92.3030, 7307.92.9000, 7307.99.1000, 7307.99.3000, 7307.99.5045, and 7307.99.5060. They may also be entered under HTSUS 7307.93.3010, 7307.93.3040, 7307.93.6000, 7307.93.9010, 7307.93.9040, 7307.93.9060, and 7326.19.0010.

The HTSUS subheadings and specifications are provided for convenience and customs purposes; the written description of the scope is dispositive.''

Background.—The final phase of these investigations is being scheduled pursuant to sections 705(b) and 731(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 1673d(b)), as a result of affirmative preliminary determinations by Commerce that certain benefits which constitute subsidies within the meaning of section 703 of the Act (19 U.S.C. 1671b) are being provided to manufacturers, producers, or exporters in India of forged steel fittings, and that such products are being sold in the United States at less than fair value within the meaning of section 733 of the Act (19 U.S.C. 1673b). The investigations were requested in petitions filed on October 23, 2019 by Bonney Forge Corporation (''Bonney''), Mount Union, Pennsylvania, and the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union (''USW''), Pittsburgh, Pennsylvania.

For further information concerning the conduct of this phase of the investigations, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Participation in the investigations and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the final phase of these investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11 of the Commission's rules, no later than 21 days prior to the hearing date specified in this notice. A party that filed a notice of appearance during the preliminary phase of the investigations need not file an additional notice of appearance during this final phase. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in the final phase of these investigations available to authorized applicants under the APO issued in the investigations, provided that the application is made no later than 21 days prior to the hearing date specified in this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the investigations. A party granted access to BPI in the preliminary phase of the investigations need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the final phase of these investigations will be placed in the nonpublic record on September 30, 2020, and a public version will be issued thereafter, pursuant to § 207.22 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the final phase of these investigations beginning at 9:30 a.m. on Thursday, October 15, 2020. Information about the place and form of the hearing, including about how to participate in and/or view the hearing, will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.* Interested parties should check the Commission's website periodically for updates.

Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before October 8, 2020. A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should participate in a prehearing conference to be held on October 13, 2020, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by §§ 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party who is an interested party shall submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of § 207.23 of the Commission's rules; the deadline for filing is October 7, 2020. Parties may also file written testimony in connection with their presentation at the hearing, as provided in § 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of § 207.25 of the Commission's rules. The deadline for

filing posthearing briefs is October 22, 2020. In addition, any person who has not entered an appearance as a party to the investigations may submit a written statement of information pertinent to the subject of the investigations, including statements of support or opposition to the petition, on or before October 22, 2020. On November 3, 2020, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before November 5, 2020, but such final comments must not contain new factual information and must otherwise comply with § 207.30 of the Commission's rules. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to § 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: June 16, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–13267 Filed 6–18–20; 8:45 am]

BILLING CODE 7020–02–P

JOINT BOARD FOR THE ENROLLMENT OF ACTUARIES

Meeting of the Advisory Committee

AGENCY: Joint Board for the Enrollment of Actuaries.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The Joint Board for the Enrollment of Actuaries gives notice of a teleconference meeting of the Advisory Committee on Actuarial Examinations (a portion of which will be open to the public) on July 6–7, 2020.

DATES: Monday, July 6, 2020 from 9:00 a.m. to 5:00 p.m. (EDT), and Tuesday, July 7, 2020 from 8:30 a.m. to 5:00 p.m. (EDT).

ADDRESSES: The meeting will be held by teleconference.

FOR FURTHER INFORMATION CONTACT: Elizabeth Van Osten, Designated Federal Officer, Advisory Committee on Actuarial Examinations, at 202–317–3648.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Advisory Committee on Actuarial Examinations will meet by teleconference on Monday, July 6, 2020 from 9:00 a.m. to 5:00 p.m. (EDT), and Tuesday, July 7, 2020 from 8:30 a.m. to 5:00 p.m. (EDT). The purpose of the meeting is to discuss topics and questions that may be recommended for inclusion in future Joint Board examinations in actuarial mathematics and methodology referred to in 29 U.S.C. 1242(a)(1)(B). Topics for inclusion on the syllabus for the Joint Board's examination program for the November 2020 Pension (EA–2F) Examination will be discussed.

A determination has been made as required by section 10(d) of the Federal Advisory Committee Act, 5 U.S.C. App., that the portions of the meeting dealing with the discussion of questions that may appear on the Joint Board's examinations fall within the exceptions to the open meeting requirement set forth in 5 U.S.C. 552b(c)(9)(B), and that the public interest requires that such portions be closed to public participation.

The portion of the meeting dealing with the discussion of other topics will commence at 1:00 p.m. (EDT) on July 6, 2020 and will continue for as long as necessary to complete the discussion, but not beyond 3:00 p.m. (EDT). Time permitting, after the close of this discussion by Advisory Committee members, interested persons may make statements germane to this subject. Persons wishing to make oral statements should contact the Designated Federal Officer at *NHQJBEA@IRS.GOV* and include the written text or outline of comments they propose to make orally. Such comments will be limited to 10 minutes in length. Persons who wish to attend the public session must contact the Designated Federal Officer at *NHQJBEA@IRS.GOV* to obtain teleconference access instructions. Notifications of intent to make an oral statement or to attend the meeting must be sent electronically to the Designated Federal Officer by no later than July 1, 2020. In addition, any interested person may file a written statement for consideration by the Joint Board and the Advisory Committee by sending it to *NHQJBEA@irs.gov.*

Dated: June 15, 2020.

Thomas V. Curtin,

Executive Director, Joint Board for the Enrollment of Actuaries.

[FR Doc. 2020–13194 Filed 6–18–20; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Reactivation Suitability Request—ATF Form 3252.5

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Department of Justice (DOJ), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for an additional 30 days until July 20, 2020.

FOR FURTHER INFORMATION CONTACT: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information

are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* New collection.

(2) *The Title of the Form/Collection:* Reactivation Suitability Request.

(3) *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: ATF Form 3252.5.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Individuals or households.

Other: None.

Abstract: The Confidential Informant (CI) handler will use the Reactivation Suitability Request—ATF Form 3252.5 to reinstate an individual to serve as a CI for ATF.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 50 respondents will respond to this collection annually, and it will take each respondent approximately 2 hours to complete their responses.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 100 hours, which is equal to 50 (# of respondents for this IC) * 2 (120 minutes, *i.e.,* the total time per response).

If additional information is required contact: Melody Braswell, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E.405A, Washington, DC 20530.

Dated: June 16, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–13285 Filed 6–18–20; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of the Extended Benefit (EB) Program for Florida, Indiana, Kansas, and Virgin Islands

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

This notice announces a change in benefit payment status under the EB program for Florida, Indiana, Kansas, and the Virgin Islands.

The following change has occurred since the publication of the last notice regarding each States' EB status:

The 13-week insured unemployment rates (IUR) for Florida, Indiana, Kansas, and the Virgin Islands, for the week ending May 23, 2020, rose above 5.0 percent and exceeded 120 percent of the corresponding average rates in the two prior years. Therefore, beginning the week of June 7, 2020, eligible unemployed workers will be able to collect up to an additional 13 weeks of UI benefits.

The trigger notice covering state eligibility for the EB program can be found at: *http://oui.doleta.gov/unemploy/claims_arch.asp.*

Information for Claimants

The duration of benefits payable in the EB program and the terms and conditions on which they are payable are governed by the Federal-State Extended Unemployment Compensation Act of 1970, as amended, and the operating instructions issued to the States by the U.S. Department of Labor. In the case of a state beginning an EB period, the State Workforce Agency will furnish a written notice of potential entitlement to each individual who has exhausted all rights to regular benefits and is potentially eligible for EB (20 CFR 615.13(c)(1)).

Persons who believe they may be entitled to EB, or who wish to inquire about their rights under the program, should contact their State Workforce Agency.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance Room S–4524, Attn: Kevin Stapleton, 200 Constitution Avenue NW, Washington, DC 20210, telephone number: (202) 693–3009 (this is not a toll-free number) or by email: *Stapleton.Kevin@dol.gov.*

Signed in Washington, DC.

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2020–13227 Filed 6–18–20; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of the Extended Benefit (EB) Program for Alabama, Arkansas, Colorado, Maryland, Missouri, North Dakota, Oklahoma, Tennessee, Texas, and Virginia

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This notice announces a change in benefit payment status under the EB program for Alabama, Arkansas, Colorado, Maryland, Missouri, North Dakota, Oklahoma, Tennessee, Texas, and Virginia.

The following change has occurred since the publication of the last notice regarding each States' EB status:

The 13-week insured unemployment rates (IUR) for Alabama, Arkansas, Colorado, Maryland, Missouri, North Dakota, Oklahoma, Tennessee, Texas, and Virginia, for the week ending May 16, 2020, rose above 5.0 percent and exceeded 120 percent of the corresponding average rates in the two prior years. Therefore, beginning the week of May 31, 2020, eligible unemployed workers will be able to collect up to an additional 13 weeks of UI benefits.

The trigger notice covering state eligibility for the EB program can be found at: *http://oui.doleta.gov/unemploy/claims_arch.asp.*

Information for Claimants

The duration of benefits payable in the EB program and the terms and conditions on which they are payable are governed by the Federal-State Extended Unemployment Compensation Act of 1970, as amended, and the operating instructions issued to the States by the U.S. Department of Labor.

In the case of a state beginning an EB period, the State Workforce Agency will furnish a written notice of potential entitlement to each individual who has exhausted all rights to regular benefits and is potentially eligible for EB (20 CFR 615.13(c)(1)).

Persons who believe they may be entitled to EB, or who wish to inquire about their rights under the program, should contact their State Workforce Agency.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance, Room S–4524, Attn: Kevin Stapleton, 200 Constitution Avenue NW, Washington, DC 20210, telephone number: (202) 693–3009 (this is not a toll-free number) or by email: *Stapleton.Kevin@dol.gov.*

Signed in Washington, DC.

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2020–13175 Filed 6–18–20; 8:45 am]

BILLING CODE 4510–FW–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Change in Status of the Extended Benefit (EB) Program for Washington DC, Delaware, Idaho, and South Carolina

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice.

SUMMARY: This notice announces a change in benefit payment status under the EB program for Washington DC, Delaware, Idaho, and South Carolina.

FOR FURTHER INFORMATION CONTACT: U.S. Department of Labor, Employment and Training Administration, Office of Unemployment Insurance Room S–4524, Attn: Kevin Stapleton, 200 Constitution Avenue NW, Washington, DC 20210, telephone number: (202)–693–3009 (this is not a toll-free number) or by email: *Stapleton.Kevin@dol.gov.*

SUPPLEMENTARY INFORMATION: The following change has occurred since the publication of the last notice regarding each States' EB status:

The 13-week insured unemployment rates (IUR) for Washington DC, Delaware, Idaho, and South Carolina, for the week ending May 9, 2020, rose above 5.0 percent and exceeded 120 percent of the corresponding average rates in the two prior years. Therefore, beginning the week of May 24, 2020, eligible unemployed workers will be able to collect up to an additional 13 weeks of UI benefits.

The trigger notice covering state eligibility for the EB program can be found at: *http://oui.doleta.gov/unemploy/claims_arch.asp.*

Information for Claimants

The duration of benefits payable in the EB program and the terms and conditions on which they are payable are governed by the Federal-State Extended Unemployment Compensation Act of 1970, as amended, and the operating instructions issued to the States by the U.S. Department of Labor. In the case of a state beginning an EB period, the State Workforce Agency will furnish a written notice of potential entitlement to each individual who has exhausted all rights to regular benefits and is potentially eligible for EB (20 CFR 615.13(c)(1)).

Persons who believe they may be entitled to EB, or who wish to inquire about their rights under the program, should contact their State Workforce Agency.

Signed in Washington, DC.

John Pallasch,

Assistant Secretary for Employment and Training.

[FR Doc. 2020–13226 Filed 6–18–20; 8:45 am]

BILLING CODE 4510–FW–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–1051; NRC–2018–0052]

Holtec International HI-STORE Consolidated Interim Storage Facility Project; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft environmental impact statement; public meeting; request for comments; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a notice that was published in the **Federal Register** on June 12, 2020, regarding the draft Environmental Impact Statement (EIS) for Holtec International's (Holtec's) application to construct and operate a consolidated interim storage facility (CISF) for spent nuclear fuel and Greater-Than Class C waste, along with a small quantity of mixed oxide fuel in Lea County, New Mexico. This action is necessary to include information for the public on how to submit comments to the NRC and to correct the ADAMS Accession Number for the draft EIS.

DATES: The NRC staff will hold a webinar on June 23, 2020. The staff will present the findings of the draft report and will receive public comments during transcribed public meeting. Members of the public are invited to submit comments by July 22, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0052. Address questions about NRC dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.
- *Email comments to: Holtec-CISFEIS@nrc.gov.*

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jill Caverly, Office of Nuclear Material Safety and Safeguards, telephone: 301–415–7674, email: *Jill.Caverly@nrc.gov,* U.S. Nuclear Regulatory Commission, Washington DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2018–0052 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2018–0052.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The draft EIS is available in

ADAMS under Accession No. ML20069G420.

• *Project Web Page:* Information related to the Holtec HI–STORE CISF project can be accessed on the NRC's Holtec HI–STORE CISF web page at *https://www.nrc.gov/waste/spent-fuel-storage/cis/holtec-international.html.* Scroll down to EIS, Draft Report for Comment.

• *Public Libraries:* A copy of the staff's draft EIS can be accessed at the following public libraries (library access and hours are determined by local policy):

• Carlsbad Public Library, 101 S Halagueno Street, Carlsbad, NM 88220.

• Hobbs Public Library, 509 N Shipp St., Hobbs, NM 88240.

• Roswell Public Library, 301 N Pennsylvania, Roswell, NM 88201.

B. Submitting Comments

Please include Docket ID NRC–2018–0052 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

The NRC issued a notice announcing a public meeting and request for comments on June 12, 2020 (85 FR 35956). The NRC is correcting the notice to include information on how the public may submit comments on the draft EIS for Holtec's application to construct and operate a CISF for spent nuclear fuel and Greater-Than Class C waste, along with a small quantity of mixed oxide fuel in Lea County, New Mexico. The NRC is also correcting the ADAMS Accession Number for the draft EIS. The draft EIS is available in ADAMS under Accession No. ML20069G420.

III. Public Meeting

Comments will be accepted during the webinar on June 23, 2020, and through the methods listed under the **ADDRESSES** section of this document.

The webinar will be held online and will offer a telephone line for members of the public to submit comments. A court reporter will be recording all comments received during the webinar. The dates and times for the public webinar are as follow:

Date	Time	Location
6/23/2020	5:00 p.m. to 9:00 p.m. (EDT) 3:00 p.m. to 7:00 p.m. (MDT)	*Webinar Information: https://usnrc.webex.com, Event Number:* 199 800 0026, *Password:* HOLTEC, *Telephone Bridge Line:* 1–888–454–7496, *Participant Passcode:* 5790355.

Persons interested in attending this meeting should monitor the NRC's Public Meeting Schedule web page at *https://www.nrc.gov/pmns/mtg* for additional information, agenda for the meeting, information on how to provide verbal comments, and access information for the meeting. Participants should register in advance of the meeting by visiting the website page (*https://usnrc.webex.com*) and using the event number provided above. A confirmation email will be generated providing additional details and a link to the meeting. Those wishing to make verbal comments at the meeting should follow instructions listed at the NRC's Public Meeting Schedule.

Dated: June 16, 2020.

For the Nuclear Regulatory Commission.

Diana B. Diaz Toro,

Acting Chief, Environmental Review Materials Branch, Division of Rulemaking, Environmental and Financial Review, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2020–13290 Filed 6–18–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0246]

Information Collection: Comprehensive Decommissioning Program, Including Annual Data Collection

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on this proposed collection of information. The information collection is entitled, ''Comprehensive Decommissioning Program Annual Site List and Point of Contact.''

DATES: Submit comments by August 18, 2020. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

• *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0246. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0246 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search

for Docket ID NRC–2019–0246. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID NRC–2019–0246 on this website.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML20162A172. The supporting statement is available in ADAMS under Accession No. ML20049A689.

• *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

Please include Docket ID NRC–2019–0246 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS, and the NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* Comprehensive Decommissioning Program Annual Site List and Point of Contact.
2. *OMB approval number:* 3150–0206.
3. *Type of submission:* Revision.
4. *The form number, if applicable:* N/A.
5. *How often the collection is required or requested:* Annually.
6. *Who will be required or asked to respond:* All Agreement States that have signed Section 274(b) Agreements with the NRC.
7. *The estimated number of annual responses:* 39 (14 responses from Agreement States with sites undergoing decommissioning + 25 responses from Agreement States with no sites undergoing decommissioning).
8. *The estimated number of annual respondents:* 39 (14 Agreement States with sites undergoing decommissioning + 25 Agreement States with no sites undergoing decommissioning).
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 40.5 (28 hours for Agreement States with sites undergoing decommissioning + 12.5 hours for Agreement States with no sites undergoing decommissioning).
10. *Abstract:* The Agreement States will be asked to provide a list of uranium recovery and complex sites undergoing decommissioning regulated by their States on an annual basis. The Agreement States will also be asked to provide a point of contact who is cognizant of site status. The information request will allow the NRC to compile, in a centralized location, updated contact information and a list of sites decommissioning in the United States to provide a national perspective on decommissioning. The information will be made available to the public by the NRC in order to ensure openness and promote communication to enhance public knowledge of the national decommissioning program.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?
2. Is the estimate of the burden of the information collection accurate?
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: June 16, 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–13253 Filed 6–18–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2016–0233]

Pressurized-Water Reactor Control Rod Ejection and Boiling-Water Reactor Control Rod Drop Accidents

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing regulatory guide (RG) 1.236, ''Pressurized-Water Reactor Control Rod Ejection and Boiling-Water Reactor Control Rod Drop Accidents.'' This is a new RG that provides guidance for analyzing control rod accidents. It defines fuel cladding failure thresholds for ductile failure, brittle failure, and pellet-clad mechanical interaction. It also describes analytical limits and guidance for demonstrating compliance with regulations governing reactivity limits. RG 1.236 supersedes the guidance for control rod ejection accidents in RG 1.77, ''Assumptions Used for Evaluation a Control Rod Ejection Accident for Pressurized Water Reactors,'' which is being withdrawn in conjunction with the issuance of RG 1.236.

DATES: RG 1.236 is available on June 19, 2020.

ADDRESSES: Please refer to Docket ID NRC–2016–0233 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2016–0233. Address questions about NRC dockets IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical

questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* RG 1.236 and the regulatory analysis may be found in ADAMS under Accession Nos. ML20055F490 and ML16124A198, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Paul Clifford, Office of Nuclear Reactor Regulation, telephone: 301–415–4043, email: *Paul.Clifford@nrc.gov* and Edward O'Donnell, Office of Nuclear Regulatory Research, telephone: 301–415–3317, email: *Edward.ODonnell@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a new guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific issues or postulated events, and information that the staff needs in its review of applications for permits and licenses.

The RG, titled ''Pressurized-Water Reactor Control Rod Ejection and Boiling-Water Reactor Control Rod Drop Accidents,'' describes one acceptable method for demonstrating compliance with appendix A of part 50 of title 10 of the *Code of Federal Regulations* (10 CFR), General Design Criteria (GDC) 28, ''Reactivity Limit,'' with respect to control rod ejection (CRE) accidents for pressurized-water reactors and control rod drop (CRD) accidents for boiling-water reactors. RG 1.236 provides guidance for analyzing these reactivity-initiated accidents. It defines fuel cladding failure thresholds for ductile failure, brittle failure, and pellet-clad mechanical interaction. It also describes analytical limits and guidance for demonstrating compliance with regulations governing reactivity limits.

The guide incorporates new empirical data from in-pile, prompt power pulse test programs and analyses from several international publications that examine fuel rod performance under reactivity-initiated accident conditions to provide guidance on acceptable analytical methods, assumptions, and limits for evaluating a CRE and CRD accidents. The guide supersedes the guidance for control rod ejection accidents in RG 1.77, ''Assumptions Used for Evaluation a Control Rod Ejection Accident for Pressurized Water Reactors,'' which is being withdrawn in conjunction with the issuance of RG 1.236.

II. Additional Information

The NRC issued RG 1.236 as Draft Guide (DG)-1327 for public comment on November 21, 2016 (81 FR 83288), with a 60 day comment period that expired on February 21, 2017. A public meeting was held at NRC Headquarters on January 25, 2017, while the guide was issued for public comment. During the meeting NRC made a commitment to hold a second public meeting to discuss the staff's proposed resolution of key comments prior to finalization of the guide. Following the public meeting the NRC extended the comment period to April 21, 2017 (82 FR 8998), to allow more time for comment. A second public meeting was held at NRC Headquarters on June 5, 2018, to discuss resolution of the public comments. To facilitate discussion at the meeting, drafts of the guide (ADAMS Accession No. ML18138A459) and a table showing resolution of the public comments (ADAMS Accession No. ML18138A458) were made publicly available.

As a result of the written public comments and discussion at the two public meetings, the NRC made several changes to the draft guide and it was released a second time for public comment on July 30, 2019 (84 FR 36961). That comment period ended November 18, 2019. The guide was further revised to address the second round of public comments. The response to this second round of public comments is located in ADAMS under Accession No. ML20055F489. Among the changes resulting from the two public meetings and the two rounds of public comments were: (1) The pellet-clad mechanical interaction cladding failure thresholds were revised; (2) the appendix that provided acceptable steady-state and transient fission product releases was removed; and (3) the implementation section was revised to be consistent with recent Commission direction on backfitting and forward fitting as found in Management Directive 8.4 ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests.''

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

RG 1.236 describes one acceptable method for demonstrating compliance with 10 CFR part 50, appendix A, GDC 28 with respect to CRE accidents for pressurized-water reactors and CRD accidents for boiling-water reactors. In general, issuance of this RG does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in NRC Management Directive 8.4; does not constitute forward fitting as that term is defined and described in Management Directive 8.4; and does not affect the issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants.'' As explained in this regulatory guide, applicants and licensees are not required to comply with the positions set forth in this RG. Licensees using RG 1.77 may continue using that RG. In future requests or applications for NRC licensing actions related to the guidance in RG 1.77, those licensees should use RG 1.236, which contains the guidance in RG 1.77. Further information on the staff's use of the RG is contained in the RG under Section D., ''Implementation.''

Dated: June 16, 2020.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2020–13254 Filed 6–18–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–331; NRC–2020–0148]

NextEra Energy Duane Arnold, LLC; Duane Arnold Energy Center; Post-Shutdown Decommissioning Activities Report

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of receipt; availability; public meeting and request for comment.

SUMMARY: On April 2, 2020, the U.S. Nuclear Regulatory Commission (NRC)

received the post-shutdown decommissioning activities report (PSDAR) for the Duane Arnold Energy Center (DAEC). The PSDAR, which includes the site-specific decommissioning cost estimate (DCE), provides an overview of NextEra Energy Duane Arnold, LLC's (NEDA or the licensee) planned decommissioning activities, schedule, projected costs, and environmental impacts for DAEC. The NRC will hold a public meeting to discuss the PSDAR's content and receive comments.

DATES: Submit comments by October 19, 2020. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0148. Address questions about NRC docket IDs to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Scott P. Wall, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001, telephone: 301–415–2855; email: *Scott.Wall@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2020–0148 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0148.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

B. Submitting Comments

Please include Docket ID NRC–2020–0148 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Discussion

NEDA is the holder of Renewed Facility Operating License No. DPR–49 for DAEC. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect. The facility consists of one boiling-water reactor located adjacent to the Cedar River approximately 2.5 miles northeast of the town of Palo in Linn County, Iowa. By letter dated January 18, 2019 (ADAMS Accession No. ML19023A196), the licensee submitted its notification of permanent cessation of power operations for DAEC. In this letter, NEDA notified the NRC of its intent to permanently cease power operations at DAEC in the fourth quarter of 2020. By letter dated March 2, 2020 (ADAMS Accession No. ML20062E489), the licensee submitted a revised notification of permanent cessation of power operations for DAEC. In this letter, NEDA notified the NRC of its intent to permanently cease power operations at DAEC on October 30, 2020.

On April 2, 2020, NEDA submitted the PSDAR, including the site-specific DCE for DAEC, in accordance with § 50.82(a)(4)(i) of title 10 of the *Code of Federal Regulations* (ADAMS Accession No. ML20094F603). The PSDAR includes a description of the planned decommissioning activities, a proposed schedule for their accomplishment, the site-specific DCE, and a discussion that provides the basis for the NRC to conclude that the environmental impacts associated with the site-specific decommissioning activities will be bounded by appropriate, previously issued generic and plant-specific environmental impact statements.

III. Request for Comment and Public Meeting

Due to the COVID–19 Public Health Emergency (PHE), the NRC has delayed holding a public meeting to obtain comments from the public on the DACE PSDAR, including the DCE. However, with recent announcements for relaxing PHE restrictions by Iowa Governor Reynolds, the NRC is tentatively planning to hold the PSDAR meeting and receive comments on Tuesday, July 28, 2020, from 6 p.m. until 9 p.m., at the Palo Community Center, 2800 Hollenbeck Rd, Palo, Iowa 52324. If PHE restrictions do not allow the meeting to be held on July 28, 2020, the NRC will notify the public by revising the date on the NRC Public Meeting Schedule on the NRC's public website at *https://www.nrc.gov/pmns/mtg.* The NRC requests that comments provided outside the July 28, 2020 meeting be submitted as noted in Section I, ''Obtaining Information and Submitting Comments,'' of this document in writing by October 19, 2020.

Dated: June 15, 2020.

For the Nuclear Regulatory Commission.

Nancy L. Salgado,

Chief, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–13215 Filed 6–18–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2019–0248]

Information Collection: Requests to Agreement States for Information

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Requests to Agreement States for Information.''

DATES: Submit comments by July 20, 2020. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2019–0248 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2019–0248.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The supporting statement is available in ADAMS under Accession No. ML20139A219.
- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–2084; email: *Infocollects.Resource@nrc.gov.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''Requests to Agreement States for Information.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on March 16, 2020 (85 FR 14979).

1. *The title of the information collection:* Requests to Agreement States for Information.
2. *OMB approval number:* 3150–0029.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* Not applicable.
5. *How often the collection is required or requested:* One time or as needed.
6. *Who will be required or asked to respond:* Thirty-nine Agreement States who have signed Section 274(b) Agreements with the NRC.
7. *The estimated number of annual responses:* 624 (1,872 over the course of the three-year clearance period).
8. *The estimated number of annual respondents:* 39.
9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 4,992 (14,976 over the course of the three-year clearance period).
10. *Abstract:* The NRC is requesting OMB approval of a plan for a generic collection of information. The need and practicality of the collection can be evaluated, but the details of the specific individual collections will not be known until a later time. The Agreement States will be asked on a one-time or as needed basis to respond to a specific incident, to gather information on licensing and inspection practices or other technical information. The results of such information requests, which are authorized under Section 274(b) of the Atomic Energy Act, will be utilized on part by the NRC in preparing responses to Congressional inquiries.

Dated: June 16, 2020.

For the Nuclear Regulatory Commission.

David C. Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2020–13289 Filed 6–18–20; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2020–0083]

Assumptions Used for Evaluating a Control Rod Ejection Accident for Pressurized Water Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; withdrawal.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is withdrawing regulatory guide (RG) 1.77, ''Assumptions Used for Evaluating a Control Rod Ejection Accident for Pressurized Water Reactors.'' This RG is being withdrawn because its guidance has been incorporated into a new RG, RG 1.236, ''Pressurized-Water Reactor Control Rod Ejection and Boiling-Water Reactor Control Rod Drop Accidents.''

DATES: The withdrawal of RG 1.77 takes effect on June 19, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0083 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2020–0083. Address questions about NRC docket IDs in *Regulations.gov* to Jennifer Borges; telephone: 301–287–9127; email: *Jennifer.Borges@nrc.gov.* For technical questions, contact the individuals listed

in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The basis for withdrawal of RG 1.77 is available in ADAMS under Accession No. ML20084N202.

FOR FURTHER INFORMATION CONTACT: Paul Clifford, Office of Nuclear Reactor Regulation, telephone: 301–415–4043, email: *Paul.Clifford@nrc.gov* and Edward O'Donnell, Office of Nuclear Regulatory Research, telephone: 301–415–3317, email: *Edward.ODonnell@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

Regulatory guides may be withdrawn by the NRC when their guidance no longer provides useful information or is superseded by technological innovations, congressional actions, or other events. The NRC is withdrawing RG 1.77 because its guidance has been incorporated into RG 1.236, ''Pressurized-Water Reactor Control Rod Ejection and Boiling-Water Reactor Control Rod Drop Accidents'' (ADAMS Accession No. ML20055F490). The basis for withdrawal is found in ADAMS under Accession No. ML20084N202.

II. Further Information

The withdrawal of RG 1.77 does not alter any prior or existing NRC licensing approval or the acceptability of licensee commitments to this RG. Although RG 1.77 is withdrawn, current licensees may continue to use it, and withdrawal does not affect any existing licenses or agreements. However, after the withdrawal of RG 1.77, licensees should use RG 1.236 in future requests or applications for NRC licensing actions related to the guidance in RG 1.77.

Dated: June 16, 2020.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2020–13258 Filed 6–18–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2020–176; Order No. 5549]

Inbound Parcel Post (at UPU Rates)

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is acknowledging a recent Postal Service filing of a change in rates not of general applicability to be effective July 1, 2020. This document informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* June 22, 2020.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Contents of Filing
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I. Introduction

On June 12, 2020, the Postal Service filed a notice with the Commission of a change in rates not of general applicability for Inbound Parcel Post at Universal Postal Union (UPU) rates, pursuant to 39 CFR 3035.105. The Postal Service intends for the proposed prices to take effect on July 1, 2020. Notice at 1.

II. Contents of Filing

In support of the Notice, the Postal Service filed an application for non-public treatment (Attachment 1), a redacted version of the UPU International Bureau (IB) circular that provides the negotiated rates (Attachment 2), a copy of the certification required under 39 CFR 3035.105(c)(2) (Attachment 3), a redacted Postal Service data used by the UPU to justify any bonus payments (Attachment 4), and a redacted copy of Governors' Decision No. 19–1 (Attachment 5). The Postal Service also filed supporting financial workpapers under seal. *Id.* at 2–3.

The Postal Service asserts that the proposed prices comply with 39 U.S.C. 3633(a) and 39 CFR 3035.107. *Id.* at 5–6. Furthermore, the Postal Service states that it has provided supporting documentation, as required by Order Nos. 2102 and 2310.[1] In addition, the Postal Service states that it provided citations and a copy of the relevant UPU IB circular, as required by prior Commission orders.[2]

III. Administrative Actions

The Commission establishes Docket No. CP2020–176 for consideration of matters raised by the Notice and appoints Katalin K. Clendenin to serve as Public Representative in this docket. The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, 3633, and 39 CFR part 3035. Comments are due no later than June 22, 2020. The public portions of the filing can be accessed via the Commission's website (*http://www.prc.gov*).

IV. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket No. CP2020–176 for consideration of the matters raised by the Postal Service's Notice.
2. Comments are due no later than June 22, 2020.
3. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin will serve as an officer of the Commission (Public Representative) to represent the interests of the general public in these dockets.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Erica A. Barker,

Secretary.

[FR Doc. 2020–13187 Filed 6–18–20; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Wednesday, June 24, 2020.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

[1] *Id.* at 4–5. *See* Docket No. CP2014–52, Order Accepting Price Changes for Inbound Air Parcel Post (at UPU Rates), June 26, 2014, at 6 (Order No. 2102); Docket No. CP2015–24, Order Accepting Changes in Rates for Inbound Parcel Post (at UPU Rates), December 29, 2014, at 4 (Order No. 2310).

[2] Notice at 5. *See e.g.,* Docket No. CP–2019–43, Order Acknowledging Changes in Prices for Inbound Parcel Post (at UPU Rates), December 19, 2018 (Order No. 4933).

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topic:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Dated: June 17, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–13411 Filed 6–17–20; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89069; File No. SR–ISE–2020–22]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the ISE Disciplinary Rules in General 5 To Incorporate by Reference The Nasdaq Stock Market LLC's Series 8000 and 9000 Rules

June 15, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 10, 2020, Nasdaq ISE, LLC (''ISE'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the ISE Disciplinary Rules in General 5 to incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') Series 8000 and 9000 Rules, currently located under the General 5 title of the Nasdaq rulebook,[3] instead of the BX Rules, which the Exchange currently incorporates by reference.

The text of the proposed rule change is available on the Exchange's website at *http://ise.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In connection with a recent rule change to relocate the Nasdaq BX, Inc. (''BX'') Disciplinary Rules under the General 5 title (''Discipline''),[4] and incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') Series 8000 and 9000 Rules, ISE proposes to similarly incorporate by reference Nasdaq's Series 8000 and 9000 Rules.

The BX Disciplinary Rules, which were relocated to General 5 of the BX Rules,[5] were replaced with introductory paragraphs that respectively incorporate by reference the Nasdaq Series 8000 and 9000 Rules (located under the General 5 title in the Nasdaq rulebook).[6] Currently, ISE incorporates the BX Disciplinary Rules within the Series 8000 and 9000 Rules, which were relocated to General 5 of the BX Rules with the aforementioned rule change.[7] At this time, ISE proposes to incorporate by reference the Nasdaq Series 8000 and 9000 Rules (located in General 5 Discipline), respectively, and state that such Nasdaq Rules shall be applicable to Exchange Members, associated persons, and other persons subject to ISE's jurisdiction.

Except as noted below, the Nasdaq Series 8000 and 9000 Rules are substantially similar to BX's Disciplinary Rules, which the Exchange currently incorporates by reference. The following discussions identify the differences between the current BX Disciplinary Rules and the corresponding Nasdaq Disciplinary Rules to be incorporated by reference into ISE:

Current BX IM–8310–3(b)

Current BX Rule 9120(f) provides that ''[t]he term ''Department of Enforcement'' means the Department of

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098).

[4] Securities Exchange Act Release No. 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009).

[5] *Id.*

[6] *Id.* The Exchange notes that the proposed changes will not become operative unless and until the Commission approves the Exchange's request, to be filed pursuant to Section 36 of the Exchange Act and SEC Rule 0–12 thereunder, for an exemption from the rule filing requirements of Section 19(b) of the Exchange Act as to changes to the ISE 8000 Series (New General 5, Section 1) and ISE 9000 Series (New General 5, Section 2) that are effected solely by virtue of a change to the Nasdaq Series 8000 or 9000 Rules Series.

[7] Securities Exchange Act Release No. 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009).

Enforcement of FINRA Regulation, acting on behalf of the Exchange pursuant to the FINRA Regulatory Contract.'' [8] Current BX IM–8310–3(b), however, uses the term ''Department of Enforcement of FINRA.'' Since Nasdaq IM–8310–3(b) uses the term ''Department of Enforcement'' ISE believes it is appropriate to utilize the Nasdaq terms going forward and incorporate by reference into the ISE rule.

Current BX Rule 8320

In 2010, Nasdaq created Rule 7007 (''Collection of Fees'') to facilitate an efficient method of collecting undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to Nasdaq from The Nasdaq Option Market (''NOM'') Participants.[9]

Similarly, in 2012, BX adopted its options market rules (''BX Options Market'') to operate as a fully automated, price/time priority execution system built on the core functionality of NOM.[10] In its filing, BX proposed to adopt, under respective Chapter XV, Section 2, a rule identical to the Nasdaq Collection of Fees rule.[11] Although, at the time of its creation, the Nasdaq Collection of Fees rule was cross-referenced to current Nasdaq Rule 8320(a)(1),[12] such cross-reference was not included in the filing that created the BX Options Market. ISE also has the same Collection of Fees rule,[13] that is identical to the Nasdaq rule. Because BX Rule 8320, which ISE incorporates by reference, does not include a cross-reference to the Collection of Fees rule, ISE will follow the Nasdaq rule going forward, which has the correct cross-reference. The Exchange also proposes to add rule text, within General 5, Section 3, to note the distinction between the location of the Collection of Fees rules. Specifically, the Exchange proposes to add rule text to provide that references in the Nasdaq 8000 Series to ''Nasdaq's Options 7, Section 1'' shall be read to refer to ISE Options 7, Section 2.

Based on the above, the Exchange believes that it is appropriate that ISE adopts the aforementioned cross-reference to make the collection of fees owed to the Exchange more efficient. Therefore, the Exchange believes that it is appropriate to incorporate by reference Nasdaq Rule 8320 into ISE Rules.

Current BX Rule 9120

In 2018, BX amended its Disciplinary Rules to align them with the investigatory and disciplinary processes of Nasdaq PHLX LLC (''Phlx'').[14] As stated in its proposal, the changes to the ''Interested Staff'' concept (which, at the time, was relocated under 9120(r)) were done to conform the BX rule to Phlx's definition. At the time, however, the proposed harmonizing changes to BX Rule 9120(r)(1)(B) inadvertently excluded the words ''Head of'' and omitted to add the word ''the''; indeed, the text should have read ''Head of the Exchange's Regulation Department'' instead of, simply, ''Exchange's Regulation Department.''

The correct definition, as explained above, would also align with the term currently defined in Nasdaq Rule 9120(r)(1)(B), which provides that ''Interested Staff'' shall mean ''an Exchange employee of the Nasdaq Regulation Department who reports, directly or indirectly, to the Head of the Nasdaq Regulation Department.''

The Exchange believes that it is appropriate to apply Nasdaq Rule 9120 and to incorporate it by reference into the ISE rule. Additionally, the Exchange notes that applying Nasdaq Rule 9120 and incorporating it by reference into the Exchange rule should correct a typo in current BX Rule 9120(v) that erroneously uses the term ''RINRA'' instead of the acronym ''FINRA.''

Current BX Rule 9231

The Exchange proposes to adopt the cross-reference in Nasdaq Rule 9231(c) concerning the appointment of arbitrators pursuant to the FINRA Rules 12000 and 13000 Series (the ''FINRA Arbitration Rules''). Current BX Rule 9231(c) provides that arbitrators shall be appointed pursuant to BX General 6 (''BX Arbitration Rules'').[15] The BX Arbitration Rules incorporate by reference the similar Nasdaq arbitration rules (also under Nasdaq's General 6 title); ISE's arbitration rules within General 6 also incorporate Nasdaq's arbitration rules; in turn, the Nasdaq rules incorporate the FINRA Arbitration Rules by reference into its text. Following the incorporation by reference of Nasdaq Rule 9231, ISE Rule 9231(c) will directly cross-reference the FINRA Arbitration Rules, which will not create any differences from the current ISE rules.

Current BX Rule 9232

Currently, Nasdaq Rule 9232(a) provides a cross-reference to subsections (A) through (D) in Nasdaq Rule 9231(b)(1), whereas current BX Rule 9232(a) simply provides a reference to BX Rule 9231(b)(1). The Exchange believes that it is appropriate to apply Nasdaq Rule 9232(a) and incorporate it by reference into the ISE rule since the Nasdaq rule contains a more precise cross-reference to Nasdaq Rule 9231(b)(1).

Current BX Rule 9522

The Exchange proposes to apply and incorporate by reference Nasdaq Rule 9522 in place of current BX Rule 9522. This proposal amends the first sentence in current BX Rule 9522(a)(1) by replacing the term ''Exchange's Regulation Department'' with the term ''Department of Member Regulation'' as currently provided in Nasdaq Rule 9522(a)(1). As previously indicated by the Exchange,[16] the FINRA Department of Member Regulation [17] currently performs the functions described in current BX Rule 9522. Therefore, applying the Nasdaq rule and incorporating it by reference into ISE Rule 9522, provides clarity to the rule text and aligns it with Nasdaq and Phlx's rules.

The ISE introductory paragraphs currently list instances in which various terms and rules within the BX Disciplinary Rules shall be read to refer to Exchange specific rules and terms. Replacing references to ''BX'' with ''Nasdaq'' in this introductory paragraph should align the Nasdaq and ISE rules. All of these specific terms are identical as between the Nasdaq and BX Rules and, therefore, the term ''BX'' is being replaced with ''Nasdaq.''

The Exchange also proposes to remove certain references within ISE General 5, Section 3, Code of Procedure,

[8] This definition mirrors the one in the Nasdaq rulebook under Rule 9120(f).

[9] *See* Securities Exchange Act Release No. 63536 (December 14, 2010), 75 FR 80102 (December 21, 2010) (SR–NASDAQ–2010–163). Nasdaq Rule 7007 was later relocated to Options Chapter XV, Section 1 and then moved to its current location under Options 7, Section 1, in the Nasdaq rulebook shell. *See* Securities Exchange Act Release No. 66158 (January 13, 2012), 75 FR 80102 (January 13, 2012) (SR–NASDAQ–2012–006) and Securities Exchange Act Release No.84684 (November 29, 2018), 83 FR 62936 (December 6, 2018) (SR–NASDAQ–2018–098).

[10] Securities Exchange Act Release No. 67256 (June 26, 2012), 77 FR 39277 (July 2, 2012) (SR–BX–2012–030). This rule was later relocated to the BX Rulebook shell. *See* Securities Exchange Act Release No. 84326 (October 1, 2018), 83 FR 50414 (October 1, 2018) (SR–BX–2018–046).

[11] *Id.*

[12] *See supra* note 9.

[13] *See* ISE Options 7, Section 2.

[14] *See* Securities Exchange Act Release No. 84354 (October 3, 2018), 83 FR 50723 (October 9, 2018) (SR–BX–2018–042).

[15] *See* Securities Exchange Act Release No. 84476 (October 24, 2018), 83 FR 54630 (October 30, 2018) (SR–BX–2018–048).

[16] *See* Securities Exchange Act Release No. 84354 (October 3, 2018), 83 FR 50724 (October 9, 2018) (SR–BX–2018–042).

[17] As defined in BX 9120(g).

which are no longer necessary because they align with the current rules referenced within the Nasdaq 9000 Rule Series.[18] The Exchange also proposes to amend certain references to Nasdaq Rules, as a result of the relocation of certain Nasdaq Rules in conjunction with a larger Rulebook relocation.[19] Specifically, the Exchange proposes to amend: (a) Rule 1160 to relocated General 2, Section 11; (b) Equity Rules 2110 and 2120 to relocated General 9, Section 1;[20] (c) Equity Rule 2150 to relocated General 9, Section 2.[21] Additionally, as noted above, the Exchange proposes to add rule text to provide that references in the Nasdaq 8000 Series to ''Nasdaq's Options 7, Section 1'' shall be read to refer to ISE Options 7, Section 2.

Other Technical Amendments

Further, the Exchange proposes to amend references to General 5 to more specific references to the Nasdaq 9000 Series Rules, which pursuant to the proposed incorporation by reference will become ISE Rules. Specifically, the Exchange proposes to amend General 1, Section 1 (Definitions); General 3, Section 2 (Denial of and Conditions to Becoming a Member); General 3, Section 6 (Dissolution and Liquidation of Members); Options 2A, Section 3 (Sale and Transfer of Market Maker Rights); Options 6A, Section 1 (Contracts of Suspended Members); Options 6E, Section 7 (Regulatory Cooperation); Options 9, Section 11 (Other Restrictions on Members); and Options 11, Section 1 (Imposition of Fines for Minor Rule Violations) to replace references to General 5 to the applicable Nasdaq 9000 Series Rule or Rules. Further, the Exchange proposes to amend General 1, ''Provisions'' to General 1, ''General Provisions'' to mirror the name of the Chapter on Nasdaq Phlx LLC, Nasdaq BX, Inc., and Nasdaq.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by consolidating its rules into a single rule set. The various Nasdaq exchanges (''Affiliated Exchanges'') have filed similar proposed rule changes to amend and relocate their disciplinary rules[24] in order that the Nasdaq 8000 Series and 9000 Series Rules, which govern the investigative and disciplinary processes, are similarly consolidated and incorporated by reference.[25] To the extent that there will be differences remaining between the two rule sets, the Exchange notes those differences in introductory paragraphs to each of ISE's Disciplinary Rules.

Incorporating the Nasdaq Disciplinary Rules by reference into the ISE Rules, instead of the BX Disciplinary Rules, will conform the alignment of these rules and permit the rules of Phlx, BX, ISE, Nasdaq GEMX, LLC and Nasdaq MRX, LLC to be incorporated by reference to one rule set. This proposal would permit the Nasdaq Series 8000 and 9000 Rules to be the source document for all of the Nasdaq Exchanges' investigative and disciplinary processes. The Exchange notes that its current Disciplinary Rules are not substantively changing. The Exchange desires to conform its rules to give its Members and the members of its Affiliated Exchanges the ability to quickly locate rules in one central location and also to have a unified disciplinary rule set.

The Exchange also believes that the proposal is consistent with Section 6(b)(6) of the Act,[26] which requires that the rules of an exchange provide that its Members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a Member, or any other fitting sanction.

Other Technical Amendments

These technical amendments are intended to align ISE with other Nasdaq affiliated markets Rulebooks. Nasdaq Phlx LLC and Nasdaq BX, Inc. Rulesets are also incorporating by reference the Nasdaq Rules and those rulesets provide specific references to the Nasdaq disciplinary rules within the 9000 Series.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that this rule change does not impose an undue burden on competition because the Nasdaq Series 8000 and 9000 Rules, which are substantially similar to BX's Disciplinary Rules, will be incorporated by reference into ISE's Rules. Those rules will now apply to ISE Members, associated persons, and other persons subject to the Exchange's jurisdiction. To the extent that there will be differences remaining between the two rule sets, the Exchange notes those differences in introductory paragraphs to each of ISE's Disciplinary Rules. As noted above, the proposed introductory paragraphs list instances in which cross references in Nasdaq Series 8000 and 9000 Rules to other Nasdaq rules shall be read to refer instead to the Exchange Rules, and references to Nasdaq terms (whether or not defined) shall be read to refer to the Exchange-related meanings of those terms. Because Nasdaq Current Series 8000 and 9000 Rules are substantially similar to BX's Disciplinary Rules, which ISE currently incorporates by reference, and because the introductory paragraphs ensure that any differences are preserved, the proposed changes do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Finally, the Exchange believes that the proposed amendments, including the technical amendments contained herein, do not impose an undue burden on competition because the amendments to relocate the Rules are non-substantive. This rule change is

[18] The following Nasdaq Rules were relocated in connection with a Nasdaq rule relocation filing: Rules 0120, 1070, 1160, 4110A, 4120A; Equity Rules 2110, 2120, 2140, 2150; Rule 1000 Series and Chapter III, Section 16. *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From Its Current Rulebook Into Its New Rulebook Shell).

[19] *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From Its Current Rulebook Into Its New Rulebook Shell).

[20] Equity Rule 2120 was more specifically relocated to General 9, Section 1(g), however the Nasdaq Rule 9000 Series only reference General 9, Section 1.

[21] *Id.*

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] *See* Securities Exchange Act Release No. 86138 (July 18, 2019), 84 FR 29567 (July 24, 2019) (SR–ISE–2019–17); Securities Exchange Act Release No. 86346 (July 10, 2019), 84 FR 33999 (July 16, 2019) (SR–GEMX–2019–08); and Securities Exchange Act Release No. 86424 (July 12, 2019), 84 FR 36134 (July 26, 2019) (SR–MRX–2019–15); and Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098). Similarly, Phlx recently submitted a proposal to relocate its disciplinary rules. *See* Securities Exchange Act Release No. 88519 (March 31, 2020), 85 FR 19203 (April 6, 2020) (SR–Phlx–2020–09).

[25] *See* Securities Exchange Act Release Nos. 88519 (March 31, 2020), 85 FR 19203 (April 6, 2020) (SR–Phlx–2020–09); and 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009), as well as SR–GEMX–2020–15 and SR–MRX–2020–12.

[26] 15 U.S.C. 78f(b)(6).

intended to bring greater clarity to the Exchange's Rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act [27] and subparagraph (f)(6) of Rule 19b–4 thereunder.[28]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–ISE–2020–22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–ISE–2020–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE–2020–22 and should be submitted on or before July 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–13209 Filed 6–18–20; 8:45 am]

BILLING CODE 8011–01–P

[27] 15 U.S.C. 78s(b)(3)(A)(iii).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89065; File No. SR–NYSENAT–2020–05]

Self-Regulatory Organizations; NYSE National, Inc.; Request for Information and Additional Comment on a Proposed Rule Change To Establish Fees for the NYSE National Integrated Feed

June 12, 2020.

I. Introduction

On February 3, 2020, NYSE National, Inc. (''NYSE National'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish fees for the NYSE National Integrated Feed. The proposed rule change was immediately effective upon filing with the Commission pursuant to Section 19(b)(3)(A) of the Act.[3] The proposed rule change was published for comment in the **Federal Register** on February 20, 2020.[4] On April 1, 2020, the Division of Trading and Markets, for the Commission pursuant to delegated authority, temporarily suspended the proposed rule change and instituted proceedings to determine whether to approve or disapprove the proposed rule change.[5]

II. Description of the Proposal and Comment Letters

NYSE National proposes to establish fees for the NYSE National Integrated Feed.[6] According to NYSE National, the NYSE National Integrated Feed is a NYSE National-only market data feed that provides vendors and subscribers on a real-time basis with a unified view of events, in sequence, as they appear on the NYSE National matching engine.[7] The NYSE National Integrated Feed includes depth-of-book order data, last sale data, security status updates (*e.g.,* trade corrections and trading halts), and stock summary messages.[8] It also includes information about NYSE

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A).

[4] *See* Securities Exchange Act Release No. 88211 (February 14, 2020), 85 FR 9847 (''Notice''). Comments received on the Notice are available on the Commission's website at *https://www.sec.gov/comments/sr-nysenat-2020-05/srnysenat202005.htm.* The Commission notes that, on December 4, 2019, NYSE National filed a proposed rule change to establish fees for the NYSE National Integrated Feed that are identical to the fees proposed in this filing. *See* Securities Exchange Act Release No. 87797 (December 18, 2019), 84 FR 71025 (December 26, 2019) (SR–NYSENAT–2019–31). Comments received on SR–NYSENAT–2019–31 are available on the Commission's website at *https://www.sec.gov/comments/sr-nysenat-2019-31/srnysenat201931.htm.* On January 31, 2020, the Commission temporarily suspended SR–NYSENAT–2019–31 and instituted proceedings to determine whether to approve or disapprove that proposed rule change. *See* Securities Exchange Act Release No. 88109, 85 FR 6982 (February 6, 2020) (''SR–NYSENAT–2019–31 OIP''). On February 3, 2020, NYSE National withdrew SR–NYSENAT–2019–31. *See* Securities Exchange Act Release No. 88118 (February 4, 2020), 85 FR 7611 (February 10, 2020).

[5] *See* Securities Exchange Act Release No. 88538, 85 FR 19541 (April 7, 2020) (''Suspension Order'').

[6] The fees became effective on February 3, 2020. Prior to February 3, 2020, NYSE National did not charge any fees for the NYSE National Integrated Feed. *See* Notice, *supra* note 4, at 9847.

[7] *See id.*

[8] *See id.*

National's best bid or offer at any given time.[9] NYSE National proposes the following fees for the NYSE National Integrated Feed:

- $2,500 per month access fee, which would be charged (once per firm) to any data recipient that receives a data feed of the NYSE National Integrated Feed;[10]
- $1,500 per month redistribution fee, which would be charged (once per redistributor account) to any redistributor[11] of the NYSE National Integrated Feed;
- $10 per month professional per user fee and $1 per month non-professional per user fee, which would apply to each display device that has access to the NYSE National Integrated Feed;[12]
- Non-display use[13] fees:
  - ○ $5,000 per month category 1 non-display fee, which would apply when a data recipient's non-display use of real-time market data is on its own behalf;
  - ○ $5,000 per month category 2 non-display fee, which would apply when a data recipient's non-display use of real-time market data is on behalf of its clients;
  - ○ $5,000 per platform per month category 3 non-display fee (capped at $15,000), which would apply when a data recipient's non-display use of real-time market data is for the purpose of internally matching buy and sell orders within an organization, including matching customer orders on a data recipient's own behalf and on behalf of its clients;[14]
- $1,000 per month non-display use declaration late fee, which would apply to any data recipient that is paying an access fee for the NYSE National Integrated Feed and that fails to complete and submit the annual non-display use declaration by December 31 of the year, and would apply beginning January 1 and for each month thereafter until the data recipient has completed and submitted the annual non-display use declaration;[15] and
- $200 per month multiple data feed fee, which would apply to any data recipient that takes a data feed for a market data product in more than two locations, and would apply to each location, beyond the first two locations, where the data recipient receives a data feed.[16]

The access fees, professional user fees, and non-display fees would not apply to Federal agencies[17] that subscribe to the products listed on the proposed fee schedule that includes such fees.[18]

Finally, first-time subscribers[19] would be eligible for a free trial by contacting NYSE National and would not be charged the access fee, the non-display fee, any applicable professional and non-professional user fee, and the redistribution fee for one calendar month for each of the products listed on the proposed fee schedule.[20] The free trial would be for the first full calendar month following the date a subscriber is approved to receive trial access to NYSE National market data.[21] As proposed, NYSE National would provide the one-month free trial for a particular product to each subscriber only once.[22]

In its proposal, NYSE National makes multiple arguments in support of the proposed fees. With respect to whether the proposed fees are reasonable, NYSE National states that exchanges in general function as platforms between consumers of market data and consumers of trading services, and that overall competition between exchanges will limit their overall profitability.[23] In connection with these arguments, NYSE National asserts that the introduction of the NYSE Integrated Feed in 2015 attracted more trading to NYSE by both subscribers and non-subscribers to the NYSE Integrated Feed,[24] and concludes that overall competition between exchanges will limit their overall profitability (not margins on any particular side of the platform).[25] According to NYSE National, exchanges are platforms for market data and transaction services and competition for order flow on the trading side of the platform acts to constrain the pricing of market data on the other side of the platform.[26]

In addition, NYSE National argues that, due to the ready availability of substitutes and the low cost to move order flow to the substitute trading venues, an exchange setting market data fees that are not at competitive levels would expect to quickly lose business to alternative platforms with more attractive pricing.[27] NYSE National argues that subscribing to the NYSE National Integrated Feed is optional, that its customers may choose to discontinue using the feed once the proposed fees are effective, and that any customers who choose to discontinue

[9] *See id.*

[10] Data recipients that only use display devices to view NYSE National Integrated Feed data and do not separately receive a data feed would not be charged an access fee. *See id.* at 9848.

[11] A redistributor would be a vendor or person that provides a real-time NYSE National market data product externally to a data recipient that is not its affiliate or wholly-owned subsidiary, or to any system that an external data recipient uses, irrespective of the means of transmission or access. *See id.*

[12] *See id.*

[13] Non-display use would mean accessing, processing, or consuming the NYSE National Integrated Feed, delivered directly or through a redistributor, for a purpose other than in support of a data recipient's display or further internal or external redistribution. *See id.* As proposed, non-display use would include trading uses such as high frequency or algorithmic trading, as well as any trading in any asset class, automated order or quote generation and order pegging, price referencing for algorithmic trading or smart order routing, operations controls programs, investment analysis, order verification, surveillance programs, risk management, compliance, and portfolio management. *See id.* One, two, or three categories of non-display use may apply to a data recipient. *See id.* Moreover, data recipients that receive the NYSE National Integrated Feed for non-display use would be required to complete and submit a non-display use declaration before they would be authorized to receive the feed. *See id.* at 9849. In addition, if a data recipient's use of the NYSE National Integrated Feed data changes at any time after the data recipient submits a non-display use declaration, the data recipient must inform NYSE National of the change by completing and submitting an updated declaration reflecting the change of use at the time of the change. *See id.*

[14] According to NYSE National, category 3 non-display fees would apply to non-display use in trading platforms, such as, but not limited to, alternative trading systems (''ATSs''), broker crossing networks, broker crossing systems not filed as ATSs, dark pools, multilateral trading facilities, exchanges, and systematic internalization systems. *See id.* at 9848–49.

[15] *See id.* at 9849.

[16] *See id.*

[17] The term ''Federal agencies'' as used in the proposed fee schedule would include all Federal agencies subject to the Federal Acquisition Regulation (''FAR''), as well as any Federal agency not subject to FAR that has promulgated its own procurement rules. *See id.* All Federal agencies that subscribe to the NYSE National real-time proprietary market data products would continue to be required to execute the appropriate subscriber agreement, which includes, among other things, provisions against the redistribution of data. *See id.*

[18] The proposed fee schedule lists NYSE National BBO, NYSE National Trades, and NYSE National Integrated Feed, and specifies that there would be no fees for NYSE National BBO and NYSE National Trades.

[19] A first-time subscriber would be any firm that has not previously subscribed to a particular product listed on the proposed fee schedule. *See* Notice, *supra* note 4, at 9849.

[20] *See id.*

[21] *See id.* at 9849–50.

[22] *See id.* at 9850.

[23] *See id.* at 9852.

[24] *See id.* NYSE National provides a report by Marc Rysman to support these arguments. *See* Marc Rysman, *Stock Exchanges as Platforms for Data and Trading* (December 2, 2019) (''Rysman Paper''), *available at https://www.sec.gov/rules/sro/nysenat/2020/34-88211-ex3b.pdf.* NYSE National also states that, since May 2018, when NYSE National relaunched trading, it has observed a direct correlation between the steady increase of subscribers to the NYSE National Integrated Feed and the increase in NYSE National's transaction market share volume over the same period. *See* Notice, *supra* note 4, at 9850. NYSE National states that, between May 2018 and October 2019, it has grown from 0% to nearly 2% market share of consolidated trading volume and, between May 2018 and November 2019, the number of NYSE National Integrated Feed subscribers increased from 12 to 57. *See id.* at 9847–48, 9852.

[25] *See* Notice, *supra* note 4, at 9852 (citing Rysman Paper, *supra* note 24).

[26] *See id.* at 9853.

[27] *See id.*

using the feed may choose to shift order flow away from NYSE National.[28] Similarly, NYSE National argues that its market data pricing is constrained by the availability of numerous substitute platforms offering competing proprietary market data products and trading services.[29]

In addition to its platform-based arguments, NYSE National presents an alternative competition-based argument, asserting that the NYSE National Integrated Feed is sold in a competitive market.[30] NYSE National asserts that exchanges compete with each other in selling proprietary market data products, as well as with consolidated data feeds and with data provided by ATSs.[31] More specifically, NYSE National states that NYSE National BBO (which includes best bid and offer information for NYSE National on a real-time basis), NYSE National Trades (which includes NYSE National last sale information on a real-time basis), and consolidated data feeds are substitutes for the NYSE National Integrated Feed and constrain NYSE National's ability to charge supracompetitive prices for the feed.[32] In addition, NYSE National states that, since the date of filing of SR–NYSENAT–2019–31 and before the proposed fees went into effect on February 3, 2020, five subscribers to the NYSE National Integrated Feed (*i.e.,* nearly nine percent of the prior subscriber base) have cancelled their subscriptions due to the imminent imposition of the fees.[33] Moreover, NYSE National states that a sixth customer informed NYSE National that if NYSE National is permitted to impose the fees, the customer would cancel its subscription to the NYSE National Integrated Feed and instead subscribe to the NYSE National BBO feed.[34]

With respect to the other requirements under the Act, NYSE National argues that the proposed fees are equitably allocated and are not unfairly discriminatory because they would apply on an equal basis to all data recipients that choose to subscribe to the data in a manner that is subject to an applicable fee and because any differences among categories of users are justified.[35] Specifically, NYSE National argues that the professional and non-professional user fee structure has long been used by NYSE National to reduce the price of data to non-professional users and to make it more broadly available, and that the non-display fee structure results in subscribers with greater uses of the data paying higher fees and subscribers with fewer uses of the data paying lower fees.[36] For similar reasons, and because it claims numerous substitute market data products are available, NYSE National argues that the proposed fees do not impose an unnecessary or inappropriate burden on competition.[37]

With respect to the redistribution fee, NYSE National argues that the proposed fee is reasonable because vendors that would be charged the proposed fee would profit by re-transmitting NYSE National's market data to their customers,[38] and that the proposed fee is equitable and not unfairly discriminatory because the fees would be charged on an equal basis to those vendors that choose to redistribute the feed.[39] Similarly, with respect to category 3 non-display fees, which would be charged to each trading platform on which the customer uses non-display data (capped at three platforms), NYSE National argues that the proposal is reasonable, equitable, and not unfairly discriminatory because such use of data is directly in competition with NYSE National and NYSE National should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible.[40]

Finally, with respect to the non-display use declaration late fee and the multiple data feed fee, NYSE National claims that these fees are reasonable, equitable, and not unfairly discriminatory because they would offset NYSE National's administrative burdens and costs associated with incorrect billing, late payments, and tracking data usage locations.[41]

One commenter states that NYSE National fails to provide the necessary information for the Commission to determine whether the proposed fees meet the requirements of the Act.[42] This commenter argues that the NYSE National Integrated Feed is not subject to competitive forces because there are no available substitutes to NYSE National's depth-of-book product.[43] This commenter also argues that competition for order flow under the ''platform theory'' does not constrain the cost of market data, but instead results in supra-monopoly prices for market data products.[44] In addition, this commenter argues that NYSE National makes an unpersuasive attempt to show an elasticity of demand for the NYSE National Integrated Feed (*i.e.,* in response to the fee increase, 5 of the 57 subscribers notified NYSE National of their intent to cancel their subscriptions before the fees went into effect).[45] Moreover, this commenter argues that exchanges have yet to show an increase (or decrease) in trading volume after reducing (or increasing) a respective exchange's price of market data, and that NYSE National does not state the anticipated impact on order flow from losing subscribers to the NYSE National Integrated Feed.[46] Finally, the commenter argues that, because it believes competitive forces have not constrained the cost of market data, NYSE National should provide additional information on cost.[47]

[28] *See id.* at 9850, 9853.

[29] *See id.* at 9853.

[30] *See id.* at 9851.

[31] *See id.* NYSE National provides a report by Charles M. Jones to support these arguments. *See* Charles M. Jones, *Understanding the Market for U.S. Equity Market Data* (August 31, 2018) (''Jones Paper''), *available at https://www.sec.gov/rules/sro/nysenat/2020/34-88211-ex3a.pdf.* The Jones Paper also states that the market for order flow and the market for market data are closely linked, and that an exchange needs to consider the negative impact on its order flow if it raises the price of market data. *See id.*

[32] *See* Notice, *supra* note 4, at 9854.

[33] *See id.* at 9848.

[34] NYSE National states that six lost subscribers constitute 10.5 percent of the prior NYSE National Integrated Feed subscriber base. *See id.*

[35] *See id.* at 9856–58.

[36] *See id.* at 9856–57.

[37] *See id.* at 9858–59.

[38] *See id.* at 9854.

[39] *See id.* at 9856–57.

[40] *See id.* at 9855–58.

[41] *See id.*

[42] *See* letter from Ellen Greene, Managing Director, Equities & Options Market Structure, Securities Industry and Financial Markets Association (''SIFMA''), to Vanessa Countryman, Secretary, Commission, dated March 11, 2020 (''SIFMA Letter''). This commenter also refers to the comment letter it submitted on SR–NYSENAT–2019–31 in stating that the proposal does not meet the requirements of the Act. *See id.* at 2. *See also* SR–NYSENAT–2019–31 OIP, *supra* note 4, at 6984–85 (describing the commenter's letter on SR–NYSENAT–2019–31); letter from Robert Toomey, Managing Director and Associate General Counsel, SIFMA, to Vanessa Countryman, Secretary, Commission, dated January 21, 2020, *available at https://www.sec.gov/comments/sr-nysenat-2019-31/srnysenat201931-6678406-204968.pdf.*

[43] *See* SIFMA Letter, *supra* note 42, at 2.

[44] *See id.*

[45] *See id.*

[46] *See id.*

[47] *See id.*

Another commenter also states that the information provided by NYSE National is not adequate to establish that the proposed fees are consistent with the Act and Commission rules.[48] This commenter questions whether third parties can compete with NYSE National in offering data related to activity on NYSE National.[49] This commenter also questions NYSE National's assertion that market participants have a meaningful ability to choose whether or not to connect to the NYSE National Integrated Feed and believes instead that many market participants must buy the feed.[50] This commenter acknowledges that NYSE National provides the number of customers that discontinued using the NYSE National Integrated Feed in response to the proposed fees, but expresses concern that NYSE National has not provided any relevant information about these customers (*e.g.,* why they subscribed to the NYSE National Integrated Feed in the first place; whether they were proprietary trading firms, agency brokers, or data vendors; and whether and how often they sent orders to NYSE National).[51] This commenter also states that NYSE National should update and further elaborate on information about the remaining subscribers.[52]

Moreover, this commenter argues that NYSE National's discussions regarding the reasonableness of the proposed fees (*i.e.,* the comparison to similar fees charged by affiliated exchanges, the nature of the market for order flow, the availability of other data options, and the lack of a relation between the proposed fees and the costs of production) do not support a finding that the proposed fees are reasonable.[53] This commenter also states that NYSE National does not provide any information about the costs of production for the NYSE National Integrated Feed, the expected revenue NYSE National projects to generate from the proposed fees, the impact of the proposed fees on subscribers, the competition between subscribers and non-subscribers, and whether the proposed fees would be equitably allocated and would not impose any undue burden on competition.[54] In addition, the commenter states that NYSE National does not provide any information about the latency difference between the NYSE National Integrated Feed and the consolidated data feed or other methods of transmitting data.[55] Finally, this commenter objects to NYSE National's platform-based arguments, stating that the supply and demand functions for order flow and market data are separate.[56]

III. Request for Information and Additional Comment

The Commission must determine on a factual record whether NYSE National has established by a preponderance of the record that its proposed fees: (1) Provide for the equitable allocation of reasonable fees among members, issuers, and other persons using the exchange's facilities;[57] (2) perfect the mechanism of a free and open market and a national market system, protect investors and the public interest, and are not designed to permit unfair discrimination between customers, issuers, brokers, or dealers;[58] and (3) do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.[59]

The Commission believes that there are significant unresolved questions about whether NYSE National has produced sufficient factual support to satisfy its burden to demonstrate that its proposed fees meet the standards set forth in the Act. Under Commission Rule of Practice 700(b)(3), NYSE National has the ''burden to demonstrate that a proposed rule change is consistent with the [Act] and the rules and regulations issued thereunder.''[60] The description of a proposed rule change, its purpose and operation, its effect, and a legal analysis of its consistency with applicable requirements must all be sufficiently detailed and specific to support an affirmative Commission finding,[61] and any failure of an SRO to provide this level of information may result in the Commission not having a sufficient basis to make an affirmative finding that a proposed rule change is consistent with the Act and the applicable rules and regulations.[62]

In seeking additional information and comment, the Commission intends to further consider whether NYSE National has met its burden to establish that the proposed fees for the NYSE National Integrated Feed are consistent with the regulatory requirements applicable to a national securities exchange.

1. Are the proposed fees constrained by competition?

As noted above, in support of the proposed fees, NYSE National asserts that exchanges function as platforms between consumers of market data and consumers of trading services, and that competition among exchanges will limit their overall profitability (not margins on any particular side of the platform).[63] According to NYSE National, exchanges are platforms for market data and transaction services, and competition for order flow on the trading side of the platform acts to constrain the pricing of market data on the other side of the platform.[64] In connection with this platform theory-based argument, the Commission believes that it does not have sufficient information to make an affirmative finding that the rule change is consistent with the Act and the rules and regulations thereunder. The Commission believes that additional information from NYSE National would assist the Commission's analysis of whether NYSE National has met its burden under the Act. The Commission recognizes that there are various combinations of factual information and analysis that NYSE National could provide to establish the presence of sufficient competitive forces or otherwise to meet its burden under the Act.

The Commission further believes that with regard to NYSE National's platform theory-based arguments, some or all of the following information, including in combination with other information,

[48] *See* letter from Tyler Gellasch, Executive Director, The Healthy Markets Association, to Vanessa Countryman, Office of the Secretary, Commission, dated March 12, 2020 (''Healthy Markets Letter''). *See also* SR–NYSENAT–2019–31 OIP, *supra* note 4, at 6984 (describing the commenter's letter on SR–NYSENAT–2019–31); letter from Tyler Gellasch, Executive Director, The Healthy Markets Association, to Vanessa Countryman, Office of the Secretary, Commission, dated January 16, 2020, *available at https://www.sec.gov/comments/sr-nysenat-2019-31/srnysenat201931-6663540-203934.pdf.*

[49] *See* Healthy Markets Letter, *supra* note 48, at 6–8. This commenter states that NYSE National controls who, under what terms, and when anyone other than NYSE National can obtain order-related information about NYSE National. *See id.* at 7.

[50] *See id.* at 4–5. According to this commenter, if one set of market participants has access to a faster, richer data set, then those without that information will not be as competitive and may not be able to quote or otherwise route orders in a manner that could effectively achieve best execution. *See id.* at 8.

[51] *See id.* at 5–6.

[52] *See id.* at 6.

[53] *See id.* at 8–9.

[54] *See id.* at 9.

[55] *See id.*

[56] *See id.* at 9–10.

[57] 15 U.S.C. 78f(b)(4).

[58] 15 U.S.C. 78f(b)(5).

[59] 15 U.S.C. 78f(b)(8).

[60] 17 CFR 201.700(b)(3).

[61] *See id.*

[62] *See id.* Moreover, as is the case with a proposed rule change under Section 19(b)(2) of the Act, the Commission must make an affirmative finding to approve any fee filing for which it has instituted proceedings to determine whether the proposed rule change is consistent with the Act.

[63] *See* Notice, *supra* note 4, at 9852 (citing Rysman Paper, *supra* note 24).

[64] *See id.* at 9853.

would assist its analysis of whether NYSE National has met its burden:

• An explanation of NYSE National's characterization that market data and transaction services are the two sides of the exchange platform, including whether there are any other sides of the exchange platform (*e.g.,* connectivity; listings, for an exchange that lists securities) and, if so, whether the other sides of the exchange platform should also be considered in analyzing the proposed fees.

• Information sufficient to assess whether aggregate profit margins, returns on assets, or other metrics indicate the presence of competition. In discussing these metrics, it may be relevant to discuss whether and, if so, to what extent some of NYSE National's business lines would cross-subsidize its other business lines with the proposed fees in place. For example, NYSE National could compute operating profit margins and returns on assets for the entirety of NYSE National and for each of its business lines (including proprietary market data products, consolidated market data products, market connectivity services, and transaction services) for a period when the proposed fees were in place (*e.g.,* for the period from February 3, 2020 to the date of the Suspension Order). NYSE National could also estimate projected operating profit margins and returns on assets for the entirety of NYSE National and for each of its business lines (including proprietary market data products, consolidated market data products, market connectivity services, and transaction services) for a period in the second half of 2020 (*e.g.,* for the third calendar quarter of 2020), with the assumption that the proposed fees are in place during that period.[65] Accordingly, explaining the methodology for computing profit margins, returns on assets, or any other metrics provided (including the methodology for allocating expenses and assets to business lines and among the affiliated exchanges under the NYSE Group[66]) and supporting any assumptions that it may need to make (such as assumptions underlying its treatment of costs of revenues and assumptions needed to project financials) may be necessary for the metrics to be meaningful.

• Any other information to support the argument that competition between exchanges will limit the overall profitability of NYSE National and meaningfully constrain NYSE National's ability to price its proprietary market data products at supracompetitive prices. In particular, NYSE National should consider providing empirical support substantiating its claims. For example, because NYSE National supported its arguments with information relating to NYSE and the NYSE Integrated Feed,[67] such empirical support could include the financial information specified above for NYSE before and after specific increases or decreases in the NYSE Integrated Feed fees. To the extent that NYSE National argues that competition from other exchanges on the trading side meaningfully constrains the pricing on the market data side (or other applicable sides) of the platform, it could produce disaggregated (*i.e.,* by business line) profit-margin and return-on-assets information in order to establish that it has met its burden under the Act.

• An explanation of whether platform-based competition functions differently for an exchange with a smaller market share (*e.g.,* NYSE National) as compared to an exchange with a larger market share (*e.g.,* NYSE) and if so, an explanation of any differences.

• NYSE National may provide other data to substantiate its platform theory-based argument, including the claims that competition among exchanges will limit the overall profitability of NYSE National's platform and competition for order flow on the trading side of the platform acts to constrain the pricing of market data on the other side of the platform.

As noted above, in addition to its platform theory-based arguments, NYSE National argues that an exchange setting market data fees that are not at competitive levels would expect to quickly lose business to alternative platforms with more attractive pricing.[68] NYSE National argues that subscribing to the NYSE National Integrated Feed is optional, that its customers may choose to discontinue using the feed once the proposed fees are effective, and that any customer who chooses to discontinue using the feed may choose to shift order flow away from NYSE National.[69] The Commission believes that some or all of the following information (including in combination with other information) would inform the Commission's analysis of these arguments:

• For periods that would provide meaningful comparisons (*e.g.,* each completed calendar quarter of 2019 and 2020, and for each full month from November 2019 to date): (1) The number of NYSE National Integrated Feed customers and the market participant type of each customer (*e.g.,* ATS, broker-dealer, market data vendor, any other specified type of market participant); (2) the total number of unique clients, and the average number of unique clients per customer, under each of the proposed fees (*i.e.,* each product code as used by NYSE National) (calculated separately for the group of customers that discontinued using the NYSE National Integrated Feed after the proposed fees became effective (''discontinued NYSE National customers''), the group of customers that continued using the NYSE National Integrated Feed after the proposed fees became effective (''continued NYSE National customers''), and others (*e.g.,* customers that discontinued using the NYSE National Integrated Feed before the proposed fees became effective, customers that started using the NYSE National Integrated Feed after the proposed fees became effective)); and (3) the aggregate dollar trading volume for customers and firms on NYSE National and the average dollar trading volume per customer or firm on NYSE National (calculated separately for discontinued NYSE National customers, continued NYSE National customers, and others (*e.g.,* customers that discontinued using the NYSE National Integrated Feed before the proposed fees became effective, customers that started using the NYSE National Integrated Feed after the proposed fees became effective, firms that have not used the NYSE National Integrated Feed)). The Commission believes that this type of information would inform the Commission's analysis of NYSE National's argument that customers who choose to discontinue using the NYSE National Integrated Feed may choose to shift order flow away from NYSE National.

• Other specific, factual information that demonstrates that customers may choose to discontinue using an

[65] NYSE National may seek confidential treatment for such projected financial information, or other information requested in this order. The Commission anticipates that such information will remain non-public subject to federal law.

[66] The Commission notes that NYSE National, New York Stock Exchange LLC (''NYSE''), NYSE Arca, Inc., NYSE American LLC, and NYSE Chicago, Inc. are all, directly or indirectly, wholly-owned subsidiaries of NYSE Group, Inc. (''NYSE Group''). The methodology for allocating expenses across affiliated exchanges under the NYSE Group would enable the Commission to assess how an analysis of NYSE National may be different from its affiliated exchanges because it is a smaller exchange that is part of a larger exchange group. In this context, infrastructure and other NYSE National expenses may be cross-subsidized from investments and services provided by the other NYSE Group exchanges. To the extent that this is the case, NYSE National should explain how this potentially affects the analysis and computation of its expenses, profit margins, and returns-on-assets.

[67] *See* Rysman Paper, *supra* note 24.

[68] *See* Notice, *supra* note 4, at 9853.

[69] *See id.* at 9850, 9853.

exchange proprietary depth-of-book market data feed in response to a new fee or fee increase, and that the customers who choose to discontinue using the market data feed also shift order flow away from such exchange. For example, because NYSE National supported its arguments with information relating to the NYSE Integrated Feed,[70] NYSE National could provide the following information, calculated before and after specific increases in the NYSE Integrated Feed fees: (1) The number of NYSE Integrated Feed customers and the market participant type of each customer; (2) the total number of unique clients, and the average number of unique clients per customer, under each fee (*i.e.,* each product code as used by NYSE) (calculated separately for the group of customers that discontinued using the NYSE Integrated Feed after the fee was initially imposed or after the fee increase (''discontinued NYSE customers''), the group of customers that continued using the NYSE Integrated Feed after the fee was initially imposed or after the fee increase (''continued NYSE customers''), and others); and (3) the aggregate dollar trading volume for customers and firms on NYSE and the average dollar trading volume per customer or firm on NYSE (calculated separately for discontinued NYSE customers, continued NYSE customers, and others). This type of information would inform the Commission's analysis of whether NYSE National has met its burden to demonstrate that customers who choose to discontinue using a depth-of-book market data feed also shift order flow away from the exchange offering the feed.

- NYSE National may provide other data to substantiate its claim that customers may choose to discontinue using the NYSE National Integrated Feed once the proposed fees are effective, and that customers who choose to discontinue using the feed may choose to shift order flow away from NYSE National.

2. Are there substitutes for the NYSE National Integrated Feed?

The Commission also believes that additional information regarding NYSE National's substitution-based arguments would assist the Commission in its analysis of whether NYSE National has met its burden under the Act. The Commission believes that some or all of the following information (including in combination with other information) would further inform the Commission's analysis of NYSE National's substitution-based arguments:

- Information regarding how many of the five original subscribers that cancelled their NYSE National Integrated Feed subscription subsequently started using the NYSE National BBO or NYSE National Trades feed, or any other proprietary market data feed, and the market participant type of each of these five subscribers.
- Information regarding how many additional customers discontinued (or notified NYSE National of their intention to discontinue) using the NYSE National Integrated Feed after the proposed fees were implemented on February 3, 2020, how many of these customers subsequently started (or notified NYSE National of their intention to start) using the NYSE National BBO or NYSE National Trades feed, or any other proprietary market data feed, and the market participant type of each of these customers.
- NYSE National may provide other data to substantiate its substitution-based arguments.

The Commission believes that responses to some or all of these requests would inform the Commission's analysis of NYSE National's argument that the NYSE National Integrated Feed is sold in a competitive market and that other market data feeds are substitutes for the NYSE National Integrated Feed.

3. Are the fees reasonable, equitable, and not unfairly discriminatory?

The Commission believes that additional information from NYSE National could inform the Commission's analysis of the allocation of the proposed fees to different types of market participants (*e.g.,* whether most of the fees are borne by a particular type of customer and whether such an outcome would result in an inequitable allocation of the fees or render the fees unfairly discriminatory). For example, some or all of the following information (including in combination with other information) could meaningfully inform the Commission's analysis:

- In addition to the customer, unique client, and dollar trading volume information discussed in Item 1 above,[71] NYSE National could provide projections of the same customer and unique client information (with the assumption that the proposed fees are in place, and including the methodology for and assumptions underlying such projections) for the uncompleted calendar quarters of 2020 up to the third calendar quarter of 2020. The Commission believes that this type of information would inform the Commission's analysis of the impact of the proposed fees on different groups of market participants, including because this type of information would allow the Commission to compare: (1) The number of discontinued NYSE National customers against the number of continued NYSE National customers and the number of other customers; and (2) the total and average number of unique clients and the aggregate and average dollar trading volume across these three groups of customers.
- NYSE National may provide other data to substantiate its claims that the proposed fees are equitably allocated, are not unfairly discriminatory, and do not impose an unnecessary or inappropriate burden on competition.

With respect to the redistribution fee, as noted above, NYSE National argues that the proposed fee is reasonable because vendors that would be charged the proposed fee would profit by re-transmitting NYSE National's market data to their customers,[72] and that the proposed fee is equitable and not unfairly discriminatory because the fee would be charged on an equal basis to those vendors that choose to redistribute the feed.[73] Similarly, with respect to category 3 non-display fees, which would be charged to each trading platform on which the customer uses non-display data (capped at three platforms), NYSE National argues that the proposal is reasonable, equitable, and not unfairly discriminatory because such use of data is directly in competition with NYSE National and NYSE National should be permitted to recoup some of its lost trading revenue by charging for the data that makes such competition possible.[74] The Commission believes its analysis of the proposed redistribution fee and category 3 non-display fees would benefit from a fuller explanation, with supporting facts, of why these fees, which are applied specifically to NYSE National's competitors, would not be unfairly discriminatory toward those competitors or impose an unnecessary or inappropriate burden on competition.

[70] *See* Rysman Paper, *supra* note 24.

[71] NYSE National states that, based on usage at the time of the filing of SR–NYSENAT–2019–31, at least 34 firms would be subject to category 1 non-display fees, at least 14 firms would be subject to category 2 non-display fees, and at least 10 firms would be subject to category 3 non-display fees. *See* Notice, *supra* note 4, at 9850. However, NYSE National does not provide the same usage information for each of the other proposed fees (*e.g.,* the number of professional users and non-professional users).

[72] *See id.* at 9854.

[73] *See id.* at 9856–57.

[74] *See id.* at 9855–58.

Finally, as noted above, with respect to the non-display use declaration late fee and the multiple data feed fee, NYSE National claims that these fees are reasonable, equitable, and not unfairly discriminatory because they would offset NYSE National's administrative burdens and costs associated with incorrect billing, late payments, and tracking data usage locations.[75] The Commission again believes that its analysis would benefit from a fuller explanation, with supporting facts, of NYSE National's ''administrative burdens'' and ''administrative costs'' associated with these activities. The Commission believes that such information would inform the Commission's analysis of the non-display use declaration late fee and the multiple data feed fee.

4. General Request for Comment

The Commission asks that commenters address the sufficiency and merit of NYSE National's statements in support of the proposal, in addition to any other comments they may wish to submit about the proposed rule change. For example, the Commission believes that its analysis may benefit from comment, including, where relevant, any specific data, statistics, or studies, on the following:

- Do the proposed fees represent an equitable allocation of reasonable fees, not permit unfair discrimination, and not impose any unnecessary or inappropriate burden on competition? Please explain and provide supporting information.
- Are the proposed fees constrained by robust competition? Please explain and provide supporting information.
- Are NYSE National's characterization of platform competition and characterization of market data and transaction services as two sides of an exchange platform correct? Are there any other sides of an exchange platform (*e.g.,* connectivity, listing) and should these other sides be considered in analyzing the proposed fees?
- Should the question of whether the NYSE National Integrated Feed fees are constrained by competitive forces be analyzed using any separate methodology not discussed in the proposal (*i.e.,* other than substitution and platform competition)? If so, please explain such methodology.
- Does an analysis of the total market data revenue from NYSE National's parent company demonstrate or support NYSE National's assertion that the market for proprietary market data products is characterized by robust competition?[76] Why or why not? Should other data, such as operating profit margins and returns on assets for the entirety of NYSE National and for each of its business lines (including proprietary market data products, consolidated market data products, market connectivity services, and transaction services), also be analyzed in order to evaluate NYSE National's assertion? Why or why not?
- Does an analysis of the effect of the introduction of the NYSE Integrated Feed on trading volume on NYSE demonstrate or support NYSE National's assertions that platform economics applies to exchanges' sale of proprietary market data products and trading services and that platform competition effectively constrains the pricing of those data products?[77] Why or why not?

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSENAT–2020–05 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSENAT–2020–05. The file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of NYSE National. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make publicly available. All submissions should refer to File No. SR–NYSENAT–2020–05 and should be submitted on or before July 10, 2020.

By the Commission.

Eduardo A. Aleman,

Deputy Secretary.

[FR Doc. 2020–13201 Filed 6–18–20; 8:45 am]

BILLING CODE 8011–01–P

[75] *See id.*

[76] *See* Jones Paper, *supra* note 31.

[77] *See* Rysman Paper, *supra* note 24.

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89071; File No. SR–GEMX–2020–15]

Self-Regulatory Organizations; Nasdaq GEMX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the GEMX Disciplinary Rules in General 5 To Incorporate by Reference The Nasdaq Stock Market LLC's Series 8000 and 9000 Rules

June 15, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 10, 2020, Nasdaq GEMX, LLC (''GEMX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the GEMX Disciplinary Rules in General 5 to incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') Series 8000 and 9000 Rules, currently located under the General 5 title of the Nasdaq rulebook,[3] instead of the BX Rules, which the Exchange currently incorporates by reference.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqgemx.cchwallstreet.com/,*

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098).

at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In connection with a recent rule change to relocate the Nasdaq BX, Inc. (''BX'') Disciplinary Rules under the General 5 title (''Discipline''),[4] and incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') Series 8000 and 9000 Rules, GEMX proposes to similarly incorporate by reference Nasdaq's Series 8000 and 9000 Rules.

The BX Disciplinary Rules, which were relocated to General 5 of the BX Rules,[5] were replaced with introductory paragraphs that respectively incorporate by reference the Nasdaq Series 8000 and 9000 Rules (located under the General 5 title in the Nasdaq rulebook).[6] Currently, GEMX incorporates the BX Disciplinary Rules within the Series 8000 and 9000 Rules, which were relocated to General 5 of the BX Rules with the aforementioned rule change.[7] At this time, GEMX proposes to incorporate by reference the Nasdaq Series 8000 and 9000 Rules (located in General 5 Discipline), respectively, and state that such Nasdaq Rules shall be applicable to Exchange Members, associated persons, and other persons subject to GEMX's jurisdiction.

Except as noted below, the Nasdaq Series 8000 and 9000 Rules are substantially similar to BX's Disciplinary Rules, which the Exchange currently incorporates by reference. The following discussions identify the differences between the current BX Disciplinary Rules and the corresponding Nasdaq Disciplinary Rules to be incorporated by reference into GEMX:

Current BX IM–8310–3(b)

Current BX Rule 9120(f) provides that ''[t]he term ''Department of Enforcement'' means the Department of Enforcement of FINRA Regulation, acting on behalf of the Exchange pursuant to the FINRA Regulatory Contract.''[8] Current BX IM–8310–3(b), however, uses the term ''Department of Enforcement of FINRA.'' Since Nasdaq IM–8310–3(b) uses the term ''Department of Enforcement'' GEMX believes it is appropriate to utilize the Nasdaq terms going forward and incorporate by reference into the GEMX rule.

Current BX Rule 8320

In 2010, Nasdaq created Rule 7007 (''Collection of Fees'') to facilitate an efficient method of collecting undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to Nasdaq from The Nasdaq Option Market (''NOM'') Participants.[9]

Similarly, in 2012, BX adopted its options market rules (''BX Options Market'') to operate as a fully automated, price/time priority execution system built on the core functionality of NOM.[10] In its filing, BX proposed to adopt, under respective Chapter XV, Section 2, a rule identical to the Nasdaq Collection of Fees rule.[11] Although, at the time of its creation, the Nasdaq Collection of Fees rule was cross-referenced to current Nasdaq Rule 8320(a)(1),[12] such cross-reference was not included in the filing that created the BX Options Market. GEMX also has the same Collection of Fees rule,[13] that is identical to the Nasdaq rule. Because BX Rule 8320, which GEMX incorporates by reference, does not include a cross-reference to the Collection of Fees rule, GEMX will follow the Nasdaq rule going forward, which has the correct cross-reference. The Exchange also proposes to add rule text, within General 5, Section 3, to note the distinction between the location of the Collection of Fees rules. Specifically, the Exchange proposes to add rule text to provide that references in the Nasdaq 8000 Series to ''Nasdaq's Options 7, Section 1'' shall be read to refer to GEMX Options 7, Section 2.

Based on the above, the Exchange believes that it is appropriate that GEMX adopts the aforementioned cross-reference to make the collection of fees owed to the Exchange more efficient. Therefore, the Exchange believes that it is appropriate to incorporate by reference Nasdaq Rule 8320 into GEMX Rules.

Current BX Rule 9120

In 2018, BX amended its Disciplinary Rules to align them with the investigatory and disciplinary processes of Nasdaq PHLX LLC (''Phlx'').[14] As stated in its proposal, the changes to the ''Interested Staff'' concept (which, at the time, was relocated under 9120(r)) were done to conform the BX rule to Phlx's definition. At the time, however, the proposed harmonizing changes to BX Rule 9120(r)(1)(B) inadvertently excluded the words ''Head of'' and omitted to add the word ''the''; indeed, the text should have read ''Head of the Exchange's Regulation Department'' instead of, simply, ''Exchange's Regulation Department.''

The correct definition, as explained above, would also align with the term currently defined in Nasdaq Rule 9120(r)(1)(B), which provides that ''Interested Staff'' shall mean ''an Exchange employee of the Nasdaq Regulation Department who reports, directly or indirectly, to the Head of the Nasdaq Regulation Department.''

The Exchange believes that it is appropriate to apply Nasdaq Rule 9120 and to incorporate it by reference into the GEMX rule. Additionally, the

[4] *See* Securities Exchange Act Release No. 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009).

[5] *Id.*

[6] *Id.* The Exchange notes that the proposed changes will not become operative unless and until the Commission approves the Exchange's request, to be filed pursuant to Section 36 of the Exchange Act and SEC Rule 0–12 thereunder, for an exemption from the rule filing requirements of Section 19(b) of the Exchange Act as to changes to the Current GEMX 8000 Series (new General 5, Section 1) and Current GEMX 9000 Series (new General 5, Section 2) that are effected solely by virtue of a change to the Nasdaq Series 8000 or 9000 Rules Series.

[7] Securities Exchange Act Release No. 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009).

[8] This definition mirrors the one in the Nasdaq rulebook under Rule 9120(f).

[9] *See* Securities Exchange Act Release No. 63536 (December 14, 2010), 75 FR 80102 (December 21, 2010) (SR–NASDAQ–2010–163). Nasdaq Rule 7007 was later relocated to Options Chapter XV, Section 1 and then moved to its current location under Options 7, Section 1, in the Nasdaq rulebook shell. *See* Securities Exchange Act Release No. 66158 (January 13, 2012), 75 FR 80102 (January 13, 2012) (SR–NASDAQ–2012–006) and Securities Exchange Act Release No.84684 (November 29, 2018), 83 FR 62936 (December 6, 2018) (SR–NASDAQ–2018–098).

[10] Securities Exchange Act Release No. 67256 (June 26, 2012), 77 FR 39277 (July 2, 2012) (SR–BX–2012–030). This rule was later relocated to the BX Rulebook shell. *See* Securities Exchange Act Release No. 84326 (October 1, 2018), 83 FR 50414 (October 1, 2018) (SR–BX–2018–046).

[11] *Id.*

[12] *See supra* note 9.

[13] *See* GEMX Options 7, Section 2.

[14] *See* Securities Exchange Act Release No. 84354 (October 3, 2018), 83 FR 50723 (October 9, 2018) (SR–BX–2018–042).

Exchange notes that applying Nasdaq Rule 9120 and incorporating it by reference into the Exchange rule should correct a typo in current BX Rule 9120(v) that erroneously uses the term ''RINRA'' instead of the acronym ''FINRA.''

Current BX Rule 9231

The Exchange proposes to adopt the cross-reference in Nasdaq Rule 9231(c) concerning the appointment of arbitrators pursuant to the FINRA Rules 12000 and 13000 Series (the ''FINRA Arbitration Rules''). Current BX Rule 9231(c) provides that arbitrators shall be appointed pursuant to BX General 6 (''BX Arbitration Rules'').[15] The BX Arbitration Rules incorporate by reference the similar Nasdaq arbitration rules (also under Nasdaq's General 6 title); GEMX's arbitration rules within General 6 also incorporate Nasdaq's arbitration rules; in turn, the Nasdaq rules incorporate the FINRA Arbitration Rules by reference into its text. Following the incorporation by reference of Nasdaq Rule 9231, GEMX Rule 9231(c) will directly cross-reference the FINRA Arbitration Rules, which will not create any differences from the current ISE rules.

Current BX Rule 9232

Currently, Nasdaq Rule 9232(a) provides a cross-reference to subsections (A) through (D) in Nasdaq Rule 9231(b)(1), whereas current BX Rule 9232(a) simply provides a reference to BX Rule 9231(b)(1). The Exchange believes that it is appropriate to apply Nasdaq Rule 9232(a) and incorporate it by reference into the GEMX rule since the Nasdaq rule contains a more precise cross-reference to Nasdaq Rule 9231(b)(1).

Current BX Rule 9522

The Exchange proposes to apply and incorporate by reference Nasdaq Rule 9522 in place of current BX Rule 9522. This proposal amends the first sentence in current BX Rule 9522(a)(1) by replacing the term ''Exchange's Regulation Department'' with the term ''Department of Member Regulation'' as currently provided in Nasdaq Rule 9522(a)(1). As previously indicated by the Exchange,[16] the FINRA Department of Member Regulation [17] currently performs the functions described in current BX Rule 9522. Therefore, applying the Nasdaq rule and incorporating it by reference into GEMX Rule 9522, provides clarity to the rule text and aligns it with Nasdaq and Phlx's rules.

The GEMX introductory paragraphs currently list instances in which various terms and rules within the BX Disciplinary Rules shall be read to refer to Exchange specific rules and terms. Replacing references to ''BX'' with ''Nasdaq'' in this introductory paragraph should align the Nasdaq and GEMX rules. All of these specific terms are identical as between the Nasdaq and BX Rules and, therefore, the term ''BX'' is being replaced with ''Nasdaq.''

The Exchange also proposes to remove certain references within GEMX General 5, Section 3, Code of Procedure, which are no longer necessary because they align with the current rules referenced within the Nasdaq 9000 Rule Series.[18] The Exchange also proposes to amend certain references to Nasdaq Rules, as a result of the relocation of certain Nasdaq Rules in conjunction with a larger Rulebook relocation.[19] Specifically, the Exchange proposes to amend: (a) Rule 1160 to relocated General 2, Section 11; (b) Equity Rules 2110 and 2120 to relocated General 9, Section 1; [20] (c) Equity Rule 2150 to relocated General 9, Section 2.[21] Additionally, as noted above, the Exchange proposes to add rule text to provide that references in the Nasdaq 8000 Series to ''Nasdaq's Options 7, Section 1'' shall be read to refer to GEMX Options 7, Section 2.

The Exchange also proposes to update certain GEMX rule references. The proposed updated reference to ''General 9, Section 1'', replacing Equity Rule 2110, would refer to Nasdaq GEMX Options 9, Section 1. The Section 1 is being added as a more specific reference. Additionally, the proposed updated reference to ''General 9, Section 1'', replacing Equity Rule 2120, would refer to Nasdaq GEMX Options 9, Section 6. The Section 6 is being added as a more specific reference.

Other Technical Amendments

Further, the Exchange proposes to amend references to General 5 to more specific references to the Nasdaq 9000 Series Rules, which pursuant to the proposed incorporation by reference will become GEMX Rules. Specifically, the Exchange proposes to amend General 1, Section 1 (Definitions); General 3, Section 2 (Denial of and Conditions to Becoming a Member); and General 3, Section 6 (Dissolution and Liquidation of Members). Further, the Exchange proposes to amend General 1, ''Provisions'' to General 1, ''General Provisions'' to mirror the name of the Chapter on Nasdaq Phlx LLC, Nasdaq BX, Inc., and Nasdaq.

The Exchange also proposes to amend a typographical error within General 5, Sections 2 and 3 to remove a hyphen. The Exchange also proposes to amend a reference to Nasdaq GEMX Rule 1614 within General 5, Section 3 to instead reference Options 11, Section 1(b) to reflect a relocated rule, and correct a typographical error to remove a stray period.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by consolidating its rules into a single rule set. The various Nasdaq exchanges (''Affiliated Exchanges'') have filed similar proposed rule changes to amend and relocate their disciplinary rules [24] in order that the Nasdaq 8000 Series and 9000 Series Rules, which govern the investigative and disciplinary processes, are similarly consolidated and incorporated by reference.[25] To the extent there will be

[15] *See* Securities Exchange Act Release No. 84476 (October 24, 2018), 83 FR 54630 (October 30, 2018) (SR–BX–2018–048).

[16] *See* Securities Exchange Act Release No. 84354 (October 3, 2018), 83 FR 50724 (October 9, 2018) (SR–BX–2018–042).

[17] As defined in BX 9120(g).

[18] The following Nasdaq Rules were relocated in connection with a Nasdaq rule relocation filing: Rules 0120, 1070, 1160, 4110A, 4120A; Equity Rules 2110, 2120, 2140, 2150; Rule 1000 Series and Chapter III, Section 16. *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From Its Current Rulebook Into Its New Rulebook Shell).

[19] *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From Its Current Rulebook Into Its New Rulebook Shell).

[20] Equity Rule 2120 was more specifically relocated to General 9, Section 1(g), however the Nasdaq Rule 9000 Series only reference General 9, Section 1.

[21] *Id.*

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] *See* Securities Exchange Act Release No. 86138 (July 18, 2019), 84 FR 29567 (July 24, 2019) (SR–ISE–2019–17); Securities Exchange Act Release No. 86346 (July 10, 2019), 84 FR 33999 (July 16, 2019) (SR–GEMX–2019–08); and Securities Exchange Act Release No. 86424 (July 12, 2019), 84 FR 36134 (July 26, 2019) (SR–MRX–2019–15); and Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098). Similarly, Phlx recently submitted a proposal to relocate its disciplinary rules. *See* Securities Exchange Act Release No. 88519 (March 31, 2020), 85 FR 19203 (April 6, 2020) (SR–Phlx–2020–09).

[25] *See* Securities Exchange Act Release Nos. 88519 (March 31, 2020), 85 FR 19203 (April 6,

Continued

differences remaining between the two rule sets, the Exchange notes those differences in introductory paragraphs to each of GEMX's Disciplinary Rules.

Incorporating the Nasdaq Disciplinary Rules by reference into the GEMX Rules, instead of the BX Disciplinary Rules, will conform the alignment of these rules and permit the rules of Phlx, BX, Nasdaq ISE, LLC, Nasdaq MRX, LLC and GEMX to be incorporated by reference to one rule set. This proposal would permit the Nasdaq Series 8000 and 9000 Rules to be the source document for all of the Nasdaq Exchanges' investigative and disciplinary processes. The Exchange notes that its current Disciplinary Rules are not substantively changing. The Exchange desires to conform its rules to give its Members and the members of its Affiliated Exchanges the ability to quickly locate rules in one central location and also to have a unified disciplinary rule set.

The Exchange also believes that the proposal is consistent with Section 6(b)(6) of the Act,[26] which requires that the rules of an exchange provide that its Members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a Member, or any other fitting sanction.

Other Technical Amendments

These technical amendments are intended to align GEMX with other Nasdaq affiliated markets Rulebooks. Nasdaq Phlx LLC and Nasdaq BX, Inc. Rulesets are also incorporating by reference the Nasdaq Rules and those rulesets provide specific references to the Nasdaq disciplinary rules within the 9000 Series.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that this rule change does not impose an undue burden on competition because the Nasdaq Series 8000 and 9000 Rules, which are substantially similar to BX's Disciplinary Rules, will be incorporated by reference into GEMX's Rules. Those rules will now apply to GEMX Members, associated persons, and other persons subject to the Exchange's jurisdiction. To the extent that there will be differences remaining between the two rule sets, the Exchange notes those differences in introductory paragraphs to each of GEMX's Disciplinary Rules. As noted above, the proposed introductory paragraphs list instances in which cross references in Nasdaq Series 8000 and 9000 Rules to other Nasdaq rules shall be read to refer instead to the Exchange Rules, and references to Nasdaq terms (whether or not defined) shall be read to refer to the Exchange-related meanings of those terms. Because Nasdaq Current Series 8000 and 9000 Rules are substantially similar to BX's Disciplinary Rules, which GEMX currently incorporates by reference, and because the introductory paragraphs ensure that any differences are preserved, the proposed changes do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Finally, the Exchange believes that the proposed amendments, including the technical amendments contained herein, do not impose an undue burden on competition because the amendments to relocate the Rules are non-substantive. This rule change is intended to bring greater clarity to the Exchange's Rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[27] and subparagraph (f)(6) of Rule 19b–4 thereunder.[28]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–GEMX–2020–15 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–GEMX–2020–15. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should

2020) (SR–Phlx–2020–09); and 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009), as well as SR–ISE–2020–22 and SR–MRX–2020–12.

[26] 15 U.S.C. 78f(b)(6).

[27] 15 U.S.C. 78s(b)(3)(A)(iii).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

submit only information that you wish to make available publicly. All submissions should refer to File Number SR–GEMX–2020–15 and should be submitted on or before July 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

J. Matthew DeLesDernier,

Assistant Secretary.

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[29] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89074]

Order Granting a Temporary Conditional Exemption From the Broker Registration Requirements of Section 15(a) of the Securities Exchange Act of 1934 for Certain Activities of Registered Municipal Advisors

June 16, 2020.

AGENCY: Securities and Exchange Commission.

ACTION: Temporary exemptive order.

SUMMARY: The Securities and Exchange Commission (''Commission'') is granting a temporary conditional exemption from broker registration under Section 15 of the Securities Exchange Act of 1934 (''Exchange Act'') for registered municipal advisors to address disruption in the municipal securities markets as a result of the coronavirus disease 2019 (''COVID–19'') pandemic. The temporary conditional exemption permits registered municipal advisors to solicit banks, their wholly-owned subsidiaries that are engaged in commercial lending and financing activities, and credit unions in connection with direct placements of securities issued by their municipal issuer clients, subject to the requirements set forth below.

DATES: This exemptive order is effective from the date of this Order until December 31, 2020.

FOR FURTHER INFORMATION CONTACT: Emily Westerberg Russell, Chief Counsel, Joanne Rutkowski, Assistant Chief Counsel, Kelly Shoop, Special Counsel, or Geeta Dhingra, Special Counsel, at 202–551–5550, in the Division of Trading and Markets; Rebecca Olsen, Director, Adam Wendell, Senior Special Counsel, or Emily Hanson Santana, Attorney Adviser, at 202–551–5680, in the Office of Municipal Securities; Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

I. Overview

The Commission continues to closely monitor the impacts of the COVID–19 pandemic. The Commission understands that the outbreak has had far-reaching and unanticipated effects, including disruption to the municipal securities market.[1] Municipal issuers have been experiencing COVID–19-related stress, but must continue to operate despite facing increased unbudgeted costs coupled with revenue uncertainty.[2] Timely and efficient access to the capital markets is critical in order for municipal issuers to continue to meet their operational needs. On June 3, 2020, the Federal Reserve Board announced the revised terms of its Municipal Liquidity Facility, originally established in April 2020 to purchase debt from state and local governments.[3] The revised facility will support lending to U.S. states and the District of Columbia, U.S. cities with a population exceeding 250,000 residents, and U.S. counties with a population exceeding 500,000 residents that had an investment grade rating as of April 8, 2020, from at least one credit rating agency that the Federal Reserve has classified as a ''major nationally recognized statistical rating organization.''[4] In addition to the population and ratings requirements, in order to access the facility, an eligible issuer must also provide a written certification that it is unable to secure adequate credit accommodations from other banking institutions and that it is not insolvent.[5] Most municipal issuers, including many small cities, towns and villages, facing significant budget shortfalls do not meet the population thresholds and are not eligible to access the facility.[6] At the same time, municipal issuers have faced challenges accessing the primary market, and as an alternative many municipal issuers have

[1] *See, e.g.,* Heather Gillers and Gunjan Banerji, ''How the Muni Market Became the Epicenter of the Liquidity Crisis'' Wall Street Journal, April 2, 2020; Lynne Funk, ''Virus Leads to Growing, Severe Selling Pressure on Muni Market,'' The Bond Buyer, March 18, 2020 and Lynne Funk, ''Billions Pulled from Funds as Investors Flee Munis,'' The Bond Buyer, March 19, 2020.

[2] On April 14, 2020, the United States Conference of Mayors (USCM) and the National League of Cities (NLC) released findings of a survey that reported nearly nine in 10 cities expect a budget shortfall due to the impact of the COVID–19 pandemic on their economies. *See* ''Cities Report Pandemic Creating Painful Budget Shortfalls, May Force Furloughs and Layoffs'' April 14, 2020 *available at https://www.usmayors.org/2020/04/14/cities-report-pandemic-creating-painful-budget-shortfalls-may-force-furloughs-and-layoffs/* (''USCM and NLC Survey''); Tony Romm, ''More than 2,100 U.S. cities brace for budget shortfalls due to coronavirus, survey finds, with many planning cuts and layoffs,'' The Washington Post, April 14, 2020. *See also* National League of Cities—COVID *available at https://www.nlc.org/topics/health-wellness/covid-19* for general information on the impact of COVID on cities and COVID–19 Pandemic County Response Efforts & Priorities *available at https://www.naco.org/covid19* for general information the impact of COVID on counties.

[3] *See* Federal Reserve Board Term Sheet, June 3, 2020 (''Term Sheet'') *available at https://www.federalreserve.gov/newsevents/pressreleases/files/monetary20200603a1.pdf.* In addition, to ensure that each U.S. state has at least two total cities and counties (on a combined basis) that may participate in the facility, certain U.S. state governors are permitted to designate up to two of the state's most populous cities and/or counties (on a combined basis) to access the facility, resulting in an additional 34 cities and/or counties that may access the facility as of June 2020. *See* Term Sheet —Appendix A for details of the allocation.

[4] For further information on the cities and counties that meet the population requirement, *see* Federal Reserve Bank of New York FAQs: Municipal Liquidity Facility and FAQs Appendix A *available at https://www.newyorkfed.org/medialibrary/media/markets/municipal-liquidity-facility-eligible-issuers.* For details of the required ratings criteria, *see* Federal Reserve Bank of New York FAQs: Municipal Liquidity Facility and FAQs Appendix B *available at https://www.newyorkfed.org/medialibrary/media/markets/municipal-liquidity-facility-pricing.*

[5] *Id.*

[6] There are 19,495 incorporated cities, towns, and villages in the U.S. Only 87 have populations above the required 250,000 threshold. *See* City and Town Population Totals: 2010–2018, *available at https://www.census.gov/data/tables/time-series/demo/popest/2010s-total-cities-and-towns.html.* There are 3,142 counties in the U.S. Only 140 have populations above the 500,000 required threshold. *See* County Population Totals 2010–2019, *available at https://www.census.gov/data/tables/time-series/demo/popest/2010s-counties-total.html.* An additional 34 cities and/or counties that do not meet these population thresholds may be ''designated'' as eligible to access the facility. *See* Term Sheet —Appendix A; *see also* USCM and NCL Survey. A total of 2,463 cities, towns and villages provided information to NLC and USCM. 2,191 of the cities are under 50,000 population; 181 are between 50,000 and 199,999; 56 are between 200,000 and 499,999; and 35 have a population of 500,000 and above—a group that includes 19 of the nation's 20 largest cities. The cities who participated in the survey represent 57% of the nation's municipal finance sector and 10% of its municipal governments, and their population totals 93,015,252, which is 28% of the total U.S. population. The Government Finance Officers Association also conducted an online survey of finance officers regarding the fiscal impacts of the COVID–19. *See* ''Survey Results Quick Snapshot as of March 23, 2020,'' *available at https://www.gfoa.org/early-data-gfoa-survey-shows-substantial-fiscal-impact-governments-covid-19-outbreak-and-response* (''March 2020 GFOA Survey''). Approximately 1,100 finance officers responded, more than half of whom represent smaller jurisdictions. The survey responses indicated that for respondents with operating budgets of $100 million or less, nearly 15% projected that unanticipated expenses for the next six months could be anywhere from 1 percent to over 30 percent of their operating budget (*e.g.,* for a small government with an operating budget of $75 million, 1 percent is $750,000). These unanticipated expenses are expected to be driven largely by staff sick leave, equipment and technology, and staff overtime.

turned to other means of financing, such as private placements, loans, and lines of credit with banks.[7]

Municipal issuers often retain registered municipal advisors to provide advice on financing options, including but not limited to the types of financing described above. In order to facilitate more timely and efficient access to bank financing alternatives by municipal issuers during this historic COVID–19-related market disruption, we are issuing this Order granting an emergency, temporary conditional exemption permitting registered municipal advisors to solicit a defined set of banks, wholly-owned subsidiaries of banks, and credit unions in connection with certain direct placements of municipal securities by their municipal issuer clients (the ''Temporary Conditional Exemption'').

In October 2019, the Commission proposed and sought public comment on a conditional exemption from the broker registration requirements under Section 15(a)(2) of the Exchange Act for registered municipal advisors engaging in specified activities with respect to direct placements of municipal securities.[8] While the Commission is not moving forward with the proposed exemption at this time, it believes that it is important to issue the Temporary Conditional Exemption with the parameters and requirements specified to address the exigent circumstances during this unprecedented time. Specifically, the Temporary Conditional Exemption is designed to aid smaller municipal issuers that may be struggling to meet their unexpected financing needs in light of the COVID–19 pandemic. This Temporary Conditional Exemption will provide additional flexibility for registered municipal advisors to assist their municipal issuer clients in more efficiently obtaining financing during this market disruption in a way that remains consistent with investor protection. To the extent market participants have information or views related to the Proposed Exemption, including in light of actions taken pursuant to the Temporary Conditional Exemption, that information can be submitted to the comment file for the Proposed Exemption for the Commission's consideration.

The Temporary Conditional Exemption is subject to a number of conditions designed to protect investors. The Temporary Conditional Exemption requires that the Registered Municipal Advisor obtain written representations from the Qualified Provider, which limits the potential investor base for direct placements issued pursuant to the Temporary Conditional Exemption to institutions that routinely engage in credit risk analysis (and typically do so consistent with their commercial lending practices and regulatory obligations) and typically do not resell such securities to retail investors. The Temporary Conditional Exemption requires that the Registered Municipal Advisor make written representations, which protect potential investors by putting them on notice of what duties and obligations the municipal advisor will undertake in connection with the transaction. It also requires the Registered Municipal Advisor to obtain written representations from the Qualified Provider(s) regarding the Temporary Conditional Exemption's investor eligibility and transfer restriction conditions. The Temporary Conditional Exemption further requires Registered Municipal Advisors to notify the Commission staff of any instances of reliance on the exemption, which will inform the Commission about how the exemption may affect the municipal securities market.

The solicitation activities permitted under the Temporary Conditional Exemption, as discussed below, would be in addition to the core advisory activities in which a registered municipal advisor might otherwise engage under the existing regulatory regime. These core advisory activities include assisting municipal entities and/or obligated person clients in: (i) Developing a financing plan; (ii) assisting in evaluating different financing options and structures; (iii) assisting in selecting other parties to the financing, such as bond counsel; (iv) coordinating the rating process, if applicable; (v) ensuring adequate disclosure; and/or (vi) evaluating and negotiating the financing terms with other parties to the financing, including the provider of the direct placement.[9]

II. Temporary Conditional Exemption From Broker Registration for Certain Activities of Registered Municipal Advisors in Connection With Direct Placements of Municipal Securities

It is ordered, pursuant to Sections 15(a)(2) and 36(a)(1) of the Exchange Act, that:

During the Exemption Period as defined in Section III below, a Registered Municipal Advisor may (1) engage in Permitted Activities—*i.e.,* solicitation—of one or more Qualified Providers in connection with a potential Direct Placement of municipal securities by its Municipal Issuer client and (2) receive transaction-based compensation for services provided in connection with that Direct Placement, without being required to register as a broker under Section 15(a) of the Exchange Act, so long as all of the conditions in this Order are met.

Definitions

For purposes of this Temporary Conditional Exemption:

- *Registered Municipal Advisor* means a municipal advisor registered with the Commission under Section 15B of the Exchange Act.
- *Municipal Issuer* means either a municipal entity or obligated person as defined in the Exchange Act.[10]

[7] Lynne Funk, ''With Muni Primary in Limbo, Issuers Turn to Private Placements,'' The Bond Buyer, March 23, 2020 *available at https://www.bondbuyer.com/news/private-placements-on-uptick-as-issuers-search-for-buyers;* Amanda Albright and Danielle Moran ''BofA Gets States That Want to Borrow Now Rather Than Wait on Fed,'' Bloomberg, April 21, 2020; Robert Slavin, ''Alternative Muni Borrowings Have Spiked Since March,'' The Bond Buyer, May 19, 2020 *available at https://www.bondbuyer.com/news/alternative-municipal-borrowings-have-spiked-since-mid-march.*

[8] *See* Proposed Exemptive Order Granting a Conditional Exemption From the Broker Registration Requirements of Section 15(a) of the Securities Exchange Act of 1934 for Certain Activities of Registered Municipal Advisors, Release No. 34–87204 (Oct. 2, 2019), 84 FR 54062 (Oct. 9, 2019) (''Proposed Exemption''). Comments on the Proposed Exemption are available at *https://www.sec.gov/comments/s7-16-19/s71619.htm.*

[9] *See Registration of Municipal Advisors,* Exchange Act Rel. No. 70462 (Sept. 30, 2013), 78 FR 67468, 67472.

[10] *See* Exchange Act Section 15B(e)(8) (defining ''municipal entity'' as ''any State, political subdivision of a State, or municipal corporate instrumentality of a State, including (A) any agency, authority, or instrumentality of the State, political subdivision, or municipal corporate instrumentality; (B) any plan, program, or pool of assets sponsored or established by the State, political subdivision, or municipal corporate instrumentality or any agency, authority, or instrumentality thereof; and (C) any other issuer of municipal securities.''). 15 U.S.C. 78*o*–4(e)(8); *see also* 17 CFR 240.15Ba1–1(g). *See also* Exchange Act 15B(e)(10) (defining ''obligated person'' as ''any person, including an issuer of municipal securities, who is either generally or through an enterprise, fund, or account of such person, committed by contract or other arrangement to support the payment of all or part of the obligations on the municipal securities to be sold in an offering of municipal securities.'' 15 U.S.C. 78*o*–4(e)(10). Exchange Act Rule 15Ba1–1(k) generally provides that obligated person has the same meaning as in Exchange Act Section 15B(e)(10), ''provided, however, the term obligated person shall not include: (1) A person who provides municipal bond insurance, letters of credit, or other liquidity facilities; (2) a person whose financial information or operating data is not material to a municipal securities offering, without reference to any municipal bond insurance, letter of credit, liquidity facility, or other credit enhancement; or (3) the federal government.'' 17 CFR 240.15Ba1–1(k). Obligated persons can included entities acting as conduit borrowers, such as private universities,

• *Qualified Provider* means (i) a bank as defined in Section 3(a)(6) of the Exchange Act; (ii) a wholly-owned subsidiary of a bank engaged in commercial lending and financing activities, such as an equipment lease financing corporation; or (iii) a federally- or state-chartered credit union.[11]

• *Direct Placement* means a direct purchase from a Municipal Issuer of municipal securities by one or more Qualified Providers.

• *Permitted Activities* means solicitation activities to identify and assess potential Qualified Providers based upon, among other things, the Municipal Issuer's or Registered Municipal Advisor's prior knowledge and experience, the use of publicly-available information sources, or identification of Qualified Providers through broader solicitation activities.

Required Representations. The Registered Municipal Advisor must obtain written representations from the Qualified Provider(s) that the Qualified Provider:

• Is a Qualified Provider as defined in the Temporary Conditional Exemption;

• Is capable of independently evaluating the investment risks of the transaction;

• Is not purchasing with a view to distributing the securities; [12] and

• Will not transfer any portion of the direct placement within one year of the date of issuance of the securities, except to another Qualified Provider(s).

These required representations are designed to help ensure a Registered Municipal Advisor acting in reliance on this Temporary Conditional Exemption is soliciting only eligible Qualified Providers. They also are intended to help minimize the potential for resale to retail investors of direct placements, which the Commission understands may not be rated and are not required to have disclosure documents.[13]

The Registered Municipal Advisor must also make a written representation to, and obtain a written acknowledgment of receipt from, the Qualified Provider(s) that the Registered Municipal Advisor:

• Represents solely the interests of the Municipal Issuer and not the Qualified Provider;

• Is soliciting the Qualified Provider in connection with the direct placement pursuant to the Commission's Temporary Conditional Exemption;

• Has not conducted due diligence on behalf of the Qualified Provider;

• Has not, as of the date of the written representation, engaged, nor has the Municipal Issuer engaged, a broker-dealer as a placement agent in connection with the direct placement; and

• Acknowledges that the Qualified Provider nonetheless may choose to engage the services of a broker-dealer to represent the Qualified Provider's interests.

These required representations are designed to help avoid any confusion by the Qualified Provider concerning the role of the Registered Municipal Advisor in the transaction, and further to make explicit that a Qualified Provider is in no way restricted from engaging the services of a broker-dealer as intermediary in the transaction, if it chooses to do so.

Other Required Terms and Conditions

• *Restricted Scope of Temporary Conditional Exemption:* A Registered Municipal Advisor cannot rely on this Temporary Conditional Exemption to engage in broker activity relating to municipal securities offerings beyond the scope of this Order. For example, this exemption does not apply with respect to public offerings of municipal securities or the sale of securities to a retail investor. Additionally, a Registered Municipal Advisor seeking to rely on this Temporary Conditional Exemption cannot bind the Municipal Issuer, or handle funds or securities, in connection with the subject Direct Placement. The Permitted Activities have been narrowly drawn to address the needs of municipal issuers that may be struggling to meet their unexpected financing needs. These restrictions are intended to provide further protections by limiting the scope of brokerage activities permitted by this order.

• *Size Limit:* The aggregate principal amount of the Direct Placement may not exceed $20 million. This is consistent with the Commission's intended objective of facilitating access to capital for smaller Municipal Issuers that may be ineligible for the Federal Reserve's Municipal Liquidity Facility.[14]

• *Authorized Denomination Requirement:* The Direct Placement must be issued in authorized denominations of $100,000 or more. This floor on denomination size is designed to diminish the likelihood of a secondary market resale of these direct placements, particularly to retail investors, because these direct placements may not be rated and are not required to have disclosure documents.[15]

• *Restriction on Transferability:* If the Qualified Provider(s) transfers all or any portion of the direct placement within one year of the date of issuance of the direct placement, the Qualified Provider(s) may transfer the securities only to another Qualified Provider(s). This condition, along with the Authorized Denomination Requirement, is designed to discourage secondary market resale of direct placements, particularly to retail investors, for the same reasons stated above.

• *Recordkeeping:* A Registered Municipal Advisor seeking to rely on the Temporary Conditional Exemption must make and keep the records required by Exchange Act Rule 15Ba1–8(a)(1).

• *Notification Requirement:* A Registered Municipal Advisor seeking to rely on the Temporary Conditional Exemption must notify staff in the Division of Trading and Markets of any Direct Placement for which it has relied on the Temporary Conditional Exemption no later than 30 calendar days after the sale of securities in the Direct Placement. The notification must identify: (1) The Municipal Issuer; (2)

non-profit hospitals, and private corporations. *See* Municipal Advisor Adopting Release, 78 FR at 67483 n. 200 (Nov. 12, 2013).

[11] The Commission believes these institutions typically perform their own credit evaluations of the municipal issuer consistent with their commercial lending practices and regulatory obligations and therefore likely are in less need of a placement agent to undertake the due diligence activities on their behalf. The Commission notes that federal credit unions are already expressly permitted pursuant to National Credit Union Administration regulations to purchase municipal securities so long as they undertake a required analysis. *See, e.g.,* 14 U.S.C. 1752(1) (defining federal credit union as, among other things, an association ''creating a source of credit for provident or productive purposes''); 12 CFR 703.14(e) (permitting a federal credit union to purchase municipal securities so long as it performs an analysis and ''reasonably concludes the security is at least investment grade'').

[12] These restrictions, which apply to the Qualified Provider, are consistent with the restrictions applicable to broker-dealers with respect to the limited offering exemption in Exchange Act Rule 15c2–12 regarding Municipal Securities Disclosure. *See* 17 CFR 240.15c2–12(d)(1)(i).

[13] In contrast to direct placements, which are not subject to Exchange Act Rule 15c2–12's requirements, a participating underwriter in a primary offering of municipal securities subject to Rule 15c2–12 must obtain and review a ''deemed final'' official statement and a final official statement prepared by an issuer or its representatives. *See* 17 CFR 240.15c2–12(b)(1) and (3) and (f)((3).

[14] *See, e.g., supra* n. 6. The March 2020 GFOA Study states that of the subgroup of respondents with an operating budget of less than $100 million, over 15 percent of those smaller governments anticipate issuing debt for projects in amounts ranging from 10 percent to nearly 50 percent of their operating budgets. *See id.* The Commission believes that, in light of these responses, a size limit of $20 million would be sufficiently large to permit these smaller jurisdictions to address their liquidity needs through the use of direct placements if they choose to do so.

[15] *See supra* note 13.

the date of the Direct Placement; (3) principal amount of the Direct Placement; (4) the Qualified Provider(s); and (5) the CUSIP, if available. Notification should be made by sending this information in an email to Commission staff at *tradingandmarkets@sec.gov.*

III. Time Period for the Temporary Conditional Exemption

The relief provided by this Temporary Conditional Exemption begins on the date of this Order and will expire on December 31, 2020.

The Commission intends to continue to monitor the situation as it develops. The Temporary Conditional Exemption may be modified as appropriate.

IV. Conclusion

In light of the current and potential ongoing effects of COVID–19 on the municipal securities market discussed above, the Commission finds that the Temporary Conditional Exemption set forth above is consistent with the public interest and the protection of investors and is necessary or appropriate in the public interest, consistent with Sections 15(a)(2) and 36(a)(1) of the Exchange Act.

By the Commission.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–13284 Filed 6–18–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89067; File No. SR–CboeBZX–2020–047]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule

June 15, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 2, 2020, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to amend the fee schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule applicable to its equities trading platform (''BZX Equities'') to modify non-displayed add volume Tiers 2, 3, and 4 of the Add Volume Tiers, add a new supplemental incentive program to the Add Volume Tiers, modify Step-Up Tier 2, and add Step-Up Tier 5.[3]

The Exchange first notes that it operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to members that provide liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Particularly, for orders priced at or above $1.00, the Exchange provides a standard rebate of $0.0025 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity. In response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Non-Displayed Add Volume Tiers

One of the tiered pricing models referenced above is set forth in Footnote 1 of the fee schedule (Add Volume Tiers), which provides Members an opportunity to qualify for an enhanced rebate on their orders that add liquidity on the Exchange and meet certain criteria. For example, one set of criteria is applied to non-displayed orders that meet certain add volume thresholds on the Exchange. Under the current non-displayed add volume tiers, a Member receives a rebate ranging from $0.0018 (Tier 1) up to $0.0029 (Tier 4) per share for qualifying orders which yield fee codes HB,[4] HI,[5] HV,[6] or HY[7] if the corresponding required criteria per tier is met.[8] Non-displayed add volume Tiers 1 through 4 each require that Members reach certain ADV[9] thresholds as compared to the TCV[10] of non-displayed orders that yield fee codes HB, HI, HV or HY. The Exchange notes that the non-displayed add volume tiers

[3] The Exchange initially filed the proposed fee changes on June 1, 2020 (SR–CboeBZX–2020–045). On June 2, 2020, the Exchange withdrew that filing and submitted a subsequent filing (SR–CboeBZX–2020–047).

[4] Fee code HB is appended to non-displayed orders which add liquidity to Tape B and is provided a rebate of $0.00150.

[5] Fee code HI is appended to non-displayed orders that receive price improvement and adds liquidity and is free.

[6] Fee code HV is appended to non-displayed orders which add liquidity to Tape A and is provided a rebate of $0.00150.

[7] Fee code HY is appended to non-displayed orders which add liquidity to Tape C and is provided a rebate of $0.00150.

[8] *See* Cboe BZX U.S. Equities Fee Schedule, Footnote 1, Add Volume Tiers.

[9] ''ADV'' means average daily volume calculated as the number of shares added or removed, combined, per day, and is calculated on a monthly basis.

[10] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

are designed to encourage Members that provide non-displayed liquidity on the Exchange to meet certain order flow criteria, which would benefit all Members by providing greater execution opportunities on the Exchange.

The Exchange now proposes to modify non-displayed add volume Tiers 2 through 4 to update and ease the ADV threshold. Currently, the non-displayed add volume Tier 1 [sic] provides a rebate of $0.0020 to a Member that adds an ADV of greater than or equal to 0.15% of the TCV as non-displayed orders that yield fee codes HB, HI, HV or HY. The Exchange proposes to modify the required criteria to provide that the Member must add an ADV of equal to or greater than 0.10% of the TCV as non-displayed orders that yield fee codes HB, HI, HV or HY. The non-displayed add volume Tier 3 currently provides a rebate of $0.0025 to a Member that adds an ADV of greater than or equal to 0.25% of the TCV as non-displayed orders that yield fee codes HB, HI, HV or HY. The Exchange proposes to modify the required criteria to provide that the Member must add an ADV of equal to or greater than 0.15% of the TCV as non-displayed orders that yield fee codes HB, HI, HV or HY. Lastly, the non-displayed add volume Tier 4 currently provides a rebate of $0.0029 to a Member that adds an ADV of greater than or equal to 0.38% of the TCV as non-displayed orders that yield fee codes HB, HI, HV or HY. The Exchange proposes to modify the required criteria to provide that the Member must add an ADV of equal to or greater than 0.35% of the TCV as non-displayed orders that yield fee codes HB, HI, HV or HY.

The proposed changes are intended to ease the applicable tier's current criteria, which the Exchange believes will encourage Members who could not achieve the tier previously to strive to achieve the new criteria. To achieve the non-displayed add volume Tiers 2 through 4, even as modified, Members are still required to meet liquidity requirements on the Exchange, thereby contributing to a deeper and more liquid market, which benefits all market participants. The proposed changes continue to provide Members an opportunity to receive a rebate and is designed to provide Members that provide non-displayed liquidity on the Exchange a further incentive to increase that order flow, which would benefit all Members by providing greater execution opportunities on the Exchange. The Exchange notes the tiers, as modified, continue to be available to all Members.

Supplemental Incentive Program Tier

The Exchange proposes to adopt a new tier under Footnote 1 (Add Volume Tiers) that will apply to displayed orders that add liquidity in Tape B securities (*i.e.,* orders that yield fee code B) [11] called the supplemental incentive program tier. The supplemental incentive program tier would provide an additional enhanced rebate of $0.0001 to Members that add Tape B ADV of greater than or equal to 0.50% of the Tape B TCV. The Exchange believes the proposed new tier will encourage Members to increase their Displayed liquidity in Tape B securities on the Exchange.

Step-Up Tiers

Pursuant to Footnote 2 of the fee schedule, the Exchange offers four Step-Up Tiers that provide Members an opportunity to qualify for an enhanced rebate on their orders that add liquidity where they increase their relative liquidity each month over a predetermined baseline. Under the current Step-Up Tiers, a Member receives a rebate of $0.0030 (Tier 1), $0.0031 (Tier 2), or $0.0032 (Tier 3 and 4) per share for qualifying orders which yield fee codes B, V,[12] or Y [13] if the corresponding required criteria per tier is met.[14] Step-Up Tiers 1 through 5 [sic] also each require that Members reach certain Step-Up Add TCV thresholds. As currently defined in the BZX Equities fee schedule, Step-Up Add TCV means ADAV [15] as a percentage of TCV in the relevant baseline month subtracted from the current ADAV as a percentage of TCV.[16] The Exchange notes that Step-Up Tiers are designed to encourage Members that provide displayed liquidity on the Exchange to increase their order flow, which would benefit all Members by providing greater execution opportunities on the Exchange.

The Exchange now proposes to modify Step-Up Tier 2 to add an alternative baseline month and criteria. Currently, Step-Up Tier 2 provides that a Member will receive a rebate of $0.0031 per share for their qualifying orders which yield fee codes B, V, or Y where the Member has a Step-Up Add TCV from December 2018 equal to or greater than 0.20%. The Exchange proposes to offer an alternative criteria to provide that the Member will receive the rebate if it has a Step-Up Add TCV from April 2020 of equal to or greater than 0.15%. The proposed additional criteria is intended to provide alternative criteria from a more recent month for the predetermined baseline, which the Exchange believes is more representative of current volume trends for market participants. The Exchange hopes these changes will encourage those Members who could not achieve the tier previously to increase their order flow as a means to receive the tier's enhanced rebate. To achieve the Step-Up Tier 2, even as modified, Members are still required to increase the amount of liquidity that they provide on BZX, thereby contributing to a deeper and more liquid market, which benefits all market participants. The proposed change continues to provide Members an opportunity to receive a rebate and is designed to provide Members that provide displayed liquidity on the Exchange a further incentive to increase that order flow, which would benefit all Members by providing greater execution opportunities on the Exchange. The Exchange notes the tier, as modified, continues to be available to all Members.

The Exchange also proposes to adopt an additional Step-Up Tier (Step-Up Tier 5), which would provide Members an enhanced rebate of $0.0033 per share where the Member has a Step-Up Add TCV from April 2020 of equal to or greater than 0.30%. The Exchange notes that the proposed Step-Up Tier 5 provides Members an additional way to qualify for an enhanced rebate where they increase their relative liquidity each month over a predetermined baseline, which would benefit all Members by providing greater execution opportunities on the Exchange. The Exchange notes the proposed tier will be available to all Members.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with

[11] Fee code B is appended to displayed orders which add liquidity to Tape B and is provided a rebate of $0.00250.

[12] Fee code V is appended to displayed orders which add liquidity to Tape A and is provided a rebate of $0.00250 per share.

[13] Fee code Y is appended to displayed orders which add liquidity to Tape C and is provided a rebate of $0.00250 per share.

[14] *See* Cboe BZX U.S. Equities Fee Schedule, Footnote 2, Step-Up Tiers.

[15] ADAV means average daily added volume calculated as the number of shares added per day, and is calculated on a monthly basis.

[16] The following demonstrates how Step-Up Add TCV is calculated: In December 2018, Member A had an ADAV of 12,947,242 shares and average daily TCV was 9,248,029,751, resulting in an ADAV as a percentage of TCV of 0.14%; In April 2020, Member A had an ADAV of 46,826,572 and average daily TCV was 7,093,306,325, resulting in an ADAV as a percentage of TCV of 0.66%. Member A's Step-Up Add TCV from December 2018 was therefore 0.52% which makes Member A eligible for the existing Step-Up Tier 4 rebate. (*i.e.,* 0.66% (April 2020) − 0.14% (Dec 2018), which is greater than 0.50% as required by current Tier 4).

the objectives of Section 6 of the Act,[17] in general, and furthers the objectives of Section 6(b)(4),[18] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members, issuers and other persons using its facilities. The Exchange operates in a highly-competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The proposed rule changes reflect a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members.

In particular, the Exchange believes the proposed changes to non-displayed add volume tiers 2 through 4 are reasonable because they will ease the tier's current criteria while continuing to provide an opportunity for Members to receive an enhanced rebate. The Exchange believes the proposed change to Step-Up Tier 2 is reasonable because it provides Members an alternate criteria to achieve the tier based on more recent volume trends. The Exchange also believes the proposals to adopt the supplemental incentive program tier and Step-Up Tier 5 are reasonable because they will provide an additional opportunity for Members to receive an enhanced rebate. The Exchange notes that volume-based incentives (including relative volume-based incentives) and discounts have been widely adopted by exchanges,[19] including the Exchange,[20] and are reasonable, equitable and non-discriminatory because they are open to all members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and/or (ii) associated higher levels of growth patterns. Additionally, as noted above, the Exchange operates in highly competitive market. The Exchange is only one of several equity venues to which market participants may direct their order flow, and it represents a small percentage of the overall market. It is also only one of several maker-taker exchanges. Competing equity exchanges offer similar tiered pricing structures to that of the Exchange, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds. These competing pricing schedules, moreover, are presently comparable to those that the Exchange provides, including the pricing of comparable tiers.[21]

The Exchange believes that the proposal represents an equitable allocation of rebates and is not unfairly discriminatory because all Members are eligible for the proposed tiers and have a reasonable opportunity to meet the tier's criteria. Further, the proposed modifications to non-displayed add volume tiers 2 through 4 are less stringent than the current criteria, while the proposed modification to Step-Up Tier 2 provides an alternative criteria for Members to meet the tier threshold. Without having a view of Members' activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tiers. While the Exchange has no way of predicting with certainty how the proposed changes will impact Member activity, based on this month's data to date, the Exchange expects at least two Members to reasonably compete for and satisfy each of the proposed modified non-displayed add volume tiers 2 through 4 [22] and expects at least two Members to reasonably and compete for and satisfy proposed Step-Up Tiers 2 and 5.[23] Additionally, the Exchange expects three Members to reasonably compete for and satisfy the proposed supplemental incentive program tier. The Exchange also notes that the proposal will not adversely impact any Member's pricing or their ability to qualify for other rebate tiers. Rather, should a Member not meet the proposed criteria, the Member will merely not receive an enhanced rebate. Furthermore, the proposed rebate would apply to all Members that meet the applicable required criteria.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will not [sic] impose any burden on intramarket or intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all Members. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [24]

The Exchange believes the proposed rule change does not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed changes apply to all Members equally in that all Members are eligible for the proposed tiers and will all receive the applicable proposed rebate if such criteria is met. Additionally, the proposed change is designed to attract additional order flow to the Exchange. The Exchange believes that the proposed changes to non-displayed add volume tiers 2 through 4 would incentivize market participants to direct non-displayed order flow to the Exchange as the proposed criteria is less stringent than the current criteria. The Exchange also believes the proposed change to Step Up Tier 2 would encourage market participants to direct liquidity adding volume to the Exchange as it provides alternative criteria, in addition to the existing criteria, that would allow Members to achieve the tier threshold. Lastly, the Exchange believes the proposals to adopt Step-Up Tier 5 and the supplemental incentive program tier will incentivize Members to grow their volume on the Exchange and add volume in Tape B securities, respectively. Greater liquidity benefits all market participants on the Exchange by providing more trading opportunities and encourages Members to send orders, thereby contributing to robust levels of liquidity, which benefits all market participants.

Next, the Exchange believes the proposed rule changes do not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative

[17] 15 U.S.C. 78f.

[18] 15 U.S.C. 78f(b)(4).

[19] See *e.g.,* NYSE Arca Equities, Fees and Charges, Step Up Tiers.

[20] See *e.g.,* Cboe BZX U.S. Equities Exchange Fee Schedule, Footnote 1, Add Volume Tiers, and Footnote 2, Step-Up Tiers 1–4.

[21] See *e.g.,* NYSE Arca Equities, Fees and Charges, Step Up Tiers which offers rebates between $0.0022–$0.0034 per share if the corresponding required criteria per tier is met. NYSE Arca Equities' Step Up Tiers similarly require Members to increase their relative liquidity each month over a predetermined baseline.

[22] Based on this month's data to date, one Member has achieved the non-displayed add volume tier 2, while no Member has achieved non-displayed add volume tiers 3 and 4.

[23] Based on this month's data to date, no Member has achieved the Step-Up Tier 2.

[24] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

venues that they may participate on and direct their order flow, including 13 other equities exchanges and off-exchange venues, including 32 alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 20% of the market share.[25] Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [26] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and Exchange Commission,* the D.C. Circuit stated as follows: ''[n]o one disputes that competition for order flow is 'fierce.' . . . As the SEC explained, '[i]n the U.S. national market system, buyers and sellers of securities, and the broker-dealers that act as their order-routing agents, have a wide range of choices of where to route orders for execution'; [and] 'no exchange can afford to take its market share percentages for granted' because 'no exchange possesses a monopoly, regulatory or otherwise, in the execution of order flow from broker dealers'. . . .''.[27] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

[25] See Cboe Global Markets U.S. Equities Market Volume Summary (May 28, 2020), available at *http://markets.cboe.com/us/equities/market_share/.*

[26] See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[27] *NetCoalition* v. *SEC*, 615 F.3d 525, 539 (D.C. Cir. 2010) (quoting Securities Exchange Act Release No. 59039 (December 2, 2008), 73 FR 74770, 74782–83 (December 9, 2008) (SR–NYSEArca–2006–21)).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [28] and paragraph (f) of Rule 19b–4 [29] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–CboeBZX–2020–047 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–CboeBZX–2020–047. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CboeBZX–2020–047, and should be submitted on or before July 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–13205 Filed 6–18–20; 8:45 am]

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[28] 15 U.S.C. 78s(b)(3)(A).

[29] 17 CFR 240.19b–4(f).

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89068; File No. SR–NYSEArca–2020–37]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To Make Certain Changes Regarding the Investments of the PIMCO Enhanced Short Maturity Active ESG Exchange-Traded Fund

June 15, 2020.

I. Introduction

On April 29, 2020, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to make certain changes regarding the investments of the PIMCO Enhanced Short Maturity Active ESG Exchange-Traded Fund (''Fund''). On May 4, 2020, the Exchange filed Amendment No. 1 to the proposed rule change, which superseded and replaced

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

the proposed rule change in its entirety. The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on May 12, 2020.[3] The Commission has received no comment letters on the proposal. This order approves the proposed rule change, as modified by Amendment No. 1.

I. Description of the Proposed Rule Change, as Modified by Amendment No. 1

The Exchange proposes certain changes, as described below, regarding investments of the Fund. The shares (''Shares'') of the Fund are currently listed and traded on the Exchange under Commentary .01 to NYSE Arca Rule 8.600–E (''Managed Fund Shares'').[4] The Fund is a series of PIMCO ETF Trust (''Trust'').[5] Pacific Investment Management Company LLC is the investment adviser (''Adviser'') to the Fund.[6] PIMCO Investments LLC is the distributor of the Shares and State Street Bank & Trust Co. acts as the custodian and transfer agent for the Fund.

A. Fund Investments

According to the Exchange, the investment objective of the Fund is to seek maximum current income, consistent with preservation of capital and daily liquidity, while incorporating the Adviser's environment, social responsibility, and governance (''ESG'') investment strategy. In managing the Fund's portfolio, the Adviser may avoid investment in the securities of issuers whose ESG practices are not to the Adviser's satisfaction.

Under normal market conditions,[7] the Fund invests at least 80% of its net assets in a diversified portfolio of fixed income securities of varying maturities, which may be represented by forwards, and will consist of the following (collectively, ''Fixed Income Instruments''):

- Securities issued or guaranteed by the U.S. government, its agencies, or U.S. government-sponsored entities;
- corporate debt securities of U.S. and non-U.S. issuers, including convertible securities and corporate commercial paper;
- mortgage-backed securities (''MBS'') and other asset-backed securities (''ABS''), including non-agency, non-government-sponsored entity (''GSE'') and privately-issued mortgage-related and other asset-backed securities (''Private ABS/MBS''), collateralized bond obligations (''CBOs''), collateralized loan obligations (''CLOs''), and other collateralized debt obligations (''CDOs'');[8]
- inflation-indexed bonds issued both by governments and corporations;
- structured notes, including hybrid or ''indexed'' securities and event-linked bonds;
- bank capital and trust preferred securities;
- loan participations and assignments;
- delayed funding loans and revolving credit facilities;
- bank certificates of deposit, fixed time deposits and bankers' acceptances;
- repurchase agreements on Fixed Income Instruments and reverse repurchase agreements on Fixed Income Instruments;
- debt securities issued by states or local governments and their agencies, authorities and other government-sponsored enterprises;
- obligations of non-U.S. governments or their subdivisions, agencies and government-sponsored enterprises; and
- obligations of international agencies or supranational entities.

With respect to Fixed Income Instruments, the Fund may invest, without limitation, in U.S. dollar-denominated securities and instruments of foreign issuers and securities denominated in foreign currencies.

The Fund may invest in to-be-announced transactions. The Fund may also purchase and sell securities on a when-issued, delayed delivery or forward commitment basis. The Fund may, without limitation, seek to obtain market exposure to the securities in which it primarily invests by entering into a series of purchase and sale contracts or by using other investment techniques (such as buy backs or dollar rolls).

The Fund may also hold cash and cash equivalents.[9]

The Fund may invest in, to the extent permitted by Section 12(d) of the 1940 Act or exemptive relief therefrom, other affiliated and unaffiliated funds, such as open-end or closed-end management investment companies, including other exchange-traded funds (''ETFs'').[10]

B. Use of Derivatives by the Fund

The Exchange states that the Fund may invest in forwards to (1) provide exposure to Fixed Income Instruments, (2) enhance returns, (3) manage portfolio duration, or (4) manage the risk of securities price fluctuations. Investments in forwards will be made in accordance with the 1940 Act and consistent with the Fund's investment objective and policies. The Exchange states that, to limit the potential risk associated with such transactions, the Fund may enter into offsetting transactions or segregate or ''earmark'' assets determined to be liquid by the Adviser in accordance with procedures established by the Trust's Board of Trustees and in accordance with the 1940 Act or as permitted by applicable Commission guidance. In addition, the Fund has included risk disclosure in its offering documents, including leveraging risk.[11]

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[3] *See* Securities Exchange Act Release No. 88822 (May 6, 2020), 85 FR 28061 (''Notice'').

[4] The Shares commenced trading on the Exchange on December 10, 2019.

[5] The Exchange states that the Trust is registered under the Investment Company Act of 1940 (''1940 Act''). On November 12, 2019, the Trust filed with the Commission its registration statement on Form N–1A under the Securities Act of 1933 (15 U.S.C. 77a), and under the 1940 Act relating to the Fund (File Nos. 333–155395 and 811–22250) (''Registration Statement''). In addition, the Exchange states that the Commission has issued an order upon which the Trust may rely, granting certain exemptive relief under the 1940 Act. *See* Investment Company Act Release No. 28993 (November 10, 2009) (File No. 812–13571).

[6] The Exchange states that the Adviser is not registered as a broker-dealer, but the Adviser is affiliated with a broker-dealer and has implemented and will maintain a ''fire wall'' with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio. In the event (a) the Adviser becomes registered as a broker-dealer or newly affiliated with one or more broker-dealers, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to its relevant personnel or its broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[7] The term ''normal market conditions'' is defined in NYSE Arca Rule 8.600–E(c)(5).

[8] The Exchange states that ''Private ABS/MBS'' as referenced in the filing are non-agency, non-GSE and privately-issued mortgage-related and other asset-backed securities as stated in Commentary .01(b)(5) to NYSE Arca Rule 8.600–E. However, the Exchange also states that for purposes of this filing, CDOs, CBOs, and CLOs are excluded from the term Private ABS/MBS. CDOs/CBOs/CLOs are distinguishable from ABS because they are collateralized by bank loans or by corporate or government fixed income securities and not by consumer and other loans made by non-bank lenders, including student loans.

[9] For purposes of this filing, the term ''cash equivalents'' includes the short-term instruments enumerated in Commentary .01(c) to NYSE Arca Rule 8.600–E.

[10] The Exchange states that for purposes of this filing, the term ''ETFs'' are Investment Company Units (as described in NYSE Arca Rule 5.2–E(j)(3)); Portfolio Depositary Receipts (as described in NYSE Arca Rule 8.100–E); and Managed Fund Shares (as described in NYSE Arca Rule 8.600–E). All ETFs will be listed and traded on national securities exchanges. According to the Exchange, while the Fund may invest in inverse ETFs, the Fund will not invest in leveraged (*e.g.,* 2X, −2X, 3X or −3X) ETFs.

[11] The Exchange states that leveraging risk is the risk that certain transactions of the Fund, including

According to the Exchange, the Adviser believes there will be minimal, if any, impact to the arbitrage mechanism as a result of the Fund's use of forwards. The Exchange states that the Adviser understands that market makers and participants should be able to value derivatives as long as the positions are disclosed with relevant information. Further, according to the Exchange, the Adviser believes that the price at which Shares trade will continue to be disciplined by arbitrage opportunities created by the ability to purchase or redeem Shares at their net asset value (''NAV''), which the Exchange states should ensure that Shares will not trade at a material discount or premium in relation to their NAV.

C. Application of Generic Listing Requirements

The Exchange states that the proposed changes described below will result in the portfolio for the Fund not meeting all of the ''generic'' listing requirements of Commentary .01 to NYSE Arca Rule 8.600–E applicable to the listing of Managed Fund Shares. The Exchange states that the Fund's portfolio will meet all requirements of Commentary .01 to NYSE Arca Rule 8.600–E except for those set forth in Commentary .01(b)(1),[12] Commentary .01(b)(4) [13] and Commentary .01(b)(5).[14]

According to the Exchange, the Fund's portfolio will not comply with the requirement in Commentary .01(b)(1) to Rule 8.600–E that components that in the aggregate account for at least 75% of the fixed income weight of the portfolio each shall have a minimum original principal amount outstanding of $100 million or more. Instead, the Exchange proposes that components, excluding Private ABS/MBS and CDOs/CBOs/CLOs, that in the aggregate account for at least 50% of the fixed income weight of the portfolio, each shall have a minimum original principal amount outstanding of $50 million or more. Investments in Private ABS/MBS and CDOs/CBOs/CLOs will not be subject to a required minimum original principal amount outstanding.

The Fund will not comply with the requirements in Commentary .01(b)(4) to Rule 8.600–E that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria specified in Commentary .01(b)(4).[15] Instead, the Exchange proposes that: (1) The Fund's investments in fixed income securities that do not meet any of the criteria in Commentary .01(b)(4) will not exceed 10% of the total assets of the Fund, excluding Private ABS/MBS and CDOs/CBOs/CLOs; (2) Private ABS/MBS, which will be limited to 20% of the Fund's total assets, will not be required to comply with the criteria in Commentary .01(b)(4); and (3) CDOs/CBOs/CLOs, which will be subject to a separate limit of 20% of the Fund's total assets, will also not be required to comply with the criteria in Commentary .01(b)(4).

In addition, the Exchange states that the Fund's portfolio will not comply with the requirement in Commentary .01(b)(5) to Rule 8.600–E that investments in non-agency, non-government sponsored entity and privately issued mortgage-related and other asset-backed securities (*i.e.,* Private ABS/MBS) not account, in the aggregate, for more than 20% of the weight of the portfolio. Instead, the Fund will not invest more than 20% of the Fund's total assets in Private ABS/MBS or more than 20% of the Fund's total assets in U.S. or foreign CDOs/CBOs/CLOs.

The Exchange notes that, other than Commentary .01(b)(1), Commentary .01(b)(4), and Commentary .01(b)(5) to Rule 8.600–E, the Fund's portfolio will meet all other requirements of Rule 8.600–E.

II. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with the Act and the rules and regulations thereunder applicable to a national securities exchange.[16] In particular, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act,[17] which requires, among other things, that the Exchange's rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

According to the Exchange, other than Commentary .01(b)(1), (b)(4) and (b)(5) to Rule 8.600–E, the Fund will meet all other requirements of NYSE Arca Rule 8.600–E, and the Shares of the Fund will conform to the continued listing criteria under NYSE Arca Rule 8.600–E.

As discussed above, the Fund will not comply with the requirement in Commentary .01(b)(1) to Rule 8.600–E that components that in the aggregate account for at least 75% of the fixed income weight of the portfolio each have a minimum original principal amount outstanding of $100 million or more. Instead, the Exchange proposes that components of the portfolio, excluding Private ABS/MBS and CDOs/CBOs/CLOs, that in the aggregate account for at least 50% of the fixed income weight of the portfolio, each shall have a minimum original principal amount outstanding of $50 million or more. Private ABS/MBS and CDOs/CBOs/CLOs will not be subject to a requirement for a minimum original principal amount outstanding. The Exchange represents that at least 50% of the fixed income weight of the Fund's portfolio will still be required to have a substantial minimum original principal amount outstanding.[18] The Exchange asserts that not subjecting Private ABS/MBS and CDOs/CBOs/CLOs to a standard for minimum original principal amount outstanding would allow the Fund to invest in a larger variety of Private ABS/MBS and CDOs/CBOs/CLOs, which would help the Fund meet its investment objective and diversify its holdings in such securities.[19] In addition, the Exchange states that the Adviser has represented that, with respect to the Fund's investments in CDOs/CBOs/CLOs, the Fund will invest principally in the

the Fund's use of forwards, may give rise to leverage, causing the Fund to be more volatile than if it had not been leveraged.

[12] Commentary .01(b)(1) requires that components that in the aggregate account for at least 75% of the fixed income weight of the portfolio each have a minimum original principal amount outstanding of $100 million or more.

[13] Commentary .01(b)(4) requires that component securities that in aggregate account for at least 90% of the fixed income weight of the portfolio must be either (a) from issuers that are required to file reports pursuant to Sections 13 and 15(d) of the Act; (b) from issuers that have a worldwide market value of its outstanding common equity held by non-affiliates of $700 million or more; (c) from issuers that have outstanding securities that are notes, bonds debentures, or evidence of indebtedness having a total remaining principal amount of at least $1 billion; (d) exempted securities as defined in Section 3(a)(12) of the Act; or (e) from issuers that are a government of a foreign country or a political subdivision of a foreign country.

[14] Commentary .01(b)(5) provides that non-agency, non-GSE and privately-issued mortgage-related and other asset-backed securities components of a portfolio shall not account, in the aggregate, for more than 20% of the weight of the portfolio.

[15] *See supra* note 13.

[16] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[17] 15 U.S.C. 78f(b)(5).

[18] *See* Notice, *supra* note 3, at 28064–65.

[19] *See id.* at 28065.

senior-most tranches of these securities, generally those with an AAA investment rating that have first claim in the capital structure and that have less sensitivity to the credit risk of the underlying assets (*e.g.,* bank loans or commercial real estate).[20] The Commission notes that it has previously approved the listing of other series of Managed Fund Shares for which the fixed income weight of the portfolio does not comply with Commentary .01(b)(1) to Rule 8.600–E.[21]

In addition, the Fund will not comply with the requirements in Commentary .01(b)(4) to Rule 8.600–E that component securities that in the aggregate account for at least 90% of the fixed income weight of the portfolio meet one of the criteria specified in Commentary .01(b)(4).[22] Instead, the Exchange proposes to allow up to 50% of the Fund's portfolio to be composed of fixed income securities which would not satisfy the criteria in Commentary .01(b)(4). Specifically, the Exchange proposes that: (1) The Fund may invest up to 10% of its total assets in fixed income securities that do not satisfy the criteria of Commentary .01(b)(4), excluding Private ABS/MBS and CDOs/CBOs/CLOs; (2) the Fund's investments in Private ABS/MBS, which may constitute up to 20% of the Fund's total assets, will not be required to satisfy the criteria of Commentary .01(b)(4); and (3) the Fund's investments in CDOs/CBOs/CLOs, which may constitute up to 20% of the Fund's total assets, also will not be required to satisfy the criteria of Commentary .01(b)(4). The Commission notes that it has previously approved the listing of other series of Managed Fund Shares with similar investment strategies that are permitted to hold a similar percentage of fixed income securities that do not meet one of the criteria set forth in Commentary.01(b)(4).[23]

Finally, the Fund will not comply with the requirement in Commentary .01(b)(5) to Rule 8.600–E that investments in non-agency, non-government sponsored entity and privately issued mortgage-related and other asset-backed securities (*i.e.,* Private ABS/MBS) not account, in the aggregate, for more than 20% of the weight of the portfolio. Instead, the Fund will not invest more than 20% of the Fund's total assets in Private ABS/MBS or more than 20% of the Fund's total assets in U.S. or foreign CDOs/CBOs/CLOs. The Exchange believes that these limitations will help the Fund maintain portfolio diversification and reduce manipulation risk.[24] In addition, the Exchange states that the Fund's investment in CDOs/CBOs/CLOs will be subject to the Fund's liquidity procedures as adopted by the Trust's Board of Trustees, and the Adviser does not expect that such investments will have any material impact on the liquidity of the Fund's investments.[25] The Commission notes that it has previously approved the listing of other series of Managed Fund Shares that are permitted to hold private asset backed and mortgage-backed securities in excess of the levels permitted under Commentary .01(b)(5).[26]

The Exchange represents that all statements and representations made in the filing regarding (1) the description of the portfolio holdings or reference assets, (2) limitations on portfolio holdings or reference assets, or (3) the applicability of Exchange listing rules specified in the filing shall constitute continued listing requirements for listing the Shares of the Fund on the Exchange. In addition, the Exchange states that the issuer must notify the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Act, the Exchange will monitor[27] for compliance with the continued listing requirements. If the Fund is not in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under NYSE Arca Rule 5.5–E(m).

This approval order is based on all of the Exchange's representations, including those set forth above and in Amendment No. 1. For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendment No. 1, is consistent with Section 6(b)(5) of the Act[28] and the rules and regulations thereunder applicable to a national securities exchange.

III. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[29] that the proposed rule change (SR–NYSEArca–2020–37), as modified by Amendment No. 1, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[30]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–13207 Filed 6–18–20; 8:45 am]

BILLING CODE 8011–01–P

[20] *See id.*

[21] *See, e.g.,* Securities Exchange Act Release No. 86841 (August 30, 2019), 84 FR 47024 (September 6, 2019) (SR–NYSEArca–2019–38) (Order Approving a Proposed Rule Change, as Modified by Amendments No. 1 and No. 2, To Amend the Listing Rule Applicable to Shares of the Aware Ultra-Short Duration Enhanced Income ETF).

[22] *See supra* note 13.

[23] *See, e.g.,* Securities Exchange Act Release No. 87576 (November 20, 2019), 84 FR 65206 (November 26, 2019) (SR–NYSEArca–2019–14) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, Relating to the Permitted Investments of the PGIM Ultra Short Bond ETF) (''PGIM Ultra Short Bond ETF Order'').

[24] *See* Notice, *supra* note 3, at 28065.

[25] *See id.*

[26] *See, e.g.,* PGIM Ultra Short Bond ETF Order, *supra* note 23; Securities Exchange Act Release No. 87410 (October 28, 2019), 84 FR 58750 (November 1, 2019) (SR–NYSEArca–2019–33) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, Regarding Changes to Investments of the First Trust TCW Unconstrained Plus Bond ETF).

[27] The Commission notes that certain proposals for the listing and trading of exchange-traded products include a representation that the exchange will ''surveil'' for compliance with the continued listing requirements. *See, e.g.,* Securities Exchange Act Release No. 77499 (April 1, 2016), 81 FR 20428, 20432 (April 7, 2016) (SR–BATS–2016–04). In the context of this representation, it is the Commission's view that ''monitor'' and ''surveil'' both mean ongoing oversight of compliance with the continued listing requirements. Therefore, the Commission does not view ''monitor'' as a more or less stringent obligation than ''surveil'' with respect to the continued listing requirements.

[28] 15 U.S.C. 78f(b)(5).

[29] *Id.*

[30] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–89070; File No. SR–MRX–2020–12]

Self-Regulatory Organizations; Nasdaq MRX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the MRX Disciplinary Rules in General 5 To Incorporate by Reference The Nasdaq Stock Market LLC's Series 8000 and 9000 Rules

June 15, 2020.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 10, 2020, Nasdaq MRX, LLC (''MRX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MRX Disciplinary Rules in General 5 to incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') Series 8000 and 9000 Rules, currently located under the General 5 title of the Nasdaq rulebook,[3] instead of the BX Rules, which the Exchange currently incorporates by reference.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaqmrx.cchwallstreet.com/,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In connection with a recent rule change to relocate the Nasdaq BX, Inc. (''BX'') Disciplinary Rules under the General 5 title (''Discipline''),[4] and incorporate by reference The Nasdaq Stock Market LLC's (''Nasdaq'') Series 8000 and 9000 Rules, MRX proposes to similarly incorporate by reference Nasdaq's Series 8000 and 9000 Rules.

The BX Disciplinary Rules, which were relocated to General 5 of the BX Rules,[5] were replaced with introductory paragraphs that respectively incorporate by reference the Nasdaq Series 8000 and 9000 Rules (located under the General 5 title in the Nasdaq rulebook).[6] Currently, MRX incorporates the BX Disciplinary Rules within the Series 8000 and 9000 Rules, which were relocated to General 5 of the BX Rules with the aforementioned rule change.[7] At this time, MRX proposes to incorporate by reference the Nasdaq Series 8000 and 9000 Rules (located in General 5 Discipline), respectively, and state that such Nasdaq Rules shall be applicable to Exchange Members, associated persons, and other persons subject to MRX's jurisdiction.

Except as noted below, the Nasdaq Series 8000 and 9000 Rules are substantially similar to BX's Disciplinary Rules, which the Exchange currently incorporates by reference. The following discussions identify the differences between the current BX Disciplinary Rules and the corresponding Nasdaq Disciplinary Rules to be incorporated by reference into MRX:

Current BX IM–8310–3(b)

Current BX Rule 9120(f) provides that ''[t]he term ''Department of Enforcement'' means the Department of Enforcement of FINRA Regulation, acting on behalf of the Exchange pursuant to the FINRA Regulatory Contract.''[8] Current BX IM–8310–3(b), however, uses the term ''Department of Enforcement of FINRA.'' Since Nasdaq IM–8310–3(b) uses the term ''Department of Enforcement'' MRX believes it is appropriate to utilize the Nasdaq terms going forward and incorporate by reference into the MRX rule.

Current BX Rule 8320

In 2010, Nasdaq created Rule 7007 (''Collection of Fees'') to facilitate an efficient method of collecting undisputed or final fees, fines, charges and/or other monetary sanctions or monies due and owing to Nasdaq from The Nasdaq Option Market (''NOM'') Participants.[9]

Similarly, in 2012, BX adopted its options market rules (''BX Options Market'') to operate as a fully automated, price/time priority execution system built on the core functionality of NOM.[10] In its filing, BX proposed to adopt, under respective Chapter XV, Section 2, a rule identical to the Nasdaq Collection of Fees rule.[11] Although, at the time of its creation, the Nasdaq Collection of Fees rule was cross-referenced to current Nasdaq Rule 8320(a)(1),[12] such cross-reference was not included in the filing that created the BX Options Market. MRX also has the same Collection of Fees rule,[13] that is identical to the Nasdaq rule. Because BX Rule 8320, which MRX incorporates by reference, does not include a cross-reference to the Collection of Fees rule, MRX will follow the Nasdaq rule going forward, which has the correct cross-reference. The Exchange also proposes to add rule text, within General 5, Section 3, to note the distinction between the location of the Collection of Fees rules. Specifically, the Exchange proposes to add rule text to provide that references in the Nasdaq 8000 Series to ''Nasdaq's Options 7, Section 1'' shall be read to refer to MRX Options 7, Section 2.

Based on the above, the Exchange believes that it is appropriate that MRX adopts the aforementioned cross-reference to make the collection of fees owed to the Exchange more efficient. Therefore, the Exchange believes that it is appropriate to incorporate by reference Nasdaq Rule 8320 into MRX Rules.

Current BX Rule 9120

In 2018, BX amended its Disciplinary Rules to align them with the investigatory and disciplinary processes of Nasdaq PHLX LLC (''Phlx'').[14] As stated in its proposal, the changes to the ''Interested Staff'' concept (which, at the time, was relocated under 9120(r)) were done to conform the BX rule to Phlx's definition. At the time, however, the proposed harmonizing changes to BX Rule 9120(r)(1)(B) inadvertently

[3] *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098).

[4] *See* Securities Exchange Act Release No. 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009).

[5] *Id.*

[6] *Id.* The Exchange notes that the proposed changes will not become operative unless and until the Commission approves the Exchange's request, to be filed pursuant to Section 36 of the Exchange Act and SEC Rule 0–12 thereunder, for an exemption from the rule filing requirements of Section 19(b) of the Exchange Act as to changes to the Current MRX 8000 Series (new General 5, Section 1) and Current MRX 9000 Series (new General 5, Section 2) that are effected solely by virtue of a change to the Nasdaq Series 8000 or 9000 Rules Series.

[7] *See* Securities Exchange Act Release No. 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009).

[8] This definition mirrors the one in the Nasdaq rulebook under Rule 9120(f).

[9] *See* Securities Exchange Act Release No. 63536 (December 14, 2010), 75 FR 80102 (December 21, 2010) (SR–NASDAQ–2010–163). Nasdaq Rule 7007 was later relocated to Options Chapter XV, Section 1 and then moved to its current location under Options 7, Section 1, in the Nasdaq rulebook shell. *See* Securities Exchange Act Release No. 66158 (January 13, 2012), 75 FR 80102 (January 13, 2012) (SR–NASDAQ–2012–006) and Securities Exchange Act Release No. 84684 (November 29, 2018), 83 FR 62936 (December 6, 2018) (SR–NASDAQ–2018–098).

[10] Securities Exchange Act Release No. 67256 (June 26, 2012), 77 FR 39277 (July 2, 2012) (SR–BX–2012–030). This rule was later relocated to the BX Rulebook shell. *See* Securities Exchange Act Release No. 84326 (October 1, 2018), 83 FR 50414 (October 1, 2018) (SR–BX–2018–046).

[11] *Id.*

[12] *See supra* note 9.

[13] *See* MRX Options 7, Section 2.

[14] *See* Securities Exchange Act Release No. 84354 (October 3, 2018), 83 FR 50723 (October 9, 2018) (SR–BX–2018–042).

excluded the words ''Head of'' and omitted to add the word ''the''; indeed, the text should have read ''Head of the Exchange's Regulation Department'' instead of, simply, ''Exchange's Regulation Department.''

The correct definition, as explained above, would also align with the term currently defined in Nasdaq Rule 9120(r)(1)(B), which provides that ''Interested Staff'' shall mean ''an Exchange employee of the Nasdaq Regulation Department who reports, directly or indirectly, to the Head of the Nasdaq Regulation Department.''

The Exchange believes that it is appropriate to apply Nasdaq Rule 9120 and to incorporate it by reference into the MRX rule. Additionally, the Exchange notes that applying Nasdaq Rule 9120 and incorporating it by reference into the Exchange rule should correct a typo in current BX Rule 9120(v) that erroneously uses the term ''RINRA'' instead of the acronym ''FINRA.''

Current BX Rule 9231

The Exchange proposes to adopt the cross-reference in Nasdaq Rule 9231(c) concerning the appointment of arbitrators pursuant to the FINRA Rules 12000 and 13000 Series (the ''FINRA Arbitration Rules''). Current BX Rule 9231(c) provides that arbitrators shall be appointed pursuant to BX General 6 (''BX Arbitration Rules'').[15] The BX Arbitration Rules incorporate by reference the similar Nasdaq arbitration rules (also under Nasdaq's General 6 title); MRX's arbitration rules within General 6 also incorporate Nasdaq's arbitration rules; in turn, the Nasdaq rules incorporate the FINRA Arbitration Rules by reference into its text. Following the incorporation by reference of Nasdaq Rule 9231, MRX Rule 9231(c) will directly cross-reference the FINRA Arbitration Rules, which will not create any differences from the current ISE rules.

Current BX Rule 9232

Currently, Nasdaq Rule 9232(a) provides a cross-reference to subsections (A) through (D) in Nasdaq Rule 9231(b)(1), whereas current BX Rule 9232(a) simply provides a reference to BX Rule 9231(b)(1). The Exchange believes that it is appropriate to apply Nasdaq Rule 9232(a) and incorporate it by reference into the MRX rule since the Nasdaq rule contains a more precise cross-reference to Nasdaq Rule 9231(b)(1).

Current BX Rule 9522

The Exchange proposes to apply and incorporate by reference Nasdaq Rule 9522 in place of current BX Rule 9522. This proposal amends the first sentence in current BX Rule 9522(a)(1) by replacing the term ''Exchange's Regulation Department'' with the term ''Department of Member Regulation'' as currently provided in Nasdaq Rule 9522(a)(1). As previously indicated by the Exchange,[16] the FINRA Department of Member Regulation [17] currently performs the functions described in current BX Rule 9522. Therefore, applying the Nasdaq rule and incorporating it by reference into MRX Rule 9522, provides clarity to the rule text and aligns it with Nasdaq and Phlx's rules.

The MRX introductory paragraphs currently list instances in which various terms and rules within the BX Disciplinary Rules shall be read to refer to Exchange specific rules and terms. Replacing references to ''BX'' with ''Nasdaq'' in this introductory paragraph should align the Nasdaq and MRX rules. All of these specific terms are identical as between the Nasdaq and BX Rules and, therefore, the term ''BX'' is being replaced with ''Nasdaq.''

The Exchange also proposes to remove certain references within MRX General 5, Section 3, Code of Procedure, which are no longer necessary because they align with the current rules referenced within the Nasdaq 9000 Rule Series.[18] The Exchange also proposes to amend certain references to Nasdaq Rules, as a result of the relocation of certain Nasdaq Rules in conjunction with a larger Rulebook relocation.[19] Specifically, the Exchange proposes to amend: (a) Rule 1160 to relocated General 2, Section 11; (b) Equity Rules 2110 and 2120 to relocated General 9, Section 1; [20] (c) Equity Rule 2150 to relocated General 9, Section 2.[21] Additionally, as noted above, the Exchange proposes to add rule text to provide that references in the Nasdaq 8000 Series to ''Nasdaq's Options 7, Section 1'' shall be read to refer to MRX Options 7, Section 2.

The Exchange also proposes to update certain MRX rule references. The proposed updated reference to ''General 9, Section 1'', replacing Equity Rule 2110, would refer to Nasdaq MRX Options 9, Section 1. The Section 1 is being added as a more specific reference. Additionally, the proposed updated reference to ''General 9, Section 1'', replacing Equity Rule 2120, would refer to Nasdaq MRX Options 9, Section 6. The Section 6 is being added as a more specific reference.

Other Technical Amendments

Further, the Exchange proposes to amend references to General 5 to more specific references to the Nasdaq 9000 Series Rules, which pursuant to the proposed incorporation by reference will become MRX Rules. Specifically, the Exchange proposes to amend General 1, Section 1 (Definitions); General 3, Section 2 (Denial of and Conditions to Becoming a Member); and General 3, Section 6 (Dissolution and Liquidation of Members). Further, the Exchange proposes to amend General 1, ''Provisions'' to General 1, ''General Provisions'' to mirror the name of the Chapter on Nasdaq Phlx LLC, Nasdaq BX, Inc., and Nasdaq.

The Exchange also proposes to amend a typographical error within General 5, Sections 2 and 3 to remove a hyphen. The Exchange also proposes to amend a reference to Nasdaq MRX Rule 1614 within General 5, Section 3 to instead reference Options 11, Section 1(b) to reflect a relocated rule, and correct a typographical error to remove a stray period.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is designed to promote just and equitable principles of trade and to protect investors and the public interest by consolidating its rules into a single rule set. The various Nasdaq exchanges (''Affiliated Exchanges'') have filed similar proposed rule changes to amend and relocate their disciplinary rules [24] in order that the

[15] *See* Securities Exchange Act Release No. 84476 (October 24, 2018), 83 FR 54630 (October 30, 2018) (SR–BX–2018–048).

[16] *See* Securities Exchange Act Release No. 84354 (October 3, 2018), 83 FR 50724 (October 9, 2018) (SR–BX–2018–042).

[17] As defined in BX 9120(g).

[18] The following Nasdaq Rules were relocated in connection with a Nasdaq rule relocation filing: Rules 0120, 1070, 1160, 4110A, 4120A; Equity Rules 2110, 2120, 2140, 2150; Rule 1000 Series and Chapter III, Section 16. *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From Its Current Rulebook Into Its New Rulebook Shell).

[19] *See* Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Relocate Rules From Its Current Rulebook Into Its New Rulebook Shell).

[20] Equity Rule 2120 was more specifically relocated to General 9, Section 1(g), however the Nasdaq Rule 9000 Series only reference General 9, Section 1.

[21] *Id.*

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

[24] *See* Securities Exchange Act Release No. 86138 (July 18, 2019), 84 FR 29567 (July 24, 2019) (SR–

Nasdaq 8000 Series and 9000 Series Rules, which govern the investigative and disciplinary processes, are similarly consolidated and incorporated by reference.[25] To the extent there will be differences remaining between the two rule sets, the Exchange notes those differences in introductory paragraphs to each of MRX's Disciplinary Rules.

Incorporating the Nasdaq Disciplinary Rules by reference into the MRX Rules, instead of the BX Disciplinary Rules, will conform the alignment of these rules and permit the rules of Phlx, BX, Nasdaq ISE, LLC, Nasdaq MRX, LLC and MRX to be incorporated by reference to one rule set. This proposal would permit the Nasdaq Series 8000 and 9000 Rules to be the source document for all of the Nasdaq Exchanges' investigative and disciplinary processes. The Exchange notes that its current Disciplinary Rules are not substantively changing. The Exchange desires to conform its rules to give its Members and the members of its Affiliated Exchanges the ability to quickly locate rules in one central location and also to have a unified disciplinary rule set.

The Exchange also believes that the proposal is consistent with Section 6(b)(6) of the Act,[26] which requires that the rules of an exchange provide that its Members be appropriately disciplined for violations of the Act as well as the rules and regulations thereunder, or the rules of the Exchange, by expulsion, suspension, limitation of activities, functions, and operations, fine, censure, being suspended or barred from being associated with a Member, or any other fitting sanction.

Other Technical Amendments

These technical amendments are intended to align MRX with other Nasdaq affiliated markets Rulebooks. Nasdaq Phlx LLC and Nasdaq BX, Inc. Rulesets are also incorporating by reference the Nasdaq Rules and those rulesets provide specific references to the Nasdaq disciplinary rules within the 9000 Series.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that this rule change does not impose an undue burden on competition because the Nasdaq Series 8000 and 9000 Rules, which are substantially similar to BX's Disciplinary Rules, will be incorporated by reference into MRX's Rules. Those rules will now apply to MRX Members, associated persons, and other persons subject to the Exchange's jurisdiction. To the extent that there will be differences remaining between the two rule sets, the Exchange notes those differences in introductory paragraphs to each of MRX's Disciplinary Rules. As noted above, the proposed introductory paragraphs list instances in which cross references in Nasdaq Series 8000 and 9000 Rules to other Nasdaq rules shall be read to refer instead to the Exchange Rules, and references to Nasdaq terms (whether or not defined) shall be read to refer to the Exchange-related meanings of those terms. Because Nasdaq Current Series 8000 and 9000 Rules are substantially similar to BX's Disciplinary Rules, which MRX currently incorporates by reference, and because the introductory paragraphs ensure that any differences are preserved, the proposed changes do not impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Finally, the Exchange believes that the proposed amendments, including the technical amendments contained herein, do not impose an undue burden on competition because the amendments to relocate the Rules are non-substantive. This rule change is intended to bring greater clarity to the Exchange's Rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A)(iii) of the Act[27] and subparagraph (f)(6) of Rule 19b–4 thereunder.[28]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MRX–2020–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–MRX–2020–12. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the

ISE–2019–17); Securities Exchange Act Release No. 86346 (July 10, 2019), 84 FR 33999 (July 16, 2019) (SR–GEMX–2019–08); and Securities Exchange Act Release No. 86424 (July 12, 2019), 84 FR 36134 (July 26, 2019) (SR–MRX–2019–15); and Securities Exchange Act Release No. 87778 (December 17, 2019), 84 FR 70590 (December 23, 2019) (SR–NASDAQ–2019–098). Similarly, Phlx recently submitted a proposal to relocate its disciplinary rules. *See* Securities Exchange Act Release No. 88519 (March 31, 2020), 85 FR 19203 (April 6, 2020) (SR–Phlx–2020–09).

[25] *See* Securities Exchange Act Release Nos. 88519 (March 31, 2020), 85 FR 19203 (April 6, 2020) (SR–Phlx–2020–09); and 88938 (May 26, 2020), 88 FR 33235 (June 1, 2020) (SR–BX–2020–009), as well as SR–ISE–2020–22 and SR–GEMX–2020–15.

[26] 15 U.S.C. 78f(b)(6).

[27] 15 U.S.C. 78s(b)(3)(A)(iii).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change. Persons submitting comments are cautioned that we do not redact or edit personal identifying information from comment submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MRX–2020–12 and should be submitted on or before July 10, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[29]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–13204 Filed 6–18–20; 8:45 am]

BILLING CODE 8011–01–P

[29] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice 11142]

U.S. Department of State Advisory Committee on Private International Law: Notice of Annual Meeting

The Department of State's Advisory Committee on Private International Law (ACPIL) will hold its annual meeting on Tuesday, July 28, 2020. The meeting will be held in WebEx. The program is scheduled to run from 1:00 p.m. to 5:00 p.m.

During the meeting, we will discuss major developments in private international law over the past year, including the finalization of the Convention on the Recognition and Enforcement of Foreign Judgments and the Singapore Convention on Mediation. We will also discuss expected work in the area of international family law in the coming year and seek comments on the draft Code of Conduct for Adjudicators in Investor-State Dispute Settlement, prepared jointly by the secretariats of United Nations Commission on International Trade Law (UNCITRAL) and the International Centre for the Settlement of Investment Disputes (ICSID). Finally, we will be seeking input from members on possible future projects for the United Nations Commission on International Trade Law (UNCITRAL) and United Nations International Institute for Unification of Private Law (UNIDROIT). If time allows other topics of interest could be discussed.

Members of the public may attend this virtual session and will be permitted to participate in the question and answer discussion period following the formal ACPIL presentation on each agenda topic in accordance with the Chair's instructions. Members of the public may also submit a brief statement (less than three pages) or comments to the committee in writing for inclusion in the public minutes of the meeting to *pil@state.gov.* Virtual attendance is limited to 100 persons, so each member of the public that wishes to attend this session must provide: Name, contact information, and affiliation to Tricia Smeltzer at *pil@state.gov,* not later than July 14, 2020. When you register, please indicate whether you require captioning. The WebEx site and agenda will be forwarded to individuals who register by that time, up to the capacity of the meeting. Requests made after that date will be considered but might not be able to be fulfilled.

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2020–13193 Filed 6–18–20; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

Updating the State Department's List of Entities and Subentities Associated With Cuba (Cuba Restricted List); Correction

ACTION: Updated publication of list of entities and subentities; notice; correction.

SUMMARY: The Department of State published a document in the **Federal Register** of June 12, 2020, concerning an update to its List of Restricted Entities and Subentities Associated with Cuba (Cuba Restricted List). The document contained one omission from the list.

FOR FURTHER INFORMATION CONTACT: Emily Belson, Office of Economic Sanctions Policy and Implementation, 202–647–6526; Robert Haas, Office of the Coordinator for Cuban Affairs, tel.: 202–453–8456, Department of State, Washington, DC 20520.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of June 12, 2020, in FR Doc. 2020–12746, on page 35974, in the third column, correct subheading ''Additional Subentities of CIMEX'' to include ''FINCIMEX *Effective [DATE PUBLISHED IN* **FEDERAL REGISTER***]*'' on a line after ''ECUSE — Empresa Cubana de Servicios'' and before ''Inmobiliaria CIMEX (Real Estate).''

Zachary A. Parker,

Director, Office of Directives Management, Department of State.

[FR Doc. 2020–13192 Filed 6–18–20; 8:45 am]

BILLING CODE 4710–29–P

SURFACE TRANSPORTATION BOARD

30-Day Notice of Intent To Seek Extension of Approval of Collection: Report of Fuel Cost, Consumption, and Surcharge Revenue

AGENCY: Surface Transportation Board.

ACTION: Notice; withdrawal and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an extension of the collection of the Report of Fuel Cost, Consumption, and Surcharge Revenue, as described below. The Board previously published a notice about this collection in the **Federal Register** on April 17, 2020. That notice allowed for a 60-day public review and comment period. No comments were received.

DATES: The document published on May 29, 2020 (85 FR 32437) is withdrawn as of June 19, 2020. Comments on the information collection in this document should be submitted by July 20, 2020.

ADDRESSES: Written comments should be identified as ''Paperwork Reduction Act Comments, Surface Transportation Board: Report of Fuel Cost, Consumption, and Surcharge Revenue.'' Written comments for the proposed information collection should be submitted via *www.reginfo.gov/public/do/PRAMain.* This information collection can be accessed by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. As an alternative, written comments may be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Michael J. McManus, Surface Transportation Board Desk Officer: by email at *oira_submission@omb.eop.gov;* by fax at (202) 395–1743; or by mail to Room 10235, 725 17th Street NW, Washington, DC 20503.

Please also direct comments to Chris Oehrle, PRA Officer, Surface

Transportation Board, 395 E Street SW, Washington, DC 20423–0001 and to *PRA@stb.gov.* For further information regarding this collection, contact Michael Higgins, Deputy Director, Office of Public Assistance, Governmental Affairs (OPAGAC), and Compliance, at (202) 245–0284 or *michael.higgins@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: This notice replaces a notice prematurely published on May 29, 2020 (85 FR 32437). Comments are requested concerning: (1) The accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Description of Collection

Title: Report of Fuel Cost, Consumption, and Surcharge Revenue.

OMB Control Number: 2140–0014.

STB Form Number: None.

Type of Review: Extension without change.

Respondents: Class I [large] railroads.

Number of Respondents: Seven.

Estimated Time per Response: One hour.

Frequency: Quarterly.

Total Burden Hours (annually including all respondents): 28.

Total ''Non-hour Burden'' Cost: None identified. Filings are submitted electronically to the Board.

Needs and Uses: Under 49 U.S.C. 10702, the Board has the authority to address the reasonableness of a rail carrier's practices. This information collection permits the Board to monitor the current fuel surcharge practices of the Class I carriers. Failure to collect this information would impede the Board's ability to fulfill its statutory responsibilities. The Board has authority to collect information about rail costs and revenues under 49 U.S.C. 11144 and 11145.

Under the PRA, a federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Section 3507(b) of the PRA requires, concurrent with an agency's submitting a collection to OMB for approval, a 30-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: June 12, 2020.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2020–13102 Filed 6–18–20; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

30-Day Notice of Intent To Seek Extension of Approval of Collection: Statutory Licensing Authority

AGENCY: Surface Transportation Board.

ACTION: Notice; withdrawal and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an extension of approval for the information collection required from those seeking statutory licensing authority, as described below. The Board previously published a notice about this collection in the **Federal Register** on April 17, 2020. That notice allowed for a 60-day public review and comment period. No comments were received.

DATES: The document published on May 29, 2020 (85 FR 32436) is withdrawn as of June 19, 2020. Comments on this information collection should be submitted by July 20, 2020.

ADDRESSES: Written comments should be identified as ''Paperwork Reduction Act Comments, Surface Transportation Board: Statutory Licensing Authority.'' Written comments for the proposed information collection should be submitted via *www.reginfo.gov/public/do/PRAMain.* This information collection can be accessed by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. As an alternative, written comments may be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention: Michael J. McManus, Surface Transportation Board Desk Officer: by email at *oira_submission@omb.eop.gov;* by fax at (202) 395–1743; or by mail to Room 10235, 725 17th Street NW, Washington, DC 20503.

Please also direct comments to Chris Oehrle, PRA Officer, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001 and to *PRA@stb.gov.* For further information regarding this collection, contact Michael Higgins, Deputy Director, Office of Public Assistance, Governmental Affairs (OPAGAC), and Compliance, at (202) 245–0284 or *michael.higgins@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: This notice replaces a notice prematurely published on May 29, 2020 (85 FR 32436). Comments are requested concerning: (1) The accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

Description of Collection

Title: Statutory Licensing Authority.

OMB Control Number: 2140–0023.

STB Form Number: None.

Type of Review: Extension without change.

Respondents: Rail carriers and non-carriers seeking statutory licensing or consolidation authority, an exemption from filing an application for such authority, or interchange commitments.

Number of Respondents: 80.

Estimated Time per Response:

ESTIMATED HOURS PER RESPONSE

Type of filing	Number of hours per response under 49 U.S.C. 10901–03 and 11323–26
Applications	524
Petitions *	58
Notices *	19
Interchange commitments	8

Frequency: On occasion.

AVERAGE ANNUAL NUMBER OF RESPONSES FOR FY 2017–2019

Type of filing	Average number of filings per year under 49 U.S.C. 10901–03 and 11323–26
Applications	3
Petitions *	12
Notices *	103

AVERAGE ANNUAL NUMBER OF RESPONSES FOR FY 2017–2019—Continued

Type of filing	Average number of filings per year under 49 U.S.C. 10901–03 and 11323–26
Interchange commitments	4

Total Burden Hours (annually including all respondents): 4,257 (sum of estimated hours per response × number of responses for each type of filing).

TOTAL ANNUAL BURDEN HOURS

Type of filing	Hours per response	Annual number of filings	Total annual burden hours
Applications	524	3	1,572
Petitions *	58	12	696
Notices *	19	103	1,957
Interchange commitments	8	4	32
Total annual burden hours			4,257

* Under section 10502, petitions for exemption and notices of exemption are permitted in lieu of an application.

Total ''Non-hour Burden'' Cost: Because Board collections are submitted electronically to the Board, there is no cost for filing with the Board. However, for some filings, respondents are sometimes required to send consultation letters to various other governmental agencies. Copies of these letters are part of an environmental and historic report that must be filed with this collection (unless waived by the Board). Because some of these other agencies may require hard copy letters, there may be some limited mailing costs, which staff estimates in total to be approximately $1,750.

Needs and Uses: As mandated by Congress, persons seeking to construct, acquire or operate a line of railroad and railroads seeking to abandon or to discontinue operations over a line of railroad or, in the case of two or more railroads, to consolidate their interests through merger or a common-control arrangement are required to file an application for prior approval and authority with the Board. *See* 49 U.S.C. 10901–03, 11323–26. Under 49 U.S.C. 10502, persons may seek an exemption from many of the application requirements of sections 10901–03 and 11323–26 by filing with the Board a petition for exemption or notice of exemption in lieu of an application. The collection by the Board of these applications, petitions, and notices (including collection of disclosures of rail interchange commitments under 49 CFR 1121.3(d), 1150.33(h), 1150.43(h), and 1180.4(g)(4)) enables the Board to meet its statutory duty to regulate the referenced rail transactions. In cases in which the requests for authority involve agreements with interchange commitments that may limit the future interchange of traffic with third parties, certain information must be disclosed to the Board about those commitments. 49 CFR 1121.3(d), 1150.33(h), 1150.43(h), 1180.4(g)(4). The collection of this information facilitates the case-specific review of interchange commitments and enables the Board's monitoring of their usage generally.

Under the PRA, a Federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Section 3507(b) of the PRA requires, concurrent with an agency's submitting a collection to OMB for approval, a 30-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: June 12, 2020.

Jeffrey Herzig,

Clearance Clerk.

[FR Doc. 2020–13103 Filed 6–18–20; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36410]

Northeast Texas Connector, LLC—Operating Exemption—Northeast Texas Rural Rail Transportation District

Northeast Texas Connector, LLC (NETC), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to operate a rail line owned by the Northeast Texas Rural Rail Transportation District (NETEX) located between milepost 555.0 in Greenville, Tex., and milepost 489.41 in Winfield, Tex., a distance of approximately 65.59 route miles (the Line).[1]

NETC states that the proposed transaction does not involve any provision or agreement that would limit future interchange with a third-party connecting carrier. NETC certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier and will not exceed $5 million.

NETC has also filed a petition for waiver of 49 CFR 1150.32(b), which states that a notice of exemption will be effective 30 days after the notice is filed. NETC asks the Board to waive that provision and allow this notice to become effective after 23 days so that NETC can assume operations by June

[1] On February 14, 2020, another carrier, The Blacklands Railroad (BLR), was granted an exemption to discontinue its operations on the Line and an adjacent 10.41-mile segment of track owned by Union Pacific Railroad Company. *Blacklands R.R.—Discontinuance of Serv. Exemption—in Hunt, Delta, Hopkins, Franklin, & Titus Ctys., Tex.,* AB 1108 (Sub-No. 1X) (STB served Feb. 14, 2020).

26, 2020. NETC states that BLR intends to discontinue its operations on the Line on June 30, 2020, and that NETC seeks to avoid a disruption of rail service on the Line. NETC's request will be addressed in a separate decision. The Board will establish the effective date of the exemption in its separate decision on the waiver request.

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed no later than June 24, 2020.

All pleadings, referring to Docket No. 36410, must be filed with the Surface Transportation Board either via e-filing or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on NETC's representative, Charles Shewmake, Thompson & Knight, LLP, One Arts Plaza, 1722 Routh Street, Suite 1500, Dallas, TX 75201.

According to NETC, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic reporting requirements under 49 CFR 1105.8(b)(1).

Board decisions and notices are available at *www.stb.gov.*

Decided: June 15, 2020.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Brendetta Jones,

Clearance Clerk.

[FR Doc. 2020–13228 Filed 6–18–20; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2020–0616]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: Certification Procedures for Products and Parts

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection in FAA regulations that prescribe certification standards for aircraft, aircraft engines, propellers appliances and parts. The information collected is used to determine compliance and applicant eligibility. The respondents are aircraft parts designers, manufacturers, and aircraft owners.

DATES: Written comments should be submitted by August 18, 2020.

ADDRESSES: Please send written comments:

By Electronic Docket: https://www.regulations.gov (Enter docket number into search field).

By mail: Brian Cable, Federal Aviation Administration, AIR–6C0, 800 Independence Ave. SW, Washington, DC 20591.

By fax: 202–267–1813.

FOR FURTHER INFORMATION CONTACT: Brian Cable by email at: *brian.cable@faa.gov;* phone: 202–267–1579.

SUPPLEMENTARY INFORMATION:

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for FAA's performance; (b) the accuracy of the estimated burden; (c) ways for FAA to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0018.

Title: Certification Procedures for Products and Parts.

Form Numbers: FAA Forms 8110–12, 8130–1, 8130–6, 8130–9, 8130–12.

Type of Review: Renewal of an information collection.

Background: 14 CFR part 21 prescribes certification standards for aircraft, aircraft engines, propellers appliances and parts. The information collected is used to determine compliance and applicant eligibility. FAA Airworthiness inspectors, designated inspectors, engineers, and designated engineers review the required data submittals to determine that aviation products and articles and their manufacturing facilities comply with the applicable requirements, and that the products and articles have no unsafe features.

Respondents: Approximately 50,700 aircraft parts designers, manufacturers, and aircraft owners.

Frequency: On occasion.

Estimated Average Burden per Response: 30 minutes.

Estimated Total Annual Burden: 18,785 hours.

Issued in Washington, DC, on June 16, 2020.

Joy Wolf,

Management & Program Analyst for Regulatory and Guidance Processing, Aircraft Certification Service.

[FR Doc. 2020–13259 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0085]

Request for Comments on the Approval of a Previously Approved Information Collection: Determination of Fair and Reasonable Rates for Carriage of Agriculture Cargoes on U.S. Commercial Vessels

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information to be collected will be used by the Maritime Administration in determining fair and reasonable guideline rates for the carriage of preference cargoes on U.S.-flag vessels. In addition, U.S.-flag vessel operators are required to submit Post Voyage Reports to the Maritime Administration after completion of a cargo preference voyage. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before August 18, 2020.

ADDRESSES: You may submit comments [identified by Docket No. MARAD–2019–0085] through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the Department's

performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information.

The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Albert Bratton, Telephone Number: (202) 366–5769, Office of Business Finance, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Determination of Fair and Reasonable Rates for Carriage of Agriculture Cargoes on U.S.-Commercial Vessels.

OMB Control Number: 2133–0514.

Type of Request: Renewal of a previously approved collection.

Abstract: 46 U.S.C. 55305 and the Food Security Act of 1985 require that at least 50% of U.S. government sponsored agriculture bulk and packaged cargoes be shipped on U.S.-flag vessels to the extent that such vessels are available at fair and reasonable rates. Pursuant to 46 CFR part 381, Government agencies must comply with the cargo preference laws and must submit data to the Maritime Administration (MARAD) on U.S. and foreign-flag carriage of preference cargoes under their control. Part 382 requires U.S. operators to submit specific data to MARAD regarding fair and reasonable guideline rates for the carriage of preference cargoes on U.S.-flag vessels. The collection of vessel data contributes toward the U.S. Department of Transportation's strategic goal of National Security. In addition, this data collection requires U.S.-flag operators to submit vessel-operating costs and capital costs data to MARAD officials on an annual basis. This information is needed by MARAD to establish fair and reasonable guideline rates for carriage of specific cargoes on U.S. vessels.

Respondents: U.S. citizens who own and operate U.S.-flag vessels.

Affected Public: Business or other for profit.

Estimated Number of Respondents: 41.

Estimated Number of Responses: 68.

Estimated Hours per Response: 1–4 hours.

Annual Estimated Total Annual Burden Hours: 176.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.)

* * * * *

Dated: June 15, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–13220 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0084]

Request for Comments on the Approval of a Previously Approved Information Collection: Application for Construction Reserve Fund and Annual Statements (CRF)

AGENCY: Maritime Administration, DOT.

ACTION: Notice and request for comments.

SUMMARY: The Maritime Administration (MARAD) invites public comments on our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The information to be collected is required in order for MARAD to determine whether the applicant is qualified for the benefits of the CRF program. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Comments must be submitted on or before August 18, 2020.

ADDRESSES: You may submit comments [identified by Docket No. MARAD–2020–0084] through one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Search using the above DOT docket number and follow the online instructions for submitting comments.
- *Fax:* 1–202–493–2251.
- *Mail or Hand Delivery:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

FOR FURTHER INFORMATION CONTACT: Daniel Ladd, 202–366–1859, Office of Financial Approvals, Maritime Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE, Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

Title: Application for Construction Reserve Fund (CRF) and Annual Statements.

OMB Control Number: 2133–0032.

Type of Request: Renewal of a previously approved collection.

Abstract: The Construction Reserve Fund (CRF), authorized by 46 U.S.C. Chapter 533, is a financial assistance program which provides tax deferral benefits to U.S.-flag operators. Eligible parties can defer the gain attributable to the sale or loss of a vessel, provided the proceeds are used to expand or modernize the U.S. merchant fleet. The primary purpose of the CRF is to promote the construction, reconstruction, reconditioning, or acquisition of merchant vessels which are necessary for national defense and to the development of U.S. commerce.

Respondents: Citizens who own or operate vessels in the U.S. foreign or domestic commerce who desire tax benefits under the CRF program must respond.

Affected Public: Owners or operators of vessels in the domestic or foreign commerce.

Estimated Number of Respondents: 17.

Estimated Number of Responses: 17.

Estimated Hours per Response: 9 Hours.

Annual Estimated Total Annual Burden Hours: 153.

Frequency of Response: Annually.

(Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.93.)

* * * * *

Dated: June 15, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–13219 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0087]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel AEGIS (Sailing Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 20, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0087 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0087 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0087, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel AEGIS is:

—*Intended Commercial Use of Vessel:* ''Applicant intends to operate AEGIS as a midsized luxury charter sailing vessel. AEGIS intends to provide a safe platform from which guests may experience multi-day voyages and the exceptional aesthetics of living aboard an OYSTER yacht.''

—*Geographic Region Including Base of Operations:* ''Maine, New Hampshire'' Currently, the AEGIS has a small vessel waiver for Rhode Island, Connecticut, and Massachusetts with a base of operations in Newport, RI (See *www.regulations.gov* search docket ''MARAD–2019–0177'').

—*Vessel Length and Type:* 72′ sailing vessel.

The complete application is available for review identified in the DOT docket as MARAD–2020–0087 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2020–0087 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: June 15, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2020–13218 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0086]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel PLATINUM PRINCESS (Motor Vessel); Invitation for Public Comments

AGENCY: Maritime Administration, DOT.

ACTION: Notice.

SUMMARY: The Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirements of the coastwise trade laws to allow the carriage of no more than twelve passengers for hire on vessels, which are three years old or more. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before July 20, 2020.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0086 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Search MARAD–2020–0086 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* Docket Management Facility is in the West Building, Ground Floor of the U.S. Department of Transportation. The Docket Management Facility location address is: U.S. Department of Transportation, MARAD–2020–0086, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name and a mailing address, an email address, or a telephone number in the body of your document so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments, see the section entitled Public Participation.

FOR FURTHER INFORMATION CONTACT: Bianca Carr, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE, Room W23–453, Washington, DC 20590. Telephone 202–366–9309, Email *Bianca.carr@dot.gov.*

SUPPLEMENTARY INFORMATION: As described by the applicant the intended service of the vessel PLATINUM PRINCESS is:

—*Intended Commercial Use of Vessel:* ''Inter Costal Charters''

—*Geographic Region Including Base of Operations:* ''New Hampshire, Massachusetts, Connecticut, Rhode Island'' Currently, the Platinum Princess has a small vessel waiver for Florida and New York (excluding New York harbor) with a base of operations in East Islip, NY (See *www.regulations.gov* search docket ''MARAD–2019–0111'').

—*Vessel Length and Type:* 105′ motor vessel

The complete application is available for review identified in the DOT docket as MARAD–2020–0086 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the vessel name, state the commenter's interest in the waiver application, and address the waiver criteria given in section 388.4 of MARAD's regulations at 46 CFR part 388.

Public Participation

How do I submit comments?

Please submit your comments, including the attachments, following the instructions provided under the above heading entitled **ADDRESSES**. Be advised that it may take a few hours or even days for your comment to be reflected on the docket. In addition, your comments must be written in English. We encourage you to provide concise comments and you may attach additional documents as necessary. There is no limit on the length of the attachments.

Where do I go to read public comments, and find supporting information?

Go to the docket online at *http://www.regulations.gov,* keyword search MARAD–2020–0086 or visit the Docket Management Facility (see **ADDRESSES** for hours of operation). We recommend that you periodically check the Docket for new submissions and supporting material.

Will my comments be made available to the public?

Yes. Be aware that your entire comment, including your personal identifying information, will be made publicly available.

May I submit comments confidentially?

If you wish to submit comments under a claim of confidentiality, you should submit three copies of your complete submission, including the information you claim to be confidential business information, to the Department of Transportation, Maritime Administration, Office of Legislation and Regulations, MAR–225, W24–220, 1200 New Jersey Avenue SE, Washington, DC 20590. Include a cover letter setting forth with specificity the basis for any such claim and, if possible, a summary of your submission that can be made available to the public.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, to *www.regulations.gov,* as described in the system of records notice, DOT/ALL–14 FDMS, accessible through *www.dot.gov/privacy.* To facilitate comment tracking and response, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. Whether or not commenters identify themselves, all timely comments will be fully considered. If you wish to provide comments containing proprietary or confidential information, please contact the agency for alternate submission instructions.

(Authority: 49 CFR 1.93(a), 46 U.S.C. 55103, 46 U.S.C. 12121)

* * * * *

Dated: June 15, 2020.

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2020–13217 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary of Transportation

Notice of Funding Opportunity for Letters of Interest for the RRIF Express Pilot Program Under the Railroad Rehabilitation & Improvement Financing Program

AGENCY: Office of the Secretary of Transportation and U.S. Department of Transportation.

ACTION: Notice of funding opportunity.

SUMMARY: This notice modifies the pilot Railroad Rehabilitation and Improvement Financing (''RRIF'') Express Program (''RRIF Express'') aimed at increasing access to the RRIF program by short line and regional railroads. Specifically, this notice provides a 60-day extension of the existing RRIF Express Deadline of June 15, 2020 due to the current and on-going crisis. The new deadline is August 15, 2020.

The original NOFO with modifications follows.

The RRIF Express Program will be administered by the DOT's National Surface Transportation and Innovative Finance Bureau (the ''Build America Bureau'' or ''Bureau''). The overall RRIF program finances development of railroad infrastructure, and is authorized to have up to $35 billion in outstanding principal amounts from direct loans and loan guarantees at any one time.

The 2018 Consolidated Appropriations Act [1] appropriated $25 million in budget authority to the DOT to cover the cost to the Federal Government (''the Government'') of RRIF credit assistance (Credit Risk Premium (''CRP'') Assistance or ''CRP Assistance''). Additionally, the 2016 Consolidated Appropriations Act [2] and the 2018 Consolidated Appropriations Act [3] provided $1.96 million and $350,000, respectively (of which approximately $1 million remains available), to the DOT to fund certain expenses incurred by prospective RRIF borrowers in preparation of their applications for RRIF credit assistance (this approximately $1 million assistance, collectively, ''Cost Assistance''). Using existing authorities and these new budget authorities, the DOT has established the RRIF Express Program.

Subject to the availability of funds, applicants accepted into the RRIF Express Program may benefit from two types of financial assistance: (a) Cost Assistance up to $100,000 per application to pay for a portion of the Bureau's advisor expenses borne by applicants; and (b) for those applicants that ultimately receive RRIF credit assistance, CRP Assistance up to 5% of the final RRIF loan amount to offset the CRP paid by the borrower. Any costs beyond $100,000 and any CRP beyond 5% would be paid by the prospective RRIF borrower. These funds will be made available to benefit applicants accepted into the RRIF Express Program on a first come, first served basis until each source of funding is expended or this notice is superseded by a new Notice of Funding Opportunity. Letters of Interest will be accepted in the order received and will be allocated cost assistance based on the date of acceptance into the pilot program. CRP assistance will be allocated in the order of financial close. For more information about potential financial assistance for RRIF Express applicants, see Supplementary Information: Section II. Funding of CRP and Cost Assistance.

This notice solicits Letters of Interest from prospective RRIF borrowers seeking acceptance into the RRIF Express Program, establishes eligibility criteria and describes the process that prospective borrowers must follow when submitting Letters of Interest.

DATES: Letters of Interest from prospective RRIF borrowers for the RRIF Express Program must be submitted by August 15, 2020.

Prospective RRIF borrowers that have previously submitted a Letter of Interest but that also seek acceptance into the RRIF Express Program should resubmit a Letter of Interest during the submission window above and follow the instructions below.

ADDRESSES: Applicants to the RRIF Express Program must use the latest version of the Letter of Interest form available on the Build America Bureau website: *https://www.transportation.gov/content/build-america-bureau* (including applicants who have previously submitted Letters of Interest and who are now seeking participation in the RRIF Express Program). Letters of Interest must be submitted to the Build America Bureau via email at: *RRIFexpress@dot.gov* using the following subject line: ''Letter of Interest for RRIF Express Program.'' Submitters should receive a confirmation email, but are advised to request a return receipt to confirm transmission. Only Letters of Interest received via email at the above email address with the subject line listed above shall be deemed properly filed.

FOR FURTHER INFORMATION CONTACT: For further information regarding this notice please contact William Resch via email at *william.resch@dot.gov* or via telephone at 202–366–2300. A TDD is available at 202–366–3993.

SUPPLEMENTARY INFORMATION: RRIF Express pilot program information, including any additional resources, terms, conditions and requirements when they become available, can be found on the Build America Bureau website at: *https://www.transportation.gov/buildamerica/rrif-express.* For further information about the overall RRIF program in general, including details about the types of credit assistance available, eligibility requirements and the creditworthiness review process, please refer to the *Build America Bureau Credit Programs Guide* (''*Programs Guide*)'', available on the Build America Bureau website: *https://www.transportation.gov/buildamerica/programs-services/tifia/program-guide.*

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I. Background

The Transportation Equity Act for the 21st Century,[4] established the RRIF program, authorizing the DOT to provide credit assistance in the form of direct loans and loan guarantees to public and private applicants for eligible railroad projects. The RRIF program is a DOT program and final approval of credit assistance is reserved for the Secretary of the DOT. The 2005 Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users; [5] the Rail Safety Improvement Act of 2008; [6] and the 2015 Fixing America's Surface Transportation Act [7] (the ''FAST Act'') each made a number of changes to the RRIF program. In addition, the FAST Act authorized the creation of the Bureau to consolidate

[1] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

[2] Public Law 114–113, div. L, tit. I, § 152, 129 Stat. 2242, 2856.

[3] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

[4] Public Law 105–178, 7203, 112 Stat. 107, 471.

[5] Public Law 109–59, 9003, 119 Stat. 1144, 1921.

[6] Public Law 110–432, 701(e), 122 Stat. 4848, 4906.

[7] Public Law 114–94, Subtitle F, 129 Stat. 1312, 1693.

administration of certain DOT credit and grant programs, including the RRIF program.

II. Funding of CRP Assistance and Cost Assistance

Through the RRIF program, the DOT is authorized to have, at any one time, up to $35 billion in unpaid principal amounts of obligations under direct loans and loan guarantees to finance development of railroad infrastructure.

CRP Assistance

Prior to the 2018 Consolidated Appropriations Act, the RRIF program did not have an appropriation of budget authority to pay the cost to the Government of providing RRIF credit assistance. As a result, the RRIF borrower or a third party was required to bear this cost through the payment of a CRP. The 2018 Consolidated Appropriations Act [8] provided $25 million to the DOT to cover the cost to the Government of RRIF credit assistance. The DOT will use this funding to pay or offset the CRP (up to 5% of the RRIF loan amount) payable by participants in the RRIF Express Program, until this funding is expended or this notice is superseded by a new Notice of Funding Opportunity.

Cost Assistance

As described in the *Programs Guide,* RRIF borrowers are required to pay (or reimburse the DOT) for costs incurred by the Bureau in connection with the review of Letters of Interest and applications for RRIF credit assistance. The 2016 Consolidated Appropriations Act [9] and the 2018 Consolidated Appropriations Act [10] collectively provided $2.31 million to the DOT to be used to fund expenses incurred by prospective RRIF borrowers in preparation to apply for RRIF credit assistance. A portion of these funds have already been allocated for prior RRIF projects. The DOT is reserving approximately $1 million of remaining funds from these appropriations to offset the cost of DOT advisors (up to $100,000 per application) that would be payable by participants in the RRIF Express Program, until this funding is expended or this notice is superseded by a new Notice of Funding Opportunity.

[8] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

[9] Public Law 114–113, div. L, tit. I, § 152, 129 Stat. 2242, 2856.

[10] Public Law 115–141, div. L, tit. I, H.R. 1625 at 646 (as enrolled Mar. 23, 2018).

III. Eligibility Requirements for RRIF Credit Assistance

The RRIF statute and implementing rules set forth eligibility requirements for applicants and projects. These requirements as well as other applicable federal requirements are described in detail in the *Programs Guide* and apply to all applicants and projects, including those seeking acceptance into the RRIF Express Program. In addition, for prospective borrowers seeking RRIF Express Program benefits, the requirements set forth in section IV (Eligibility Criteria for the RRIF Express Program) of this notice also apply.

IV. Eligibility Criteria for the RRIF Express Program

The DOT has identified the following strategic objectives for the RRIF Express Program: Encouraging increased utilization of RRIF credit assistance by Class II and Class III railroads; reducing transaction costs for Class II and Class III railroads; and streamlining the underwriting process for Class II and Class III railroads. These priorities are reflected in the eligibility criteria below. Generally, projects most suitable for the RRIF Express Program are rail line modernization projects where the borrower has a well-documented financial history and easily identified revenue stream(s) for loan repayment.

To differentiate among Letters of Interest received for projects under this notice of funding opportunity, the DOT will consider whether the project satisfies the following eligibility criteria as demonstrated by the Letter of Interest:

(i) *Applicant:* The applicant must be a Class II railroad, a Class III railroad, or a joint venture with a Class II or III railroad.

(ii) *Project Size:* The project must have eligible project costs of $50 million or less.

(iii) *Project Scope:* The project scope, as described in Section B4 of the Letter of Interest, must be limited to the activities below:

(a) Track improvement predominantly within existing railroad right-of-way, including stabilizing embankments, installing or reinstalling track, re-grading, replacing rail, ties, slabs and ballast, installing, maintaining, or restoring drainage ditches, cleaning ballast, constructing minor curve realignments, improving or replacing interlockings, improving grade crossings and warning devices, and the installation of ancillary equipment such as for communication, signals and train control;

(b) Bridge rehabilitation, including reconstruction or replacement, the rehabilitation of the rail elements of docks or piers for the purposes of intermodal transfers, and the construction of bridges, culverts, or grade separation projects that are predominantly within existing right-of-way and that do not involve extensive in-water construction activities, such as projects replacing bridge components including stringers, caps, piles, or decks, the construction of roadway overpasses to replace at-grade crossings, construction or reconstruction of approaches or embankments to bridges, or construction or replacement of short span bridges;

(c) Rolling stock acquisition including locomotives, passenger coaches, freight cars, trainsets, and construction, maintenance or inspection equipment;

(d) Planning and design related to the project activities included under items (a)–(c) above;

(e) Refinancing of non-federal debt (incurred at least three years prior to [*DATE OF PUBLICATION OF THIS NOTICE*] and for the purpose of one or more of the activities listed in 45 U.S.C. 822(b)(1)(A) or (C). Refinancing is limited to up to 40% of the final RRIF loan amount. Letters of Interest including refinancing must demonstrate with specificity in Section D5 how the refinancing would improve the creditworthiness of the applicant and document how such improvement would facilitate the activities referenced in items (a)–(c) above and would increase the applicant's ability to repay a RRIF loan and the overall financial health of the applicant.

(iv) *Applicant Financial History and Projections:* Attachment D–1 of the Letter of Interest must include audited financial statements (by a qualified third party, *e.g.,* a certified public accountant) for the two (2) most recent consecutive years preceding the year of application and that have no significant unresolved findings (*e.g.,* fiscal years 2018 and 2019). Interim unaudited financial statements may be submitted with a letter pledging to provide these audited statements within 60 days of submitting of the LOI and supporting materials. Failure to provide the audited financial statements within 60 days will disqualify the LOI. Applicants choosing this option must still provide unaudited financial statements for the previous five years and prospective financial projections (pro-forma) for the term of the loan.

(v) *Collateral:* If collateral will be pledged for the RRIF loan, Section D9 of the Letter of Interest must be supported with an independent appraisal of the collateral that must have been completed within the past 12 months

preceding submission of an LOI. Section D9 of the Letter of Interest must demonstrate that the collateral will be unencumbered at time of closing, including a description of any lien release process that would occur prior to closing on the RRIF loan to render currently pledged collateral unencumbered.

(vi) *Environmental Clearance:* Section B6 and Attachment B–6 of the Letter of Interest must demonstrate that either NEPA review is complete or the project qualifies for a Categorical Exclusion under NEPA, in which case Attachment B–6 must include a completed Federal Railroad Administration Categorical Exclusion worksheet with its Letter of Interest. For projects involving replacement of existing railroad bridges, supporting documentation must be provided that assesses the eligibility of the bridge for listing in the National Register of Historic Places and addressing compliance with Section 106 of the National Historic Preservation Act.

(vii) *Domestic Preference:* Section B4(a) of the Letter of Interest must demonstrate that the steel, iron, and manufactured goods used in the project will be produced in the United States in accordance with the Federal Railroad Administration ''RRIF Buy America'' policy, which follows 49 U.S.C. 24405(a). Projects that require a waiver are not eligible for the RRIF Express Program, however, prospective borrowers can seek a loan from the overall RRIF program for projects that require a waiver.

(viii) *Project Readiness:* Section B4(c) of the Letter of Interest must demonstrate the prospective borrower's ability to commence the contracting process for construction of the project (*e.g.,* issuance of a final RFP) by not later than 90 days after the date on which a RRIF credit instrument is obligated for the project.

V. Letter of Interest Process and Review and Next Steps

A. Submission of Letters of Interest

All prospective borrowers seeking acceptance into the RRIF Express Program should submit a Letter of Interest following the instructions described in this notice of funding opportunity. The Letter of Interest should be annotated with ''RRIF EXPRESS'' immediately following the Applicant Name in the Summary Information section on page one of the Letter of Interest. The Letter of Interest must, among other things:

(i) Describe the project and its components, location, and purpose in Section B, and include as Attachment B–2 the project budget organized according to construction elements from preliminary engineering estimates, and including costs as appropriate for property, vehicles, professional services, allocated and unallocated contingency, and finance charges;

(ii) Outline the proposed financial plan in Section C, and include the financial model, that addresses such aspects as model assumptions, annual cash flows, balance sheets, income statements and repayment schedules for the duration of the loan, as well as coverage ratios and debt metrics. The model should allow reviewers the flexibility to evaluate scenarios in the native spreadsheet (Microsoft Excel, or equivalent) format and be included in the application as Attachment C–1;

(iii) Provide information regarding satisfaction of other statutory eligibility requirements of the RRIF credit program; and

(iv) Provide information regarding satisfaction of the RRIF Express Program eligibility criteria (as described in Section IV above).

Prospective RRIF Express borrowers should describe in Letter of Interest Section D8 if the project will (1) decrease transportation costs and improve access, especially for rural communities or communities in Opportunity Zones,[11] through reliable and timely access to employment centers and job opportunities; (2) improve long-term efficiency, reliability or costs in the movement of workers or goods; (3) increase the economic productivity of land, capital, or labor, including assets in Opportunity Zones; (4) result in long-term job creation and other economic opportunities; or (5) help the United States compete in a global economy by facilitating efficient and reliable freight movement. Projects that bridge gaps in service in rural areas, and projects that attract private economic development, all support local or regional economic competitiveness.

Letters of Interest must be submitted using the latest form on the Build America Bureau website: *https://www.transportation.gov/content/build-america-bureau.* Other RRIF Express pilot program information including any additional terms, conditions, and requirements can be found on the Build America Bureau website at: *https://www.transportation.gov/buildamerica/rrif-express.* The Bureau may contact a prospective borrower for clarification of specific information included in the Letter of Interest. The Bureau will review all Letters of Interest properly filed and received in the submission time window provided herein.

[11] See *https://www.cdfifund.gov/Pages/Opportunity-Zones.aspx* for more information on Opportunity Zones.

B. Review and Evaluation

Each Letter of Interest that is properly filed and received will be evaluated for completeness and eligibility for the RRIF Express Program using the criteria in this notice. This initial step of the review process will include (1) an evaluation as to whether the proposed project and applicant satisfy RRIF statutory eligibility requirements, and (2) an evaluation as to whether the proposed project and applicant satisfy the RRIF Express Program eligibility criteria.

The Letters of Interest determined to be eligible for the RRIF Express Program will then be advanced to the Bureau's creditworthiness review process, which is an in-depth creditworthiness review of the project sponsor and the revenue stream proposed to repay the RRIF credit assistance as described in the *Programs Guide.* The Secretary reserves the right to limit the number of applications from a single entity or subordinates of a single parent or holding company. Prospective RRIF borrowers whose RRIF Express Program Letters of Interest are determined to be ineligible, but whose projects are otherwise statutorily eligible for standard RRIF credit assistance, have the option to be considered under the overall RRIF program.

Issued in Washington, DC.

Morteza Farajian,

Executive Director, The Build America Bureau.

[FR Doc. 2020–13212 Filed 6–18–20; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

[Case ID: CYBER2–16237]

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in

property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for effective date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The Specially Designated Nationals and Blocked Persons List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On June 16, 2020, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals:

1. BENSON, Nnamdi Orson, Nigeria; DOB 21 Mar 1987; nationality Nigeria; Gender Male; Passport A06417829 (Nigeria) (individual) [CYBER2].

Designated pursuant to section 1(a)(iii)(B) of Executive Order 13694 of April 1, 2015, ''Blocking Property of Certain Persons Engaging in Significant Malicious Cyber-Enabled Activities,'' as amended by Executive Order 13757 of December 28, 2016, ''Taking Additional Steps to Address the National Emergency With Respect to Significant Malicious Cyber-Enabled Activities,'' (E.O. 13694, as amended), for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Richard Izuchukwu UZUH, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

2. KAYODE, Abiola Ayorinde, Nigeria; DOB 14 Nov 1987; nationality Nigeria; Gender Male; Passport A05637743 (Nigeria) (individual) [CYBER2].

Designated pursuant to section 1(a)(iii)(B) of E.O. 13694, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Richard Izuchukwu UZUH and Micheal OLORUNYOMI, persons whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

3. OGUNSHAKIN, Alex Afolabi, Nigeria; DOB 23 Feb 1983; nationality Nigeria; Gender Male; Passport A05285583 (Nigeria) (individual) [CYBER2].

Designated pursuant to section 1(a)(iii)(B) of E.O. 13694, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Richard Izuchukwu UZUH, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

4. OKPOH, Felix Osilama, Nigeria; DOB 09 Mar 1989; nationality Nigeria; Gender Male; Passport A06415967 (Nigeria) (individual) [CYBER2].

Designated pursuant to section 1(a)(iii)(B) of E.O. 13694, as amended, for having materially assisted, sponsored, or provided financial, material, or technological support for, or goods or services to or in support of, Richard Izuchukwu UZUH, a person whose property and interests in property are blocked pursuant to E.O. 13694, as amended.

5. OLORUNYOMI, Micheal, Nigeria; DOB 12 May 1983; nationality Nigeria; Gender Male; Passport A50143448 (Nigeria) (individual) [CYBER2].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13694, as amended, for being responsible for or complicit in, or having engaged in, directly or indirectly, cyber-enabled activities originating from, or directed by persons located, in whole or in substantial part, outside the United States that are reasonably likely to result in, or have materially contributed to, a significant threat to the national security, foreign policy, or economic health or financial stability of the United States and that have the purpose or effect of causing a significant misappropriation of funds or economic resources, trade secrets, personal identifiers, or financial information for commercial or competitive advantage or private financial gain.

6. UZUH, Richard Izuchukwu, Nigeria; DOB 29 Apr 1986; nationality Nigeria; Gender Male; Passport A05284868 (Nigeria) (individual) [CYBER2].

Designated pursuant to section 1(a)(ii)(D) of E.O. 13694, as amended, for being responsible for or complicit in, or having engaged in, directly or indirectly, cyber-enabled activities originating from, or directed by persons located, in whole or in substantial part, outside the United States that are reasonably likely to result in, or have materially contributed to, a significant threat to the national security, foreign policy, or economic health or financial stability of the United States and that have the purpose or effect of causing a significant misappropriation of funds or economic resources, trade secrets, personal identifiers, or financial information for commercial or competitive advantage or private financial gain.

Dated: June 16, 2020.

Andrea Gacki,

Director, Office of Foreign Assets Control.

[FR Doc. 2020–13271 Filed 6–18–20; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0342]

Agency Information Collection Activity: Application and Training Agreement for Apprenticeship and On-the-Job Training Programs

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Veterans Benefits Administration (VBA), Department of Veterans Affairs (VBA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 18, 2020.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0342'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Danny S. Green at (202) 421–1354.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: 10 U.S.C. 16131(d), 16136, and section 510 of chapter 31. 38 U.S.C. 3034(a)(1), 3241(a)(1), 3323(a), 3534(a), 3671, 3672, 3687(a); 38 CFR 21.4150(c), 21.4261(b) and (c), 21.5250(a), 21.7220(a), and 21.7720.

Title: Application and Training Agreement For Apprenticeship and On-the-Job Training Programs.

OMB Control Number: 2900–0342.

Type of Review: Revision of a currently approved collection.

Abstract: Each on-the-job trainee must receive a training agreement in accordance with statutory and regulatory requirements. VA form 22–8864 (or the training agreement provided by the SAA) is used to meet these requirements. VA Form 22–8865 (or the equivalent tool provided by the SAAs) is used to ensure that training programs meet the statutory and regulatory requirements for approval.

Affected Public: Individuals and households.

Estimated Annual Burden: 11,744 hours.

Estimated Average Burden per Respondent: 120 minutes.

Frequency of Response: Once on occasion.

Estimated Number of Respondents: 5,872.

By direction of the Secretary.

Danny S. Green,

VA PRA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2020–13206 Filed 6–18–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0655]

Agency Information Collection Activity: Residency Verification Report—Veterans and Survivors

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before August 18, 2020.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0655 in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Danny S. Green at (202) 421–1354.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or the use of other forms of information technology.

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Residency Verification Report—Veterans and Survivors (FL21–914).

OMB Control Number: 2900–0655.

Type of Review: Extension of a currently approved collection.

Abstract: Form Letter 21–914 is used to gather information which is necessary to verify whether a veteran or beneficiary who is receiving benefits at the full-dollar rate based on U.S. residency continues to meet the residency requirements. Continued eligibility to benefits at the full-dollar rate cannot be determined without complete information about a veteran's or beneficiary's residency.

Affected Public: Individuals and households.

Estimated Annual Burden: 417 hours.

Estimated Average Burden per Respondent: 20 minutes.

Frequency of Response: Once.

Estimated Number of Respondents: 1,250.

By direction of the Secretary:

Danny S. Green,

Department Clearance Officer, Office of Quality, Privacy and Risk (OQPR), Department of Veterans Affairs.

[FR Doc. 2020–13247 Filed 6–18–20; 8:45 am]

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Part II

Department of Health and Human Services

Centers for Medicare and Medicaid Services

42 CFR Parts 438, 440, and 460

45 CFR Parts 86, 92, 147, et al.

Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 438, 440, and 460

Office of the Secretary

45 CFR Parts 86, 92, 147, 155, and 156

RIN 0945–AA11

Nondiscrimination in Health and Health Education Programs or Activities, Delegation of Authority

AGENCY: Centers for Medicare & Medicaid Services (CMS); Office for Civil Rights (OCR), Office of the Secretary, Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Department of Health and Human Services (''the Department'' or ''HHS'') is committed to ensuring the civil rights of all individuals who access or seek to access health programs or activities of covered entities under Section 1557 of the Patient Protection and Affordable Care Act (''ACA''). After considering public comments, in this final rule, the Department revises its Section 1557 regulations, Title IX regulations, and specific regulations of the Centers for Medicare & Medicaid Services (''CMS'') as proposed, with minor and primarily technical corrections. This will better comply with the mandates of Congress, address legal concerns, relieve billions of dollars in undue regulatory burdens, further substantive compliance, reduce confusion, and clarify the scope of Section 1557 in keeping with pre-existing civil rights statutes and regulations prohibiting discrimination on the basis of race, color, national origin, sex, age, and disability.

DATES: This rule is effective August 18, 2020.

FOR FURTHER INFORMATION CONTACT: Luben Montoya, Supervisory Civil Rights Analyst, HHS Office for Civil Rights, at (800) 368–1019 or (800) 537–7697 (TDD).

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I. Executive Summary

A. Purpose

This regulation finalizes the Department's proposed rule concerning Nondiscrimination in Health and Health Education Programs or Activities issued in the **Federal Register** on June 14, 2019 (84 FR 27846), with minor and primarily technical corrections. It makes changes to the Department's existing regulation [1] (''2016 Rule'') implementing Section 1557 of the ACA, 42 U.S.C. 18116. It makes a related amendment to the Department's regulations implementing Title IX of the Education Amendments of 1972 (''Title IX''), and it makes conforming amendments to nondiscrimination provisions within various CMS regulations.

Through Section 1557 of the ACA, Congress applied certain long-standing civil rights nondiscrimination requirements to any health programs or activities that receive Federal financial assistance, and any programs or activities administered by an Executive agency under Title I of the ACA or by an entity established under such Title. It did so by cross-referencing statutes that specify prohibited grounds of discrimination, namely, race, color, national origin, sex, age, or disability, in an array of Federally funded and administered programs or activities. To ensure compliance, Congress dictated that ''[t]he enforcement mechanisms provided for and available under'' such laws ''shall apply for purposes of violations of'' Section 1557.[2]

This final rule returns to the enforcement mechanisms provided for, and available under, those longstanding statutes and the Department's implementing regulations. It eliminates many of the provisions of the 2016 Rule in order to better comply with the mandates of Congress, relieves approximately $2.9 billion in undue regulatory burdens (over five years), furthers substantive compliance, reduces confusion, and clarifies the scope of Section 1557. It empowers the Department to continue its robust enforcement of civil rights laws by making clear that the substantive protections of Title VI of the Civil Rights Act of 1964 (''Title VI''), Title IX, the Age Discrimination Act of 1975 (''Age Act''), and Section 504 of the Rehabilitation Act of 1973 (''Section 504'') remain in full force and effect.[3]

This final rule is needed because the Department has determined that portions of the 2016 Rule are duplicative or confusing, impose substantial unanticipated burdens, or impose burdens that outweigh their anticipated benefits. Additionally, two Federal district courts have determined that the Department exceeded its authority in promulgating parts of the regulation, and one has vacated and remanded those parts of the 2016 Rule. By substantially repealing much of the 2016 Rule, including removing the vacated provisions from the Code of Federal Regulations, the Department reverts to longstanding statutory interpretations that conform to the plain meaning of the underlying civil rights statutes and the United States Government's official position concerning those statutes.

The Department initially estimated the costs from the 2016 Rule at over $942 million across the first five years. 81 FR 31458–59. This figure, however, significantly underestimated actual costs, according to the Department's current estimates. As estimated now, the costs derived merely from the 2016 Rule's requirement to provide notices and taglines with all significant communications, after accounting for electronic delivery, amount to an average annual burden of $585 million per year, for a five-year burden of $2.9 billion. Based on the Department's re-examination of the burden on regulated entities, and after reviewing public comments, the Department has determined that the potential public benefits of imposing such requirements are outweighed by the large costs those requirements impose on regulated entities and other parties.

B. Summary of Major Provisions

(1) Changes to the Section 1557 Regulation

a. Elimination of Overbroad Provisions Related to Sex and Gender Identity

This final rule eliminates certain provisions of the 2016 Rule that exceeded the scope of the authority delegated by Congress in Section 1557. The 2016 Rule's definition of discrimination ''on the basis of sex'' encompassed discrimination on the basis of gender identity (''an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female''). In line with that definition, the 2016 Rule imposed several requirements regarding medical treatment and coverage on the basis of gender identity. The same definition also encompassed discrimination on the basis of ''termination of pregnancy'' without incorporating the explicit abortion-neutrality language of 20 U.S.C. 1688 (which some commenters referred to as the Danforth Amendment) in Title IX, and it imposed a high burden of proof on providers to justify offering gynecological or other single-sex medical services.

All of these are essentially legislative changes that the Department lacked the

[1] 81 FR 31375–473 (May 18, 2016) codified at 45 CFR part 92.

[2] 42 U.S.C. 18116.

[3] While Section 1557 does not incorporate nondiscrimination provisions by reference to Title VII, it provides that nothing in Title I of the ACA is to be construed as invalidating or limiting the rights, remedies, procedures, or legal standards available under certain civil rights laws, and mentions Title VII specifically. 42 U.S.C. 18116(b).

authority to make. They purported to impose additional legal requirements on covered entities that cannot be justified by the text of Title IX, and in fact are in conflict with express exemptions in Title IX, even though Title IX provides the only statutory basis for Section 1557's provision against discrimination ''on the basis of sex.'' For this reason, these provisions have already been vacated and remanded by court order. This final rule omits the vacated language concerning gender identity and termination of pregnancy, thereby bringing the provisions of the Code of Federal Regulations into compliance with the underlying statutes and up-to-date as to the effect of the court's order.

The Department also believes that various policy considerations support this action. The 2016 Rule's provisions on sex discrimination imposed new requirements for care related to gender identity and termination of pregnancy that Congress has never required, and prevented covered entities from drawing reasonable and/or medically indicated distinctions on the basis of sex. As a result, those provisions would have imposed confusing or contradictory demands on providers, interfered inappropriately with their medical judgment, and potentially burdened their consciences. By contrast, under this final rule, each State may balance for itself the various sensitive considerations relating to medical judgment and gender identity, within the limits of applicable Federal statutes (which are to be read according to their plain meaning).

b. Clarification of Scope of Covered Entities

In an additional effort to avoid exceeding the Department's statutory authority, this final rule modifies the 2016 Rule's definition of entities covered by Section 1557 in order to align it more closely with the statutory text.

c. Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement

This final rule also eliminates provisions of the 2016 Rule that, by unnecessarily duplicating or overlapping with existing civil rights law and regulations, were either inconsistent or redundant with existing law and regulations, and so were likely to cause confusion about the rights of individuals and the corresponding responsibilities of providers. This final rule prohibits any covered entity from discriminating on the basis of race, color, national origin, sex, age, and disability, according to the meaning of these terms in the underlying Federal civil rights statutes that Section 1557 incorporates, and it commits the Department to enforcing these prohibitions through the enforcement mechanisms already available under those statutes' respective implementing regulations. It eliminates the 2016 Rule's definitions of terms and its list of examples of discriminatory practices, as well as its provisions related to discrimination on the basis of association, disparate impact on the basis of sex, health insurance coverage, certain employee health benefits programs, notification of beneficiaries' rights under civil rights laws, designation of responsible employees and adoption of grievance procedures, access granted to OCR for review of covered entities' records of compliance, prohibitions on intimidation and retaliation, enforcement procedures, private rights of action, remedial action, and voluntary action. In all of these matters, this final rule will defer to the relevant existing regulations and the relevant case law with respect to each of the underlying civil rights statutes, as applied to the health context under Section 1557. It will not create, as the 2016 Rule did, a new patchwork regulatory framework unique to Section 1557 covered entities.

d. Elimination of Unnecessary Regulatory Burdens

This final rule modifies provisions of the 2016 Rule that imposed regulatory burdens on covered entities greater than what was needed in order to ensure compliance with civil rights law. Specifically, it eliminates the burdensome requirement for covered entities to send notices and taglines with all significant communications, clarifies that the provision of health insurance, as such, is not a ''health program or activity,'' brings requirements of meaningful access for persons with limited English proficiency (LEP) into conformity with longstanding DOJ and HHS guidance, and permits remote English-language interpreting services to be audio-based rather than requiring them to be video-based.

The final rule retains numerous other provisions of the 2016 Rule that furthered the goal of civil rights compliance without imposing burdens unnecessary to that goal. These include the obligation for covered entities to submit assurances of compliance, as well as most of the 2016 Rule's provisions ensuring access for individuals with LEP and individuals with disabilities.

e. Other Clarifications and Minor Modifications

This final rule modifies the 2016 Rule's discussion of its own relation to other laws, offering a clearer commitment to implement Section 1557 in conformity with the text of the statutes it incorporates, as well as with the text of numerous other applicable civil rights and conscience statutes. It also makes other minor modifications to the regulatory text.

(2) Related and Conforming Amendments to Other Regulations

a. Title IX

Because the Department's failure to incorporate the abortion neutrality language at 20 U.S.C. 1688 (hereinafter ''abortion neutrality'') and the Title IX religious exemption formed part of the *Franciscan* court's reasoning when it vacated parts of the 2016 Rule, this final rule amends the Department's Title IX regulations to explicitly incorporate relevant statutory exemptions from Title IX, including abortion neutrality and the religious exemption.

b. CMS

Ten provisions in CMS regulations, all of which cover entities that are also subject to Section 1557, have in recent years had language inserted that prohibits discrimination on the basis of sexual orientation and gender identity. In light of this final rule's return to the plain meaning of ''on the basis of sex'' in the civil rights statutes incorporated under Section 1557, and the overarching applicability of Section 1557 to these programs, the Department here finalizes amendments to those regulations to ensure greater consistency in civil-rights enforcement across the Department's different programs by deleting the provisions on sexual orientation and gender identity.

C. Summary of the Costs and Benefits of the Major Provisions

This final rule is an economically significant deregulatory action. The Department projects that this final rule will result in approximately $2.9 billion in cost savings (undiscounted) over the first five years after finalization. The Department anticipates that the largest proportion of these estimated savings would result from repealing the 2016 Rule's provisions related to mandatory notices. The Department projects additional savings from eliminating the requirement for OCR to weigh the presence or absence of language access plans, and from repealing provisions that duplicate existing regulatory requirements regarding the

establishment of grievance procedures. The Department estimates that there will be some additional costs to covered entities regarding training and revision of policies and procedures.

The Department believes that the anticipated benefits—which include consistency with Federal statutes, appropriate respect for the roles of Federal courts and Congress, and reduction or elimination of ineffective, unnecessary, or confusing provisions—far outweigh any costs or burdens that may arise from the changes.

Provision(s)	Savings and benefits	Costs
Sec. 1557: Elimination of Overbroad Provisions Related to Sex and Gender Identity.	For provisions already vacated, eliminating them brings the Code of Federal Regulations in line with current law. For other provisions, eliminating them restores the rule of law by confining regulation within the scope of the Department's legal authority; restores Federalism by leaving to the States decisions properly reserved to them; and removes unjustified burdens on providers' medical judgment.	No costs are anticipated for provisions already vacated, and any possible costs for related provisions are not calculable based on available data.
Sec. 1557: Clarification of Scope of Covered Entities.	Correcting this provision improves the rule of law by interpreting the statute according to its plain meaning as closely as possible.	Costs are not calculable based on available data.
Sec. 1557: Elimination of Unnecessary or Duplicative Language on Civil Rights Enforcement.	Eliminating these provisions reduces duplication, inconsistency, and possible confusion in the Department's civil rights regulations, making it easier for covered entities and individuals to know their respective responsibilities and rights.	The Department estimates $275.8 million of costs in the first year for revision of policies and procedures, along with corresponding retraining of employees. (These costs encompass the next listed set of provisions as well.)
Sec. 1557: Elimination of Unnecessary Regulatory Burdens.	Eliminating these provisions reduces unnecessary, unjustified, or excessive burdens on health providers, as well as excessive and confusing paper notices for patients. This will make healthcare more affordable and accessible for Americans and is estimated to save $585 million per year over the first five years.	See above.
Sec. 1557: Other Clarifications and Minor Modifications.	Amending these provisions improves the rule of law by ensuring that regulations remain subject to statutory protections for conscience and other civil rights, and otherwise contributes to the goals of the other regulatory changes listed above.	No costs are anticipated, and any possible costs are not calculable based on available data.
Title IX regulations, related amendment.	This amendment ensures the rule of law by clarifying that Title IX regulations are subject to the statute's own abortion-neutrality language and religious exemption.	No costs are anticipated, and any possible costs are not calculable based on available data.
CMS regulations, conforming amendments.	These amendments restore the rule of law by confining regulations within the scope of their legal authority, and ensure consistency in civil-rights enforcement across the Department's different programs.	Costs are not calculable based on available data.

II. Background

On May 18, 2016, the Department finalized a regulation implementing Section 1557 of the ACA. The Department had received 402 comments [4] in response to a related request for information in 2015, and 24,875 comments [5] in response to the relevant Notice of Proposed Rulemaking, 80 FR 54172–221 (''2015 NPRM'').

Multiple States and private plaintiffs challenged the 2016 Rule in Federal district courts in Texas and North Dakota on the grounds that it violated Federal laws, including the Administrative Procedure Act (''APA'') and the Religious Freedom Restoration Act (''RFRA'').[6] On December 31, 2016, the U.S. District Court for the Northern District of Texas preliminarily enjoined, on a nationwide basis, portions of the 2016 Rule that had interpreted Section 1557 to prohibit discrimination on the basis of gender identity and termination of pregnancy.[7]

On May 2, 2017, the Department of Justice, on behalf of HHS, filed a motion for voluntary remand to reassess the reasonableness, necessity, and efficacy of the enjoined provisions. On May 24, 2019, HHS issued a notice of proposed rulemaking (''the proposed rule'' or ''the 2019 NPRM'') to amend the 2016 Rule, as well as its regulations effectuating Title IX,[8] and to make conforming amendments to certain nondiscrimination provisions of CMS regulations [9] covered by Section 1557. On June 14, 2019, HHS published the proposed rule in the **Federal Register** [10] and accepted public comment for 60 days thereafter.

On October 15, 2019, upon motion of the plaintiffs, and adopting the reasoning from its preliminary injunction order, the U.S. District Court for the Northern District of Texas vacated and remanded the ''the unlawful portions'' of the 2016 Rule that had been subject to that order.[11] On

[4] *https://www.regulations.gov/docket?D=HHS-OCR-2013-0007.* The comment docket identifies 162 submissions, but some submissions to the docket aggregated multiple comments.

[5] *https://www.regulations.gov/docket?D=HHS-OCR-2015-0006.* The comment docket identifies 2,188 submissions, but some submissions to the docket aggregated multiple comments, and ''the great majority'' of comments were not electronic but were submitted by mail as part of ''mass mail campaigns organized by civil rights/advocacy groups.'' 81 FR 31376.

[6] Complaint, *Franciscan All., Inc.* v. *Burwell,* No. 7:16–cv–00108–O (N.D. Tex. Aug. 23, 2016); *Religious Sisters of Mercy* v. *Burwell,* No. 3:16–cv–386 (D.N.D. filed Nov. 7, 2016); *Catholic Benefits Association* v. *Burwell,* No.3:16–cv–432 (D.N.D. filed Dec. 28, 2016).

[7] *See Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 696 (N.D. Tex. 2016).

[8] 20 U.S.C. 1681 *et seq.;* 45 CFR part 86 (Nondiscrimination on the Basis of Sex in Education Programs or Activities Receiving Federal Financial Assistance).

[9] 42 CFR 438.3, 438.206, 440.262, 460.98, 460.112; 45 CFR 147.104, 155.120, 155.220, 156.200, 156.1230.

[10] 84 FR 27846 (June 14, 2019) (''Nondiscrimination in Health and Health Education Programs'').

[11] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (''Since the Court concludes that ''the Rule's conflict with its incorporated statute—Title IX—renders it contrary to law under the APA,'' the appropriate remedy is *vacatur.* Order 38, ECF No. 62. Accordingly, the Court VACATES and REMANDS the unlawful portions of the Rule for Defendants' further consideration in light of this opinion and the Court's December 31, 2016 Order.''; *id.* at 947 (''The Court ADOPTS its prior reasoning from the

Continued

November 21, 2019, the court clarified that ''the Court vacates only the portions of the Rule that Plaintiffs challenged in this litigation,'' namely, ''insofar as the Rule defines *'On the basis of sex'* to include gender identity and termination of pregnancy . . . The remainder of 45 CFR part 92 remains in effect.'' [12]

The Department herein finalizes the proposed rule without change, except as set forth below, after careful consideration of and responses to public comments.

III. Response to Public Comments on the Proposed Rule

The Department received 198,845 comments in response to the proposed rule during the public comment period.[13] Commenters included Members of Congress, State and local governments, State-based Exchanges, tribes and tribal governments, healthcare providers, health insurers, pharmacies, religious organizations, civil rights groups, non-profit organizations, and individuals, among others.

A. General Comments

Comment: Several commenters, including healthcare providers, explained that although they support nondiscrimination in healthcare and equal access to healthcare for all patients, they have difficulty complying with the parameters of the 2016 Rule. They believe that civil rights protections should be balanced against the burdens they create. Accordingly, these commenters support the proposed regulation as it limits the burdens imposed on providers.

Response: The Department agrees with these commenters' support of nondiscrimination in healthcare and intends to robustly enforce the civil rights authorities. The Department is also cognizant of unduly burdensome regulations. For example, the 2016 Rule did not anticipate some costs to covered entities that range from hundreds of millions to billions of dollars as a result of notice and taglines requirements. Therefore, this final rule seeks to alleviate certain burdens on covered entities while still enforcing the nondiscrimination requirements of Title VI, Title IX, the Age Act, and Section 504.

Comment: Some commenters said the proposed rule would stabilize services for individuals with disabilities and create a more equitable distribution of health services.

Response: The Department agrees. This final rule maintains appropriate protections for individuals with disabilities and will provide clarity for providers and individuals.

Comment: Several commenters expressed concern that eliminating discrimination protections in Section 1557 will cause confusion about patients' rights and remove access to administrative remedies that were previously available.

Response: The Department recommits itself in this rule to enforcing nondiscrimination on the basis of all categories protected by statute. The Department is confident that the clarity associated with maintaining longstanding prohibitions on discrimination under Title VI, Title IX, the Age Act, and Section 504, and their respective implementing regulations, will outweigh any initial confusion stemming from the change.

Comment: Some commenters noted the extensive process involved in developing the 2016 Rule, which included a request for information, the 2015 NPRM, and the 2016 Rule, with the Department considering more than 24,875 public comments. Such commenters suggested this proposed rule unnecessarily reopens the 2016 Rule and ignores the reasoned process that the Department had previously completed. Also, a commenter asked why the Department did not publish a request for information before the proposed rule. Others stated that the proposed rule relies disproportionately on a single district court case, *Franciscan Alliance,*[14] to justify a new interpretation of sex. The commenters go on to suggest that the Department relied exclusively on *Franciscan Alliance* to open up the entire 2016 Rule for edits while ignoring numerous other court cases that come to opposing conclusions regarding sex discrimination.[15]

Response: On December 31, 2016, the *Franciscan Alliance* court preliminarily enjoined the 2016 Rule's gender identity and termination of pregnancy provisions on a nationwide basis, finding them unlawful under the APA and RFRA. A few weeks later, a second Federal district court preliminarily stayed enforcement of the 2016 Rule against two other plaintiffs, citing the *Franciscan* decision.[16] Because of the nationwide preliminary injunction, the Department could not enforce certain provisions from the 2016 Rule. In the process of reconsidering the 2016 Rule, and consistent with applicable Executive Orders and deregulatory priorities, the Department examined the rule more broadly and concluded that, for the reasons explained in the 2019 NPRM, the 2016 Rule had significantly underestimated the costs and burdens it imposed. Because Section 1557 authorizes, but does not require, the creation of new implementing regulations, the Department considered it appropriate to repeal certain portions of the 2016 Rule and enforce Section 1557 using the underlying regulations the Department has used to enforce the relevant civil rights statutes identified in Section 1557. The Department also considered the Executive Branch's most recent statements concerning the interpretation of statutory provisions that prohibit discrimination on the basis of sex.

The Department published its proposed rule in the **Federal Register** on June 14, 2019, opening a two-month public comment period. The Department received nearly 200,000 comments for its review. Through this public comment period, the public was given a full opportunity to provide the Department with information regarding the proposal. It is not necessary to engage in an additional solicitation of public comments through a request for information before the notice of proposed rulemaking. The Department also reviewed the 2016 Rule record and its public comments in considering this final rule.

Through this rulemaking, the Department has provided a comprehensive rationale for this final rule. The 2019 NPRM summarized the Department's legal authority to change the 2016 Rule along with policy rationales for doing so. The quantum of evidence necessary to justify rescinding provisions of a rule is not greater than the evidence needed for issuing it in the

preliminary injunction (ECF No. 62) and now HOLDS that the Rule violates the APA and RFRA. Accordingly, the Court VACATES and REMANDS the Rule for further consideration.'').

[12] Order, *Franciscan Alliance,* No. 7:16–cv–00108–O *2 (N.D. Tex. filed Nov. 21, 2019).

[13] *See https://www.regulations.gov/docket?D=HHS-OCR-2019-0007.* The comment docket identifies 155,966 submissions, but some submissions to the docket aggregated multiple comments. HHS estimates the disaggregated number of comments to be 198,845.

[14] *Franciscan Alliance, Inc.* v. *Burwell,* 227 F. Supp. 3d 660 (N.D. Tex. 2016).

[15] Commenters cited *Boyden* v. *Conlin,* 341 F. Supp. 3d 979 (W.D. Wisc. 2018) (holding Wisconsin's use of transgender exclusions in its state employee health insurance plan constituted sex discrimination in violation of Section 1557 and Title VII); *Flack* v. *Wis. Dept. of Health Servs.,* 328 F. Supp. 3d 931, 951 (W.D. Wis. 2018); *Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (finding Section 1557's plain language bars gender identity discrimination); *Tovar* v. *Essential Health,* 342 F. Supp. 3d 947, 957 (D. Minn. 2018) (same).

[16] *Religious Sisters of Mercy* v. *Burwell,* Nos. 3:16–cv–386 & 3:16–cv–432 (D.N.D. Order of January 23, 2017). *See* 84 FR 27848.

first place.[17] Moreover, after publication of the proposed rule, the Court in *Franciscan Alliance* issued its final judgment vacating and remanding the unlawful portions of the 2016 Rule for the Department's further consideration. The Department has considered that *vacatur,* along with the legal authorities and policy rationales discussed in the NPRM and this preamble, and more thoroughly calculated the costs and effects of the notice and taglines requirements, to arrive at this final rule. Specific responses to comments on its various provisions, including on sex discrimination, are found below.

Comment: Some commenters expressed concern that the updated Section 1557 regulations will have unintended consequences and costs for healthcare providers and individuals seeking healthcare and insurance, particularly pertaining to access standards for people with LEP and communication-based disabilities, in part because the regulatory drafting period was shorter than the period for the 2016 Rule.

Response: The Department has spent several months carefully reviewing comments, providing responses to them in this rule, and finalizing the proposed rule. The Department is leaving several substantive provisions of the 2016 Rule unchanged or substantially unchanged. The changes largely consist of excisions of regulatory text as opposed to the addition of new text, so it is unsurprising that the regulatory drafting period was shorter than the period for the 2016 Rule. In many instances where new or modified regulatory text was proposed, such text was based on existing guidance or regulatory text. The Department considers this to be an adequate process and a sufficient period of time to engage in such rulemaking.

This final rule maintains vigorous protections for people with LEP and communication-based disabilities, as discussed in detail below, and the Department intends to continue robust enforcement of those protections.

Comment: Several commenters indicated that the cost savings cited in the proposed rule are unsupported or based on insufficient data. Several commenters also contend that the proposed rule ignores the costs to individuals, especially LEP individuals, who will allegedly encounter additional barriers to accessing healthcare as a result of the proposed changes. Some commenters were concerned that the proposed rule would help eliminate access to a wide range of affordable preventive health services, including cancer screenings, contraception, and reproductive health services. The commenters believe this loss of access will largely be caused by the proposed changes to the definition of sex discrimination. Many commenters expressed concern that the proposed rule would remove civil rights protections for a number of vulnerable groups, including LEP individuals, LGBT individuals, individuals with disabilities, and women seeking reproductive healthcare. Such commenters state that the removal of these protections would, in turn, result in even greater health disparities for these vulnerable populations. Some commenters stated that the proposed rule would lead to increased discrimination in healthcare, which would lead people to delay or forego healthcare and would result in adverse health outcomes and greater overall healthcare costs to individuals. Some of these commenters note that based on these anticipated increased disparities, the proposed rule is effectively encouraging discrimination.

Response: This final rule leaves in place all statutory civil rights protections for vulnerable groups. Cost savings are treated in the Regulatory Impact Analysis below, which discusses the data, estimates, and assumptions used to support its calculations. Potential health disparities or other alleged costs to individuals or vulnerable groups, including those due to discrimination or barriers to access, are discussed in the relevant sections below (*e.g.,* potential costs to LEP individuals are discussed in comments on those sections of the regulation that deal with national-origin discrimination and/or LEP, while potential costs relating to the gender identity provision are discussed in comments on the section regarding ''discrimination on the basis of sex'').

Comment: Many commenters expressed their belief that this proposed rule diverges from the current body of civil rights laws. These commenters believe that limiting protections based on gender identity, termination of pregnancy, and LEP, runs contrary to civil rights protections.

Response: Current civil rights laws and their protections are discussed, respectively, in the relevant sections below (*e.g.,* civil rights law on gender identity is discussed in the section on ''discrimination on the basis of sex,'' because the 2016 Rule had classified gender identity discrimination as a form of sex-based discrimination).

Comment: Some commenters stated that civil rights protections should not be eliminated because of compliance costs faced by covered entities, and that such balancing runs contrary to the Affordable Care Act and the Administrative Procedure Act. Such commenters argue that if the Department determines that particular protections are too costly or onerous, it should advance more limited protections rather than eliminating them entirely.

Response: This final rule does not, and could not, repeal or eliminate specific protections under any of the four civil rights statutes referenced in Section 1557, and it does not remove the protections provided by the implementing regulations for those statutes.

The Department has, however, chosen to reduce some excessive burdens that were applied to covered entities by the 2016 Rule, but were not required by Section 1557, where the relevant civil rights protections could be enforced using the underlying regulations without the unnecessary burdens imposed by the 2016 Rule.

Comment: Commenters stated that the Department exceeded its authority by proposing this rule. Some commenters indicated that the Department's positions as advanced in the proposed rule are not worthy of deference under the framework established in *Chevron, U.S.A., Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1984), because the proposed rule is contrary to clear congressional intent and is inconsistent with the agency's past policies concerning sex protections. Many of these commenters assert that the changes set forth in the proposed rule run contrary to the requirements of the ACA, pointing to 42 U.S.C. 18114 (Section 1554), which states that the Department shall not ''promulgate any regulation that—(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care; (2) impedes timely access to health care services. . .'' These commenters also state that the Department is attempting to make a legislative change through an administrative action. Some commenters contend that the proposed rule runs contrary to the general intent of the ACA, namely that all individuals should be provided access to healthcare.

Response: The 2016 Rule tried to make essentially legislative changes through administrative action, and those changes were rightly held to be in violation of the APA. The Department does not exceed its authority by rescinding the portions of the 2016 Rule that exceeded the Department's authority. The Department also does not

[17] *See* 84 FR 27850; *F.C.C.* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 514–15 (2009).

violate Section 1554 of the ACA by not including the gender identity and termination of pregnancy provisions in this final rule, which were not supported by the text of the underlying civil rights laws incorporated in Section 1557, and in addition were vacated by court order.

With respect to both Sections 1554 and 1557, the Department interprets the ACA by the plain meaning of its text, and as will be shown below, this final rule brings the Department's Section 1557 regulations in line with a proper understanding of the ACA's text. Parts of the 2016 Rule exceeded the Department's authority under the ACA, and this final rule formally eliminates those portions from the Code of Federal Regulations. The Department believes this approach adheres more closely to the text of the statutes referenced in Section 1557, along with the regulations that the Department has used to implement those statutes for decades. Other parts of the 2016 Rule are being modified or repealed in order to save providers from unnecessary burdens not required by the ACA, so that they are better able to achieve the statute's goal of providing healthcare access to all Americans. Such a reconsideration and elimination of certain regulatory provisions, particularly regulations that the ACA itself did not require to be issued, neither ''creates'' unreasonable regulatory barriers nor impedes timely access to healthcare. If it were otherwise, Section 1554 would essentially serve as a one-way ratchet, preventing the Department from ever reconsidering a regulation that could be characterized as improving access to healthcare in some sense, regardless of the other burdens such regulation may impose on access to health care. The Department's approach in this final rule is also consistent with the Ninth Circuit's recent interpretation of Section 1554: ''[t]he most natural reading of § 1554 is that Congress intended to ensure that HHS, in implementing the broad authority provided by the ACA, does not improperly impose regulatory burdens on doctors and patients.'' [18] As explained throughout the preamble, the Department's rule avoids precisely such burdens by bringing the section 1557 regulations into alignment with the longstanding requirements of the applicable civil rights laws and their implementing regulations (thereby also avoiding additional conscience burdens that the 2016 Rule potentially imposed) and by removing notice and taglines requirements that imposed unjustified burdens on the healthcare system as a whole (some of which would likely have been passed on to individuals).

Comment: Commenters said that Section 1557 should be construed broadly because throughout the ACA, Congress prohibited a variety of forms of discrimination, such as against pre-existing conditions and combating health disparities. Commenters also indicated that the ACA is intended to reduce the cost of healthcare discrimination against the poor, so the Section 1557 rule should implement cost sharing and other insurance requirements.

Response: In the ACA, Congress labeled several provisions other than 1557 as prohibiting discrimination [19] in healthcare, but did not incorporate those other provisions of the ACA into Section 1557. Those other provisions are different from the civil rights provisions set forth in Section 1557 in substance, implementation, and enforcement. This final rule commits the Department to robust enforcement of the nondiscrimination grounds applicable under Section 1557.

Comment: A commenter contended that the Department provided little or no legal, policy, or cost-benefit analysis along with the proposed rule and combined too many changes into a single rule. Some commenters claimed the proposed rule is arbitrary, capricious, and contrary to law, is inconsistent with the agency's mission, and lacks reasoned explanations justifying the policy reversals. Other commenters stated that HHS failed to account for the extensive history of healthcare discrimination, and provided no contrary data to counter the original factual findings in the 2016 Rule. Furthermore, they said that individuals have reasonably placed their reliance upon the Federal government to protect their civil rights as explained in the 2016 Rule.

Response: The Department provided ample legal, policy, and cost-benefit analysis for the proposed rule and provides additional support here for the final rule.[20] The Department proposed changes to the provisions of the 2016 Rule because that rule exceeded the Department's authority under Section 1557, adopted erroneous and inconsistent interpretations of civil rights law, caused confusion, imposed unjustified and unnecessary costs, and conflicted with applicable court decisions. It is unfortunate that, by administrative action, the 2016 Rule may have unreasonably raised expectations about nondiscrimination protections that are not found in the underlying statutes, but this final rule cannot be held responsible for that. The Department gave extensive reasons for its changes in the 2019 NPRM, and gives further reasons in response to comments below. The public comment process provided adequate opportunity to present legal, policy, and cost-benefit analyses, all of which were considered in finalizing this rule, as discussed herein.

The Department also updates and discusses the regulatory impact analysis based on comments and data received. While there are still some questions addressed by this final rule where robust data are unavailable, were not found by the Department, or have not been brought to the Department's attention, the Department is allowed to engage in rulemaking even where the impact of a rule change is difficult or impossible to quantify. The Department has diligently considered the relevant and significant data of which it is aware.

There is no artificial limit on the number of changes a proposed rule may contain—or on the number of parts in the Code of Federal Regulations that can be addressed in a rulemaking. This final rule contains many fewer changes than the 2016 Rule did, and it substantially streamlines the existing 1557 regulation as opposed to enlarging it. Its inclusion of conforming changes to various CMS regulations still gives the final rule a size and scope that is well within the range of other significant proposed rules.

Comment: Several commentators stated that the proposed rule's language that Title IX and Section 1557 must be ''exercised with respect for State sovereignty'' runs contrary to the Supreme Court's decision that Congress has the authority to prohibit discrimination in commercial activity.

Response: This final rule does not, nor does the Department intend to, remove any protection against State action that Congress has provided by statute. It also does not deny States the ability to provide protections that exceed those required by Federal civil rights law. The reference to State sovereignty simply refers to the Department's intention to protect the States by respecting their sovereignty to the extent that doing so does not infringe on Federal law.

Comment: One commenter noted that, after the 2016 Rule was passed, the

[18] *California* v. *Azar,* No. 19–15974, 2020 WL 878528, at *18 (9th Cir. Feb. 24, 2020 (en banc).

[19] *See, e.g.,* ACA Section 2701 (''discriminatory premium rates''); Section 2716 (''discrimination based on salary''); Section 2705 (''discrimination against individual participants and beneficiaries based on health status''); Section 2716 (''discrimination in favor of highly compensated individuals'').

[20] *See* 45 FR at 27875–88.

Department released resources and educational materials, including fact sheets, to explain the 2016 Rule. The commenter requested that the Department release similar resources and educational materials following the finalization of this rule.

Response: The Department is providing the responses to comments contained in this preamble to clarify issues and answer questions concerning this final rule. Furthermore, the Department continues to be committed to providing resources and educational materials to explain civil rights requirements and to assist covered entities with compliance with civil rights statutes and the regulations thereunder, including this regulation.

B. Section 1557 Regulation, Subpart A: General Requirements and Prohibitions

The Department proposed changes to the Section 1557 rule at 45 CFR part 92 to be composed of Subpart A on general requirements and prohibitions, and Subpart B on specific applications related to disability nondiscrimination and language access.

(1) Proposed Repeal of Definitions in § 92.4 of the 2016 Rule

Comments: A commenter contended that eliminating the definitions section in the Section 1557 Regulation would cause confusion, misinterpretation, and inconsistency of terms among the regulations that currently reference or otherwise rely on the underlying definitions in the 2016 Rule.

Response: In significant part, the definitions section of the 2016 Rule duplicates definitions already incorporated into the Section 1557 regulation by reference, and hence creates either inconsistency or redundancy. In other cases, the 2016 Rule contained definitions inconsistent with the text of applicable statutes; indeed, on those grounds, a Federal district court vacated the 2016 Rule's definition of ''on the basis of sex'' insofar as it encompassed gender identity and termination of pregnancy. The Department will continue to enforce Section 1557 using HHS regulations for the underlying civil rights statutes. Many of these regulations have definition sections and operate based on longstanding understandings of how the laws are enforced.

Comments: Some commenters argued that eliminating the phrases ''covered entities'' and ''health program or activities'' would allow many plans and programs to be exempt from the Section 1557 regulation. Other commenters stated that the existing definitions provide clarity and consistency for covered entities. Another commenter stated that the proposed rule would limit Section 1557's application to the specific program or activity that receives Federal assistance, rather than a healthcare entity's entire operations.

Response: See below, under ''Scope of Application in Proposed § 92.3,'' for a discussion of the entities subject to this final rule.

Comment: Some commenters asked the Department to retain the definition of ''auxiliary aids and services'' concerning effective communication for individuals with disabilities. They also asserted that the Department has altered important definitions related to effective communication, without explanation or acknowledgement. While some commenters appreciated the Department's efforts to incorporate many of the current definitions of Title II of the Americans with Disabilities Act [21] (''ADA''), some claim the Department has erred in tracking the language of those definitions.

Response: The Department is not required to track ADA definitions in its Section 1557 regulation. This final rule applies many definitions based on those found in the ADA or its regulations (including ''disability'' and ''auxiliary aids and services''), technical definitions and standards under the ADA, and Uniform Federal Accessibility Standards as promulgated; as discussed below, it also departs from ADA definitions in certain cases. Additionally, this final rule retains effective communication standards for individuals with disabilities under § 92.102; these provisions are drawn from regulations promulgated by the Department of Justice implementing Title II of the ADA.[22] Specific definitions and provisions related to individuals with disabilities are discussed below.

The proposed rule apprised the public of the language the Department sought to finalize in the rule, gave the Department's reasons for changes relative to the 2016 Rule, and provided an opportunity to comment on the proposed language.

Comment: Some commenters opposed the proposed removal of the definition for ''national origin,'' saying it would lead to confusion among providers and recipients as to what constitutes discrimination on the basis of national origin.

Response: The term ''national origin'' is not specifically defined in Title VI or in HHS's implementing regulation, but the Department has appropriately enforced the prohibition on national origin discrimination under Title VI for decades in accord with relevant case law. In implementing this final rule, the Department intends to enforce vigorously the prohibition on national origin discrimination in a manner consistent with the current interpretation under Title VI, including under *Lau* v. *Nichols,* as discussed below.[23]

Comment: Some commenters asserted that the removal of definitions weakens protections for LEP individuals and signals a lack of priority for enforcement by the Department.

Response: As discussed below, meaningful access for individuals with LEP is a key component of the national origin protections under Title VI and Section 1557, and will be well protected by this final rule. The streamlining of this regulation through the elimination of largely redundant definitions will in no way impede the Department's strong commitment to meaningful access for LEP individuals.

Summary of Regulatory Changes: The Department finalizes its repeal of § 92.4 of the 2016 Rule without change. Additional comments concerning the definitions of sex, gender identity, and other specific definitions are discussed in more detail below.

(2) General Changes to 2016 Rule

a. Purpose of Regulation, Revising § 92.1 of the 2016 Rule

The Department proposed to revise the statement of the purpose of the regulation in § 92.1 from ''implement[ation]'' of Section 1557 to ''provid[ing] for the enforcement'' of Section 1557. 84 FR at 27861.

Comment: A commenter said this change in language allows the Department to minimize its involvement in ensuring that nondiscrimination protections are effective.

Response: This is the opposite of the Department's intention. This final rule's title and citation to statutory authority already make clear that it is implementing Section 1557. By changing the rule's language from ''implement'' to ''provide for the enforcement of,'' the Department simply means to emphasize, in terms accessible to a lay audience, that it will fully enforce Section 1557 and the underlying nondiscrimination laws as they fall within the jurisdiction of the Department, according to the text of those laws and their implementing regulations.

[21] 42 U.S.C. 12101 *et seq.*

[22] 42 U.S.C. 12311; *see also* 28 CFR 35.160–164.

[23] *Lau* v. *Nichols,* 414 U.S. 563 (1974).

b. Effective Date

The Department proposed that the effective date of the revised regulation be 60 days after publication of the final rule, in order to relieve significant regulatory burdens, particularly the taglines requirements.[24] The 2016 Rule's effective date was July 18, 2016 (60 days after publication of the final rule), with the exception of the provisions on health insurance and benefit design, which went into effect on January 1, 2017 (the first day of the first plan year following the effective date).[25] The new rule does not include a different effective date for health insurance and benefit design.

Comment: Commenters asked that the Department make the effective date several months prior to the plan open enrollment period that occurs between November 1 and December 15, in order for the covered entities to have sufficient time to incorporate the regulatory changes into the next plan year.

Response: The Department has endeavored to issue this final rule sufficiently in advance of the plan year cycle, so that plans can incorporate the regulatory changes into the next plan year. Moreover, because this final rule generally relieves regulatory requirements rather than adding them, it should be easier for issuers to incorporate such changes into the plans they will offer for the next plan year.

Comment: Commenters stated that it is inappropriate to finalize the change to the definition of sex as it relates to Section 1557 in light of current litigation before the Supreme Court, which may be resolved by the end of the court's term or before. These commenters note that the Supreme Court's ruling in *R.G. & G.R. Harris Funeral Homes* v. *EEOC & Aimee Stephens*[26] will determine whether Title VII of the Civil Rights Act of 1964 extends sex discrimination protections to transgender status, and that the ruling may apply to the definition of sex under Title IX as well. Accordingly, these commenters urge the Department to wait until the Supreme Court decides *Harris Funeral Homes* before publishing a rule that deals with the same subject matter, or allow for commenters to comment again once the case has been decided.

Response: The Department acknowledges the commenters' point of view but respectfully disagrees. The U.S. government has taken the position in *Harris* and other relevant litigation that discrimination ''on the basis of sex'' in Title VII and Title IX does not encompass discrimination on the basis of sexual orientation or gender identity.[27] The Department shares that position and is permitted to issue regulations on the basis of the statutory text and its best understanding of the law and need not delay a rule based on speculation as to what the Supreme Court might say about a case dealing with related issues. The Department also agrees with the *Franciscan Alliance* ruling, according to which the 2016 Rule's extension of sex-discrimination protections to encompass gender identity was contrary to the text of Title IX and hence not entitled to *Chevron* deference.[28] Moreover, to the extent that a Supreme Court decision is applicable in interpreting the meaning of a statutory term, the elimination of a regulatory definition of such term would not preclude application of the Court's construction.

The Department continues to expect that a holding by the U.S. Supreme Court on the meaning of ''on the basis of sex'' under Title VII will likely have ramifications for the definition of ''on the basis of sex'' under Title IX.[29] Title VII case law has often informed Title IX case law with respect to the meaning of discrimination ''on the basis of sex,''[30] and the reasons why ''on the basis of sex'' (or ''because of sex,'' as used in Title VII) does not encompass sexual orientation or gender identity under Title VII have similar force for the interpretation of Title IX. At the same time, as explained below, the binary biological character of sex (which is ultimately grounded in genetics) takes on special importance in the health context. Those implications might not be fully addressed by future Title VII rulings even if courts were to deem the categories of sexual orientation or gender identity to be encompassed by the prohibition on sex discrimination in Title VII. As a result, the Department considers it appropriate to finalize this rule, which does not define sex, but relies on the plain meaning of the term under Title IX, and does so in the health context within which the Department applies Title IX under Section 1557.

Comment: Commenters disagreed with the Department's reliance on the litigation and court order in *Franciscan Alliance* to justify revisiting the rule, because the injunctive order was not permanent, was allegedly limited to enforcement actions of HHS, and does not require new rulemaking, and because other litigants have intervened in the case to defend the 2016 Rule. Some commenters stated that although the U.S. District Court in *Franciscan Alliance* ruled against the 2016 Rule's definition of sex, other courts have come to conclusions that suggest the opposite, and HHS is not required to alter Department-wide policy based on the injunction in *Franciscan Alliance.* Others argued that the Department improperly relied on one legal decision that they said conflicts with the clear weight of case law. Another commenter stated it would be inappropriate to publish any new rule before a final ruling in *Franciscan Alliance,* as the case is being appealed.

Response: Nearly three years after the preliminary injunction, and after the comment period on the proposed rule had concluded, the court in *Franciscan Alliance* issued a final ruling vacating the 2016 Rule ''insofar as the Rule defines *'On the basis of sex'* to include gender identity and termination of pregnancy,'' and remanding the Rule for further consideration.[31] This final ruling is binding on the Department despite the appellate proceedings still pending in that case: The Department's Section 1557 regulation, as currently operative, does not contain the 2016 Rule's definition of ''on the basis of sex'' to encompass gender identity and termination of pregnancy. The *Franciscan Alliance* court's 2016 injunction gave the Department good cause to reconsider the 2016 Rule, but neither the injunction nor the *vacatur* was the Department's only reason for revising it, as the proposed rule made clear and as the Department's responses to comments in this preamble reiterate. Nothing in the appellate litigation prohibits the Department from finalizing this rule, which it does for the reasons given in this preamble. As for the weight of case law, it is discussed below with respect to the respective provisions of this final rule.

Comment: One commenter noted that the Department's announcement of the proposed rule on May 24, 2019 had stated that a fact sheet explaining the changes in the proposed rule would be

[24] 84 FR at 27888.

[25] 81 FR at 31378.

[26] *R.G. & G.R. Harris Funeral Homes, Inc.* v. *E.E.O.C.,* 139 S. Ct. 1599 (2019).

[27] As noted elsewhere in this preamble, it has been the consistent position of the federal government that ''on the basis of sex'' under Section 1557 does not encompass sexual orientation, including the decision in the 2016 Rule not to include sexual orientation in the definition of that term. *See* 81 FR at 31390.

[28] *Franciscan All., Inc.* v. *Azar,* 414 F. Supp. 3d 928, 945 (N.D. Tex. Oct. 15, 2019) (incorporating its previous ruling at 227 F. Supp. 3d at 685–87).

[29] *See* 84 FR 27855.

[30] *See, e.g., Yusuf* v. *Vassar Coll.,* 35 F.3d 709, 714 (2d Cir. 1994).

[31] Order, *Franciscan Alliance,* No. 7:16–cv–00108–O *2 (N.D. Tex. filed Nov. 21, 2019).

provided in Spanish. However, no such fact sheet has been provided. Accordingly, the commenter requested that the comment period be extended until 60 days after the fact sheet is published in Spanish.

Response: The proposed rule itself did not purport to offer information in Spanish, and the Department was not under a legal obligation to offer a separate fact sheet or to translate it. The Department's press release indicated that a fact sheet, separately created in connection with the press release, would be translated. That is not a basis for reopening the comment period on the proposed rule, because the proposed rule provided the public with adequate notice and a 60-day public comment period, which were legally sufficient.

c. Severability

The Department proposed to repeal the provision in § 92.2(c) of the 2016 Rule stating that if a regulatory provision in this part were held invalid or unenforceable on its face or as applied to a specific person or circumstances, the provision should be construed to the maximum effect permissible by law and be severable such that it would not affect other persons or circumstances that are dissimilar.

Comment: Commenters asked the Department to add a severability provision to the final rule. Specific points recommended included severing repeal of the provisions related to the notices and taglines, and/or the changed scope of applicability, from the sex discrimination provisions. Commenters said that the Supreme Court case *K-Mart Corp.* v. *Cartier, Inc.,* 108 S. Ct. 1811 (1988), would allow the Department to sever the changes in the taglines provision from the proposed rule and implement those changes even in the event that a court delays or suspends the proposed rule.

Response: In part due to these comments, the Department has decided not to finalize the proposal to eliminate the severability provision from the 2016 Rule. Instead the Department will retain that severability provision, but has moved it to § 92.3(d), because § 92.3 is now the provision addressing the application of the rule. This change will be discussed again below in the discussion of § 92.3.

d. Summary of Regulatory Changes

For the reasons described in the proposed rule, and having considered the comments received, the Department finalizes the proposed § 92.1 without change, and confirms that the effective date of this final rule will be 60 days after its publication in the **Federal Register**.

(3) Scope of Application in Proposed § 92.3; Repeal of § 92.208

The Department proposed to repeal § 92.2 of the 2016 Rule, and instead address the scope of application of Section 1557 in a new § 92.3. 84 FR at 27862–63. The Department also proposed to repeal § 92.208 of the 2016 Rule, which had expanded the scope of the Section 1557 statutory provision to apply to certain employee health benefits programs.[32]

a. Generally

Comment: Commenters argued the Department did not provide a reasoned legal, policy, or cost-benefit analysis to support the repeal of § 92.208, which hindered their ability to provide meaningful comments as required by the APA. The commenters maintained that the Department's comparison of § 92.208 to Title IX[33] was flawed, in part because HHS's Title IX regulation does not apply to all bases of discrimination or many of the same covered entities as addressed under Section 1557. Some commenters noted that employees deserve protection from discrimination in employer-sponsored plans.

Response: As seen below in the response to a similar comment on § 92.207, § 92.208 appears in the NPRM in a list of sections of the 2016 Rule that ''are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations.''[34] The Department repeals § 92.208 for reasons similar to those given at greater length below in discussing § 92.207: It seeks to relieve regulatory burden and possible confusion by enforcing the relevant nondiscrimination statutes through their existing regulations.

The Department is not aware of data and methods available to make reliable estimates of all economic impacts predicted by various commenters. The Department's estimates of regulatory impact are discussed below.

Comment: Commenters stated that individuals protected by Section 1557, particularly individuals with disabilities, frequently experience discrimination in healthcare. Commenters expressed concerns that the narrowed application would reduce the number of covered entities and would lead to more discrimination, lack of care, and adverse health outcomes, which they argued is contrary to the stated Congressional intent and purpose of the ACA to expand access to and end discrimination in health insurance. Several State and local government commenters expressed concern that the proposed rule would negatively affect public health in their States and increase costs to States due to more people seeking care through government-funded programs, such as Medicaid.

Conversely, other commenters were supportive of the proposed rule's revised scope and agreed that the 2016 Rule was far too broad in its application. They concurred that narrowing the scope of application would help rein in the regulatory excess and burden of the 2016 rule.

Response: The Department must follow the text of the ACA. To the extent that Congressional intent and purpose are relevant, they are best determined by looking to the plain meaning of the statutory text. This final rule will enforce Section 1557's discrimination requirements against the entities that Congress intended them to be enforced against. The Department's specific reasoning in interpreting Section 1557's scope of coverage follows.

b. § 92.3(a): Covered Programs and Activities

The Department proposed in § 92.3(a) that, except as otherwise provided in part 92, the Section 1557 rule will apply to (1) any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department; (2) any program or activity administered by the Department under Title I of the ACA; or (3) any program or activity administered by any entity established under Title I of the ACA.

Comment: Some commenters opposed removing the full definition of ''Federal financial assistance'' from the 2016 Rule and replacing it with the limited text under proposed § 92.3(a)(1). They stated that the lack of specificity could lead to ambiguity and confusion. Commenters further asserted that the proposed rule was inconsistent with the Department's recently promulgated *Protecting Statutory Conscience Rights in Health*

[32] *Compare* 45 CFR 92.208 (employer liability for discrimination in employee health benefit programs in Section 1557) *with* 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX. The enforcement Memorandum of Understanding (MOU) between OPM and the Department, signed by OCR on 11 January 2017, is moot upon publication of this final rule.

[33] 84 FR at 27869, n.148 (comparing § 92.208 with 45 CFR 86.56 (discrimination on the basis of sex in fringe benefits under Title IX)).

[34] 84 FR 27869.

Care (''2019 Conscience Rule''),[35] which included an expansive definition of ''Federal financial assistance.''[36]

Response: The Department concludes it is appropriate to have a definition of Federal financial assistance that mirrors Section 1557's statutory text to include ''credits, subsidies, or contracts of insurance.'' In addition, the definitions applicable under the preexisting civil rights statutes still apply, and the Department believes it is more appropriate to apply those existing definitions than to maintain the ones in the 2016 Rule. Section 1557 says the enforcement mechanisms provided for and available under the underlying civil rights statutes shall apply, and the Department believes operating under those mechanisms and the definitions that have long been applicable to them, along with the language the Department retains in this final rule, is appropriate moving forward. The 2019 Conscience Rule was based on different statutes.

Comment: Some commenters opposed the proposed rule's exclusion of Federal financial assistance that the Department ''plays a role'' in providing or administering, which had been included in the 2016 Rule's definition of Federal financial assistance. Commenters argued that the statute applies to programs or activities administered by ''an Executive Agency'' and thus should not be limited to HHS. In particular, they objected to the result that qualified health plans (QHPs) would no longer be covered under the rule on the basis that HHS plays a role in administering tax credits. The commenters argued that this interpretation is contrary to a plain reading of the statute, which not only uses the broad term ''Federal financial assistance'' (without a modifier to limit it to assistance directly administered by HHS), but also expressly includes ''credits'' as part of Federal financial assistance. Further, some commenters noted that the Department took an inconsistent and broader approach in its Conscience Rule, wherein HHS exerts jurisdiction over statutes and funding also administered by the U.S. Departments of Labor and Education.

Response: The statutory text of Section 1557 refers simply to ''any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance.'' Because the Section 1557 regulation applies only to the Department, the 2015 NPRM had reasonably sought to limit its scope to Federal financial assistance from the Department, leaving other Departments to enforce Section 1557 within their own sphere.[37] In the 2016 Rule, however, wishing to encompass tax credits administered under Title I, the Department expanded the rule's scope to encompass ''Federal financial assistance that the Department plays a role in providing or administering.''[38] The Department now regards this expansion as overbroad. While Section 1557 still applies to any health program or activity receiving any Federal financial assistance, this final rule prescribes enforcement only by the Department and within the Department's jurisdiction. The Department does not consider it appropriate in this final rule to apply its provisions to any programs that the Department ''plays a role in'' administering.

Commenters' concerns about covering QHPs are misplaced: These plans remain subject to this rule because they are sold on the Exchanges established under Title I of the ACA (see § 92.3(a)(3) of this final rule). This final rule only prescribes enforcement of Section 1557 by the Department and within the Department's jurisdiction, so the Department believes it is appropriate for this regulation to not include activities funded or administered solely by other Federal agencies even if Section 1557 may apply in those instances.

The 2019 Conscience Rule (as stated above) relied on different statutes than the Section 1557 rule, and the Department drafts its regulations as appropriate for the underlying statutes.

Comment: Commenters disapproved of proposed § 92.3(a)(2), which would limit the rule's application in the context of HHS-administered programs or activities to only those administered under Title I of the ACA. Commenters argued that this interpretation is inconsistent with the statutory text of Section 1557, which applies to ''any program or activity administered by an Executive Agency *or* any entity established under this title [*sc.,* Title I].'' (emphasis added). Commenters argued the proposed § 92.3(a)(2) would incorrectly apply ''under this title'' to modify both phrases. Furthermore, they argued that the Department did not provide an adequate rationale for its interpretation in the proposed rule.

Response: As explained in the 2019 NPRM, the statutory text of Section 1557 applies to ''any program or activity'' administered by an Executive Agency or Title I entities, but does not include the modifier ''health'' with respect to those programs or activities.[39] In the 2016 Rule, the Department limited its application by adding ''health'' to ''programs or activities'' because the Department recognized that Section 1557 was not intended to apply to every program or activity administered by every Executive Agency, whether or not it related to health.[40] The 2016 Rule acknowledged implicitly what the Department now states more clearly: The grammar of the relevant sentence in the Section 1557 statutory text concerning limits to its scope is less clear than it could have been. In resolving the sentence's ambiguity, however, the Department no longer agrees with the 2016 Rule's decision to add a limiting modifier (*i.e.,* ''health'') that Congress did not include in the statutory text. Instead, the Department concludes that Congress had already placed a limitation in the text of Section 1557 by applying the statute to any program or activity administered by an Executive Agency ''under this title'' (meaning Title I of the ACA), as well as to any program or activity administered by an entity established under such title. The Department believes that either this interpretation of the statutory text, or the 2016 Rule's addition of the modifier ''health,'' is necessary in order to make sense of the statutory text; this final rule offers a technical reading of the text that is at least as reasonable as the 2016 Rule's addition of a word not present in the text of the statute.

Comment: Commenters argued that the proposed interpretation to limit coverage to HHS Title I programs or activities would exclude a number of important programs and activities operated by HHS and is inconsistent with Section 504's application to ''any program or activity conducted by an

[35] *Protecting Statutory Conscience Rights in Health Care; Delegations of Authority,* 84 FR 23170–01 (2019).

[36] 45 CFR 88.2.

[37] 80 FR 54173 (''Section 1557 applies to all health programs and activities, any part of which receives Federal financial assistance from any Federal Department. However, this proposed rule would apply only to health programs and activities any part of which receives Federal financial assistance from HHS. This narrowed application is consistent with HHS' enforcement authority over such health programs and activities, but other Federal agencies are encouraged to adopt the standards set forth in this proposed rule in their own enforcement of Section 1557.'').

[38] 81 FR 31467, 31384; *cf.* 80 FR 54216.

[39] 42 U.S.C. 18116(a) (applying Section 1557, in relevant part, to ''any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).''). *See also* 84 FR at 27861–62 (discussing the Department's statutory interpretation).

[40] 45 CFR 92.2 (applying the final rule, in relevant part, to ''every *health* program or activity administered by the Department; and every *health* program or activity administered by a Title I entity'') (emphasis added).

Executive Agency.'' [41] They point out that HHS's Section 504 regulation applies to ''all programs or activities'' conducted by HHS and all its components, including CMS, HRSA, CDC, and SAMHSA.[42] Further, commenters stated that excluding non-Title I HHS-administered programs and activities, contrary to Section 504, will result in confusion and cause illogical results, whereby recipients would be covered by Section 1557 but the agencies administering the program would not be covered. For example, State Medicaid programs would be subject to Section 1557, but CMS, which oversees those Medicaid programs, would not be covered.

Response: Section 1557 is a nondiscrimination statute under the ACA, which uniquely applies to healthcare, whereas Section 504 is a statute of general applicability. Section 1557 incorporates Section 504's prohibited grounds of discrimination but not its scope: Section 1557's scope differs from that of the underlying statutes. For instance, Section 504 does not include ''contracts of insurance'' in its definition of Federal financial assistance,[43] but this final rule follows the text of Section 1557 by including ''contracts of insurance'' within Federal financial assistance.[44] With respect to CMS, it is covered under this final rule to the extent that it either administers health programs and activities receiving Federal financial assistance or administers programs and activities under Title I. In addition, it is important to note that, as a federal agency, CMS has long been subject to various constitutional and statutory prohibitions on discrimination.

c. § 92.3(b): Scope of the Term ''Health Program or Activity''

The Department proposed in § 92.3(b) to clarify that ''health program or activity'' encompasses all of the operations of entities ''principally engaged in the business of providing healthcare'' that receive Federal financial assistance. The Department proposed to further clarify that for any entity not principally engaged in the business of providing healthcare, such entity's operations are subject to the Section 1557 Rule only to the extent any such operation receives Federal financial assistance provided by the Department.

Comment: Commenters opposed limiting application of the rule when the entity is not principally engaged in the business of providing healthcare. Commenters argued that this would dramatically limit the scope of the rule and is contrary to Congressional intent and the plain meaning of the statute, which covers ''any health program or activity, any part of which is receiving Federal financial assistance. . . .'' Commenters stated that the entire entity receiving Federal financial assistance should be covered, not just the portion receiving funding. Commenters also argued the new framework would cause uncertainty and confusion for covered entities, which would have to clarify the extent of their own compliance, and also would make it harder for consumers to enforce their rights because they would have difficulty determining which entities and which portion of their programs or activities are subject to the rule. Commenters contended this uncertainty could result in lack of access to care, increased health disparities, and increased uncompensated care, all of which would increase overall healthcare costs.

Some commenters stated that the rule incorrectly incorporates the Civil Rights Restoration Act (CRRA) [45] into Section 1557. Commenters argued that the CRRA predates the ACA; nothing in the CRRA's text applies it to future statutes or Section 1557; Congress did not incorporate the CRRA into the Section 1557 statute; and Section 1557 itself is more expansive than the laws amended by the CRRA. Therefore, they say, a broader definition of covered programs and activities should apply to include all health insurers as covered entities. Others argued that the proposed rule's application of the CRRA contravenes the approach taken by Congress in the CRRA. They stated that Congress made clear in the CRRA that if any part of a program or activity receives Federal financial assistance, the entire program or activity must comply with the applicable civil rights laws. Thus, the commenters argued that the proposed rule's limited application when entities are not principally engaged in the business of healthcare, to cover only the specific operation that receives Federal financial assistance, is contrary to the CRRA. Another commenter stated that incorporating the CRRA into Section 1557 would be subject to judicial review, to the extent the Department relies on Section 1557's references to ''grounds'' and ''enforcement mechanisms'' of the underlying statutes to do so, because the Supreme Court held in *Consolidated Rail Corp.* v. *Darrone* that a statute's incorporation of another statute's enforcement mechanisms does not necessarily incorporate its substantive law.[46]

Conversely, other commenters were supportive of reducing regulatory burden by limiting application of the rule in this way. They stated that the 2016 Rule defined ''covered entities'' far too broadly, and that narrowing the scope will help rein in the regulatory excess of that rule. Commenters explained that healthcare entities often provide a variety of services and products, such as insurance coverage for life, disability, or short-term limited duration insurance coverage, and third-party administrative services, which do not receive Federal financial assistance. These commenters agreed that Section 1557 is intended to apply only to those programs receiving Federal funding and not to other parts of the entity's businesses or products when an entity is not principally engaged in the business of providing healthcare.

Response: Section 1557 explicitly incorporates statutes amended by the CRRA, and in this final rule the Department is aligning Section 1557's definition of ''health program or activity'' with the standard articulated in the CRRA in order to provide clarity and consistency. The CRRA clarified the scope of nondiscrimination prohibitions under the civil rights statutes that Section 1557 incorporates. For example, with respect to the health sector, it applied those prohibitions to all health programs or activities receiving Federal financial assistance, but not to all providers of health insurance: It applied ''program or activity'' to cover all of the operations of an entity only when that entity is ''principally engaged in the business of providing . . . health care . . . .'' [47] This final rule clarifies that the term ''health program or activity'' used in Section 1557 should be understood in light of the CRRA's limitations on the term ''program or activity'' as applied to statutes on which Section 1557 relies. As for *Consolidated Rail Corp.* v. *Darrone,* Congress specifically and intentionally

[41] 29 U.S.C. 794 (applying to ''any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service'').

[42] 45 CFR, part 85.

[43] 45 CFR 84.3(h).

[44] 42 U.S.C. 18116(a).

[45] Public Law 100–259, 102 Stat. 28 (Mar. 22, 1988).

[46] *See Consolidated Rail Corp.* v. *Darrone,* 465 U.S. 624, 635 (1984) (holding that Section 504's incorporation of the ''remedies, procedures, and rights'' set forth in Title VI did not mean that Section 504 incorporated Title VI's substantive limitations on actionable discrimination).

[47] *See, e.g.,* CRRA § 3(a) (adding § 908(3)(A)(ii) to Title IX of the Education Amendments of 1972 (codified at 20 U.S.C. 1687(3)(A)(ii)).

overturned that case through the passage of the CRRA.[48]

The 2016 Rule also articulated a standard for ''health program or activity'' that relied upon the ''principally engaged'' prong of the CRRA, which was contested neither before nor after that rule's publication. In the regulatory text, the 2016 Rule defined ''health program or activity'' to apply to all operations of an entity only when it is principally engaged in providing or administering health services, health insurance coverage, or other health coverage.[49] The 2016 Rule preamble clarified that if an entity is not principally engaged in providing health benefits, the Department would apply the rule to its Federally funded health programs and activities.[50]

The Department believes that by specifying the degree to which the Section 1557 regulation covers entities not principally engaged in the business of providing healthcare, this final rule more clearly and consistently applies the CRRA's limitations on ''health program or activity'' across the regulation. The Department agrees with commenters who suggest that in doing so this final rule also advances its goal of reducing regulatory burdens under the ACA in furtherance of Executive Order 13765.

Comment: Commenters argued that limiting the application of the rule to only the portion of the health program or activity that receives Federal financial assistance for entities not principally engaged in the business of providing healthcare is not consistent with the Department's application of Title VI as set forth in HHS's 2003 LEP guidance. This guidance provided that Title VI applies to all parts of a covered entity receiving Federal financial assistance, not just the portion receiving Federal funds.[51]

Response: As a policy guidance document, the Department's LEP guidance cannot be used to create binding standards by which the Department will determine compliance with existing regulatory or statutory requirements.[52] Accordingly, the scope of application as set forth under the CRRA and this final rule would prevail over any conflicting text in the Department's LEP guidance.

d. § 92.3(c) Health Insurance and Healthcare

The Department proposed in § 92.3(c) to state that an entity principally or otherwise engaged in the business of providing health insurance would not be considered to be principally engaged in the business of providing healthcare, and on that sole basis, subject to the Section 1557 regulation. The proposed rule sought comment on whether it should define ''healthcare'' in the rule according to the statutes cited in the proposed rule.

Comment: Several commenters supported the distinction between entities principally engaged in the business of providing healthcare and those principally engaged in the business of providing health insurance. As one commenter stated, ''[p]aying for healthcare is not providing healthcare.'' Other commenters were opposed to this distinction. They argued that it is not consistent with Section 1557's statutory text or the proposed regulatory text at § 92.3(a)(1), both of which specifically include ''contracts of insurance'' as an example of Federal financial assistance. They also stated that this limited application is not consistent with Congressional intent to expand access to healthcare and create new nondiscrimination protections in health insurance.

Some commenters argued that health insurance is inextricably linked with the provision of healthcare. They pointed out that the statutory definition of ''healthcare'' relied upon in the proposed rule is unrelated to either the ACA, health insurance, or discrimination, and thus is not intended for or relevant to Section 1557 or health insurance.[53] Further, they argued that the definition of ''health insurance coverage'' referenced in the proposed rule, 42 U.S.C. 300gg–91, actually bolsters the argument that health insurance includes healthcare, as it defines ''health insurance coverage'' to include ''benefits consisting of *medical care* (provided directly, through *insurance* or reimbursement, or otherwise and including items and services paid for as medical care)'' (emphasis added). They also pointed out that definitions in 42 U.S.C. 300gg–91 are most relevant to Section 1557 because Title I of the ACA relied upon this section for definitions.

Response: The CRRA defined ''program or activity'' in the underlying statutes to apply to all of an entities' operations when it is principally engaged in the business of providing ''healthcare.'' On the other hand, the 2016 Rule expansively interpreted Section 1557's application to ''health programs or activities'' to include all operations of entities that ''provide health insurance coverage or other health coverage,'' whether or not they provided healthcare. Prior to the 2016 Rule, the Department had not interpreted the CRRA's term ''healthcare'' to cover the operations of health insurance issuers (as such).

Commenters are correct that Section 1557 includes ''contracts of insurance'' as a type of Federal financial assistance. The Department agrees that health programs or activities that receive contracts of insurance from the Federal government are covered entities under Section 1557. But this does not mean that health insurers, as such, are health programs or activities.

The Department pointed to 5 U.S.C. 5371, as well as to 45 CFR 160.103, in order to support its conclusion that the plain meaning of ''healthcare'' differs from insurance. And although 42 U.S.C. 300gg–91 explicitly encompasses payment, ''group health plans,'' and ''definitions relating to health insurance'' specifically, it should not be taken out of context: It defines ''medical care'' as ''amounts paid for'' certain medical services, which is an appropriate definition in the health insurance field but not in the healthcare field generally. (When a doctor provides ''medical care,'' she is not providing ''amounts paid for'' medical services—she is providing the services themselves.) Other portions of 42 U.S.C. 300gg–91 also support the distinction between healthcare and health insurance: It says that ''health insurance coverage means benefits consisting of medical care,'' where ''medical care'' is defined as ''amounts paid for . . . the diagnosis, cure, mitigation, treatment, or prevention of disease, or amounts paid for the purpose of affecting any structure or function of the body,'' or

[48] *See McMullen* v. *Wakulla Cty. Bd. of Cty. Commissioners,* 650 F. App'x 703, 705 (11th Cir. 2016), citing S. Rep. No. 100–64, at 2 (1988), *as reprinted in* 1988 U.S.C.C.A.N. 3, 3–4.

[49] 81 FR at 31467. In the proposed rule, the Department disagreed with the 2016 Rule's usage of ''health services, health insurance coverage, or other health coverage'' as overbroad and inconsistent with the statutory text of the CRRA that uses the term ''healthcare.'' *See* 84 FR at 27862–63. However, the Department agrees with the 2016 Rule's limitation based on whether the entity is principally engaged.

[50] 81 FR at 31385–86, 31430–32.

[51] 68 FR 47311, 47313 (Aug. 8, 2003) (''Coverage extends to a recipient's entire program or activity, *i.e.,* to all parts of a recipient's operations. This is true even if only one part of the recipient receives the Federal assistance.'').

[52] *See* U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), *https://www.justice.gov/opa/press-release/file/1012271/download;* U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), *https://www.justice.gov/file/1028756/download.*

[53] *See* 84 FR at 27862 (citing the definition of ''health care'' at 5 U.S.C. 5371). Commenters noted that this definition pertains to Federal personnel pay rates.

''amounts paid for transportation primarily for and essential to medical care'' in the primary sense just defined, or ''amounts paid for insurance covering medical care'' in either the primary sense just defined or the secondary sense of transportation for medical care.[54] It does not say that health insurance is healthcare, and it twice relies on the commonsense distinction between medical care proper and the health insurance that covers and pays for such care. It thus supports the Department's view that a health insurer is principally engaged in the business of providing coverage for benefits consisting in healthcare, which is not the same as the business of providing healthcare. This final rule brings the 1557 regulation's scope of coverage closer to the plain meaning of the 1557 statute, especially as read in light of the CRRA's definition of ''program or activity.''

Comment: Commenters were concerned that § 92.3(c) would result in exempting many of the plans, products, and operations of most health insurance issuers, such as self-funded group health plans, the Federal Employees Health Benefits (FEHB) Program, third-party administrator services, or short-term limited duration insurance plans. Commenters feared this would allow health insurance issuers to conduct their other activities in a discriminatory manner. Several commenters were particularly concerned about excluding short-term limited duration insurance plans because these plans have been known to engage in discriminatory practices based on disability, age, and sex.

Other commenters, in contrast, supported the proposed revisions. They stated the 2016 Rule was overly expansive, created an un-level playing field, and resulted in disincentives for issuers to participate in HHS-funded programs, such as offering QHPs or Medicare Advantage plans. This resulted in Section 1557's covering products that Congress explicitly excluded from the rest of the ACA, such as excepted benefits and short-term limited duration insurance plans. Commenters argued it was unlikely that Congress intended Section 1557 to regulate the same plans it had excluded from the ACA.

Response: The Department agrees with commenters who stated that the overly broad reach of the 2016 Rule subjected many insurance products that were not intended to be covered by the ACA to burdensome regulation, inconsistent with Congressional intent.

In the proposed rule, the Department stated that Section 1557 does not apply to short-term limited duration insurance as such, but only if it were offered by an entity for which all of the entity's activities are encompassed by Section 1557, or if such insurance received Federal financial assistance.[55] Under this final rule, where short-term limited duration insurance (1) is offered by an entity that is not principally engaged in the business of providing healthcare, and (2) does not receive Federal financial assistance, the protections of Section 1557 would not apply to it. The Department will robustly enforce the nondiscrimination requirements for QHPs under Title I of the ACA, for Exchange plans established by the ACA, and for any other insurance plans that Section 1557 covers. The reasons that this final rule does not cover FEHB plans are discussed in the response to the next comment.

Comment: The Department received comments related to the exclusion of employer plans and excepted benefits as a result of § 92.3(c). Several commenters objected to the exclusion of self-funded group health plans under the Employee Retirement Income Security Act of 1974 (ERISA) and the Federal Employees Health Benefits (FEHB) Program. Commenters argued that FEHB plans should be covered as a contract of insurance with the Federal government. Some suggested that employer group health plans, including self-funded plans, receive substantial Federal financial assistance in the form of favorable income tax treatment and thus should be covered.

Other commenters strongly supported excluding employer plans. Commenters noted that employers and group health plans are already subject to other Federal laws that prohibit discrimination, and that few employer-sponsored plans receive Federal financial assistance. They stated that the 2016 Rule's broad coverage exceeded statutory authority, encumbered the design and operation of employer group health plans, invited litigation regarding plan benefits, and increased the potential for costly new mandates, all of which were likely to increase healthcare costs for employers and employees alike without adding any additional protections against discrimination. Some commenters expressed support for the provision that third-party administrators of self-funded group health plans would no longer be subject to Section 1557 merely because other portions of their business receive Federal funding.

Some commenters requested further clarification by recommending that the regulatory text at proposed § 92.3(c) be revised to specify that other types of plans should not be considered entities principally engaged in the business of providing healthcare, including self-funded or fully insured group health plans under ERISA; self-funded or fully insured group health plans not covered under ERISA that are sponsored by either governmental employers (''government plans'') or certain religious employers (''church plans'' or ''denominational plans''); and benefit plans and programs excepted under the ACA.[56]

Response: The Department continues to take the position that FEHB plans are not covered under this rule. Even if FEHB plans were considered ''contracts of insurance,'' as suggested by some commenters, they still would not fall under the scope of this rule because the contract would be with the Office of Personnel Management (OPM), which operates the FEHB Program, not with the Department. As noted above, this final rule does not extend the Department's enforcement authority to a covered entity that is not principally engaged in the business of providing healthcare to the extent of its operations that do not receive financial assistance from the Department.

The Department agrees that this final rule will accomplish the Department's goal of reducing regulatory burden. The Department declines to offer further examples of non-covered entities in the regulatory text, as the rule's existing parameters are intended to broadly address different entities. To the extent that employer-sponsored group health plans do not receive Federal financial assistance and are not principally engaged in the business of providing healthcare (as set forth in the rule), they would not be covered entities. The same analysis would apply to employer-sponsored plans not covered by ERISA, such as self-insured church plans or

[54] 42 U.S.C. 300gg–91(b)(1), (a)(2).

[55] The Department notes by way of background that, subsequent to publication of the proposed rule, the U.S. District Court for the District of Columbia granted summary judgment for the Department, upholding its most recent rulemaking on short-term limited duration insurance. *See* Short-Term, Limited-Duration Insurance; Final Rule, 83 FR 38212 (August 3, 2018). The August 2018 final rule largely restored the long-standing definition for short-term limited duration insurance to the definition that was in effect from 1997 to 2016. The Court held that the restored definition was not arbitrary or capricious, finding that ''Congress clearly did *not* intend for the [ACA] to apply to all species of individual health insurance.'' *Association for Community Affiliated Plans* v. *U.S. Department of Treasury,* 392 F. Supp. 3d 22, 45 (D.D.C. 2019), *appeal filed* July 30, 2019.

[56] *See* 42 U.S.C. 300gg–91(c) (defining excepted benefits).

non-Federal governmental plans, as well as to excepted benefits.

Comment: Some commenters said that the proposed rule created confusion about whether QHPs are subject to the rule. Others requested clarification on the proposed rule's application to products offered through the Exchange. Others requested clarification on whether stand-alone dental plans and catastrophic plans, which are also sold through the Exchanges established under Title I, are covered under the rule. Another commenter requested confirmation that the proposed rule would not apply to individual or small-group market health insurance coverage that complies with the ACA but is sold outside of the Exchanges, regardless of whether the parent organization also offers on-Exchange QHPs. Others requested clarification as to how the rule would apply when one health insurance plan includes multiple types of enrollees, including subsidized Exchange enrollees, unsubsidized Exchange enrollees, and off-Exchange enrollees. The comments expressed concern that enrollees in the same plan deserved the same level of nondiscrimination protection and that the same standard should be applied.

Response: Health insurance products are often complex. While the Department provides general responses below in an attempt to clarify application of the rule, OCR will always engage in an individualized fact-based analysis when determining the extent of its jurisdiction over these or any other such products.

A QHP would be covered by the rule because it is a program or activity administered by an entity established under Title I (*i.e.,* an Exchange), pursuant to § 92.3(a)(3). A QHP could also be subject to Section 1557 if it were a recipient of Federal financial assistance, but as stated above, the premium tax credits that the Department plays a role in administering would no longer serve to bring an entity under the jurisdiction of this Section 1557 regulation.

Stand-alone dental plans and catastrophic plans offered through the Exchanges would similarly be subject to § 92.3(a)(3), as these plans are administered by an Exchange, which is an entity established under Title I.

Regarding ACA-compliant plans sold off-Exchange, because a health insurance issuer is not principally engaged in the business of providing healthcare, its operations would be subject to this rule only for the portion that receives Federal financial assistance. The issuer's components (*e.g.,* off-Exchange plans) that do not directly receive Federal financial assistance would not be subject to this rule.

Where a health insurance plan includes multiple types of enrollees, the Department would have to review the specific circumstance, but generally speaking, if a QHP is subject to Section 1557, this rule would apply consistently for all enrollees in the plan.

Comment: The Department received comments related to how the rule would apply to Medicare- and Medicaid-related products. One commenter asked whether the proposed limitation under § 92.3(c) would mean that Section 1557 would no longer apply to health insurance plans managed through Medicare and Medicaid.

A few commenters requested clarification on whether the proposed rule would apply to Employer Group Waiver Plans (EGWPs) and Medicare Part D Retiree Drug Subsidy (RDS) plans, or the employers that sponsor the plans. Commenters argued that applying the rule to these plans could disincentivize employers from sponsoring them and urged that the plans be exempt from the rule. Alternatively, one commenter requested that the Department exempt employer sponsors of ''800 series'' EGWPs, which are offered by Medicare Advantage Organizations (MAOs) or Part D Plan sponsors (PDP sponsors), because the employer is not the entity that receives funding from HHS. Finally, some commenters objected to excluding Medicare Part B from the rule.

Response: To be covered by the rule, a particular entity would have to satisfy one of the applicability requirements set forth in § 92.3. Entities that receive Federal funding through the Department's Medicare Part C (Medicare Advantage), Medicare Part D, or Medicaid programs would be subject to Section 1557 as recipients of Federal financial assistance. This would include Medicare Advantage plans, Medicaid managed care plans, EGWPs, or RDS plans, to the extent that they receive Federal financial assistance.

Pending further details, an employer that does not directly contract with CMS but offers an ''800 series'' EGWP through a MAO or PDP sponsor would not appear to be subject to this rule under this analysis because the employer does not receive the Federal financial assistance; meanwhile, the health insurance issuer offering the EGWP would be subject to the rule for its EGWP plan, due to receipt of either Medicare Part C or Part D funding.

As for Medicare Part B, it is not Federal financial assistance.[57] This remains unchanged from the 2016 Rule, which also determined that Medicare Part B was not Federal financial assistance under Section 1557.

Comment: Some commenters requested that this final rule be accompanied by explicit applicability guidance so that employers and plans could be able to ascertain if the final rule impacts their business.

Response: The Department seeks to provide sufficient clarity in this final rule. If OCR receives substantial questions about the rule's applicability after publication, OCR will consider issuing additional clarification, consistent with applicable law regarding issuance of sub-regulatory guidance.[58]

e. Summary of Regulatory Changes

For the reasons given in the proposed rule, and having considered comments received, the Department finalizes the proposed § 92.3, and repeal of § 92.2 of the 2016 Rule, without change, except that, as discussed in an earlier section of this preamble, and after considering comments on the issue, the Department is not finalizing the proposed repeal of § 92.2(c) concerning severability, but is retaining that provision and has moved it to § 92.3(d).

(4) Nondiscrimination Requirements in Proposed Revisions to § 92.2, and Repeal of § 92.8(d), 92.101, 92.206, 92.207, 92.209, and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d), 92.101, 92.206, 92.207, and Appendix B of the 2016 Rule (which includes repealing notice and taglines

[57] 45 CFR pt. 80 App A, No. 121; *https://www.hhs.gov/civil-rights/for-individuals/faqs/what-qualifies-as-Federal-financial-assistance/301/index.html. See also* 81 FR at 31383, 31385; 84 FR at 27863 (discussing the applicability of the rule to Medicare Part B and clarifying in footnote 100 that ''[t]he Department believes that the Federal financial assistance does not include Medicare Part B under the Social Security Act. *See* 2 CFR 200.40(c) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for Federal Awards); 45 CFR 75.502(h) (Uniform Administrative Requirement, Cost Principles, and Audit Requirements for HHS Awards).'').

[58] *See, e.g.,* Executive Order 13892 on Promoting the Rule of Law Through Transparency and Fairness in Civil Administrative Enforcement and Adjudication, 84 FR 55239 (Oct. 9, 2019); Executive Order 13891 on Promoting the Rule of Law Through Improved Agency Guidance Documents, 84 FR 55235 (Oct. 9, 2019); U.S. Dept. of Justice, Memorandum of the Office of the Associate Attorney General, Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases (Jan. 25, 2018), *https://www.justice.gov/file/1028756/download;* U.S. Dept. of Justice, Memorandum of the Office of the Attorney General, Prohibition on Improper Guidance Documents (Nov. 16, 2019), *https://www.justice.gov/opa/press-release/file/1012271/download.*

provisions), and instead address nondiscrimination requirements in a new § 92.2. The Department proposed to repeal provisions that made applicable across all protected categories those particular requirements, prohibitions, or enforcement mechanisms that had previously applied only to particular circumstances.

The Department requested comments on all aspects of the proposed rule. The Department also specifically requested comment on any unaddressed discrimination on the basis of race, color, or national origin as applied to State and Federally-facilitated Exchanges, with any detailed supporting information. And the Department requested comment on whether, and if so how, the proposed rule addresses clarity and confusion over compliance requirements and the rights of persons protected against discrimination on the basis of race, color, national origin, sex, disability, or age.

The Department received many comments on these proposed changes. The Department will first discuss comments concerning each of the grounds in Section 1557: Race, color, national origin, disability, age, and sex. Then other grounds of discrimination will be discussed, followed by assessment of claims of discriminatory conduct when multiple grounds of discrimination are alleged. Comments concerning disability and LEP protections will be addressed below in the section on Subpart B of the Section 1557 rule.

a. Discrimination on the Basis of Race, Color, or National Origin

i. Generally

Comment: The Department received support for its commitment to continued enforcement of race, color, and national origin protections. Commenters stated that these characteristics are clear and simple to distinguish, contrasting them with gender identity, which is fluid and more difficult to define.

Response: The Department appreciates the support for its continued commitment to the enforcement of protections against discrimination on the basis of race, color, and national origin. The Department agrees that gender identity as a category is difficult to define. This is not, however, the Department's reason for not viewing gender identity as a protected category under Section 1557. The Department enforces statutory prohibitions on discrimination on the basis of race, color, national origin, age, disability, and sex discrimination because they are set forth in the text of statutes incorporated into Section 1557, and gender identity is not set forth as a protected category in those statutes.

Comment: Commenters contended that the proposed changes, including repeal of § 92.101 and the specific discrimination it prohibited, will lead to confusion among individuals and lead healthcare providers to discriminate based on race, color, and national origin. Commenters recommended that the Department retain clear, strong language prohibiting healthcare providers from discriminating based on race, color and national origin.

Response: This final rule's § 92.2 retains clear, strong language prohibiting discrimination on the basis of race, color, or national origin. Covered entities are still required to provide the Department with an assurance, and, pursuant to the underlying civil rights regulations, to post notices, that they do not so discriminate and are in compliance with Federal civil rights law. If the Department learns of confusion among covered entities or individuals as to their civil rights, it will consider issuing further guidance as needed.

Comment: Some commenters contended that the proposed changes will negatively impact women of color, who (according to these commenters) disproportionately rely on the short-term health plans that this final rule does not cover, and are more likely to experience pregnancy-related issues that will cause them to suffer from the rollback of termination of pregnancy protections.

Response: For reasons detailed below, this final rule (a) does not generally apply to short-term limited duration health insurance and (b) only covers termination of pregnancy to the extent permitted by Title IX's abortion-neutrality language, as required by the relevant statutes. The Department will vigorously enforce the prohibitions on discrimination based on race or sex, including under disparate impact analysis with respect to race discrimination as provided for in the relevant Title VI regulations, but the Department remains bound by the limits of the statutes enacted by Congress. The Department's Office of Minority Health also supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: One commenter expressed concern that the changes in the proposed rule will have a negative impact on access to health screenings and vaccinations for patients. The commenter stated that removal of nondiscrimination requirements for many health insurance providers will leave these populations with little recourse if health insurance providers rescind coverage for preventative health services.

Response: Because this final rule continues to commit the Department to robust enforcement of its prohibitions on discrimination on the basis of race, color, national origin, sex, age, and disability, the Department does not anticipate that it will impede any population's access to preventive care and vaccinations, which (under separate provisions of the ACA) must be covered without cost sharing for group health plans and health insurance issuers offering group or individual health insurance coverage.[59]

ii. Repeal of Notice and Taglines Provisions at § 92.8(d) and Appendix B of the 2016 Rule

The Department proposed to repeal § 92.8(d) of the 2016 Rule, which required a nondiscrimination notice and taglines in all significant communications from covered entities, and also proposed to repeal the sample taglines notice in Appendix B to Part 92. 84 FR at 27857–60. The Department stated its assumption that this will correspondingly ease the burden of the LEP provision in CMS regulations at 45 CFR 155.205(c)(2)(iii)(A), which deemed compliance with the LEP provisions of the Section 1557 regulation to constitute compliance with CMS's requirements.[60]

The Department specifically sought comment to identify ''significant communications'' under the 2016 Rule sent by covered entities that include a notice and taglines but had not been considered by the analysis in the proposed rule, as well as the estimated annual volume of such communications. The Department also requested comment on which communications are significant in healthcare.

Comments: Some commenters stated that the removal of the 2016 Rule's notice and taglines provisions will result in LEP beneficiaries having less knowledge of available language assistance services and that they will likely rely more on family members to provide oral interpretation.

Response: The regulations of the underlying statutes referred to in Section 1557 (Title VI, Section 504, Title IX, and the Age Act) have long mandated that covered entities provide

[59] *See* 42 U.S.C. 300gg–13.

[60] 84 CFR 27887, n. 240, and 27881.

a notice of nondiscrimination.[61] This final rule maintains that requirement. Moreover, it continues to require covered entities to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity. It removes only the unduly broad, sometimes confusing, and inefficient requirement that all significant communications contain taglines. This requirement caused significant unanticipated expenses, as discussed in the regulatory impact analysis (RIA) below. Moreover, as discussed below, § 92.101 of this final rule reiterates longstanding criteria to help covered entities conduct an individualized assessment of their program and ensure meaningful access by persons with LEP, and retains the 2016 Rule's prohibition on covered entities' requiring an LEP individual to provide his or her own interpreter or relying on an accompanying adult to interpret or facilitate communication (except in limited circumstances).

Comment: Some commenters disagreed with the Department's proposal to make conforming amendments to the CMS requirements placed on Health Insurance Exchanges and Qualified Health Plan (QHP) issuers at 45 CFR 155.205. These commenters argued that the CMS requirements do not rely on the 2016 Rule's taglines provisions, nor does the 2016 Rule prevent the implementation of additional requirements in more specific programs, such as Medicaid and Medicare. Others agreed with the Department's proposal, raising concerns about CMS's requirements at 45 CFR 155.205, which state that Exchanges and QHP issues are only ''deemed'' in compliance with the CMS requirements ''if they are in compliance with'' the 2016 Rule's taglines provisions. These commenters argued that if the notice and taglines provisions are removed, the CMS compliance provision will cross-reference a repealed rule, which would require QHP issuers and Exchanges to comply with CMS's taglines rule instead. The CMS mandate for 15 taglines for the CMS list of critical documents is arguably as burdensome as the 2016 Rule's taglines provisions; therefore, these commenters argue that any benefit in efficiency yielded by the repeal of the 2016 Rule's taglines provisions would be lost for Exchanges and QHP issuers. These commenters suggest amending the 2016 Rule's provisions to state that there is no specific taglines requirement under Section 1557 and that a covered entity's compliance under applicable Federal and State laws will be considered under Section 1557's LEP meaningful access standards.

Response: The provision at 45 CFR 155.205(c)(2)(iii)(A) and the similar requirement placed on QHP issuers (see HHS Notice of Benefit and Payment Parameters for 2016; Final Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), have not been directly amended in this regard. Nevertheless, as the Department stated in the proposed rule,[62] both of those requirements depend on or refer to the taglines requirements repealed in this final rule. As a result, covered entities are deemed compliant with those particular taglines requirements due to this final rule. Specifically, 45 CFR 155.205(c)(2)(iii)(A) sets forth taglines requirements and then states, ''Exchanges, and QHP issuers that are also subject to § 92.8 of this subtitle, will be deemed in compliance with paragraph (c)(2)(iii)(A) of this section if they are in compliance with § 92.8 of this subtitle.'' The Department informed the public of this interpretation in the proposed rule, and after reviewing public comments, the Department maintains the same position for essentially the same reason. Because this final rule repeals the taglines requirements of the 2016 Rule at § 92.8, entities will not be out of compliance with those requirements, and therefore they will satisfy the condition of the sentence quoted above from 45 CFR 155.205(c)(2)(iii)(A) that they not be out of compliance with taglines requirements in 45 CFR part 92. Although the Department did not propose conforming amendments to those two regulations, and therefore cannot finalize such amendments in this final rule, the Department will consider making appropriate changes to other regulations in the future.

Comment: Commenters, including a health insurance issuer, noted that the 2016 Rule's preamble vaguely defined ''significant communications'' to include ''not only documents intended for the public . . . but also written notices to an individual, such as those pertaining to rights or benefits.'' 81 FR 31402. These commenters argued that because almost all written communications would be considered ''significant'' under this definition, most covered entities included a one- to two-page addition containing the nondiscrimination notice and taglines with most written communications. One health insurance issuer estimated sending the notice and taglines approximately 15 million times in 2018, or about five times for every individual served. One commenter stated that because the Department determined that the notice and taglines requirement in the 2016 Rule imposes a significant financial burden on covered entities, the Department is within its authority to rescind it, especially because of an executive order that limits the effectiveness of subregulatory guidance. Others requested that the Department issue further guidance on what constitutes ''significant'' documents and communications, instead of removing the 2016 Rule's notice and taglines provisions.

Response: The Department agrees with comments that stated the 2016 Rule's notice and taglines requirements were imprecise and overly burdensome. The Department declines to retain those requirements while merely issuing more guidance on what constitute significant communications. First, the requirements are not mandated by statute, and although the 2016 Rule is a regulation and not subregulatory guidance, the Department has determined that its financial burden on covered entities was not justified by the protections or benefits it provided to LEP individuals. Second, the Department believes that other protections as finalized in this rule (and discussed below) better serve the language access needs of LEP individuals and, therefore, are more appropriate. Repeal of the notice and taglines requirements in this rule does not repeal all other notice and taglines requirements that exist under other statutes and rules.

b. Discrimination on the Basis of Disability

The Department is committed under this final rule to enforce protections against discrimination on the basis of disability, both in specific provisions set forth in § 92.102–92.105, and as applicable through the underlying Section 504 regulations, which are more broadly applicable under Section 1557 of the ACA. Comments on these issues are discussed in the section below on Subpart B of the Section 1557 regulation.

c. Discrimination on the Basis of Age

Comment: Commenters expressed concerns that the changes in the proposed rule will lead to discriminatory practices in health plans. In the absence of explicit language prohibiting health plans from discriminating based on age as set forth in § 92.207 of the 2016 Rule, they alleged, health plans may unlawfully

[61] *See* Title VI (45 CFR 80.6 and Appendix to Part 80), Section 504 (45 CFR 84.8), Title IX (45 CFR 86.9), and the Age Act (45 CFR 91.32).

[62] 84 FR at 27881.

deny, cancel, or limit policies, deny or limit coverage for claims, impose additional cost-sharing on coverage, or use discriminatory marketing practices or benefit designs because of age. In particular, some commenters believe that health insurance plans will offer formularies and plan options that deny treatment for older individuals who generally have more health complications. For example, they say, this practice may already be in place with some health plans that offer coverage for hearing aids to children and youths but deny it to older adults. Some commenters said the proposed rule will lead to discrimination against older LGBT adults, who already have high levels of poverty and health disparities, and will contribute to worse health outcomes. Some commenters also alleged the proposed rule encourages unlawful discrimination against LGBT youth, who are already at increased risk of discrimination.

Response: This final rule retains clear language prohibiting discrimination on the basis of age, as defined in the Age Act and enforced through its implementing regulations, in any covered programs and activities, including health plan marketing and benefit design. Moreover, the ACA has specific provisions which limit the extent to which health plans offered under the ACA can charge higher premiums based on age, as well as specific provisions which require guaranteed issuance, address permissible cost sharing requirements, and establish standards for essential benefits and formularies.

The Department remains committed to vigorous enforcement of this prohibition on behalf of all Americans, including LGBT adults and youth. The Department declines to comment on specific cases outside of the normal enforcement process but encourages anyone who has experienced unlawful discrimination, including with respect to health plans, to file a complaint with OCR.

Comment: Commenters expressed concern that the proposed rule will lead to health plans using their benefit design to discriminate against individuals with chronic conditions who are more expensive to insure, including children and youth with serious health conditions. One commenter represented a 13 year old with Down syndrome who, the commenter said, was denied coverage by a private health insurer because that health insurer categorically denied coverage for individuals with Down syndrome.

Response: Many serious health conditions, including Down syndrome, qualify as disabilities under Section 504, which Section 1557 incorporates. The Department will enforce vigorously Section 1557's prohibition on discrimination on the basis of disability against all covered entities, including when discrimination is alleged to have taken place in benefit design. As finalized, the amended § 147.104 would prohibit health insurance issuers from employing ''benefit designs that . . . discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions.'' The ACA also establishes requirements, applicable to health insurance issuers offering individual and group health insurance, concerning guaranteed issuance and renewal.[63] Concerns about whether private health insurers are covered entities are addressed below in the section on this rule's scope of application.

Comment: Some commenters contended the proposed rule will allow health plans to place age restrictions on certain medications, such as age restrictions on contraceptives for youth.

Response: To the extent that covered entities (including health plans) place restrictions based on age, OCR would assess on a case-by-case basis whether such restrictions violate Section 1557's incorporation of grounds prohibited under the Age Act. The Age Act does not forbid certain age distinctions in Federal, State, or local statutes and ordinances, or an action that reasonably takes age into account as a factor that is necessary to the normal operation or achievement of a statutory objective of a program.[64]

d. Discrimination on the Basis of Sex

i. Generally

Comment: Commenters offered different points of view on the definition of the term ''sex,'' as this relates to the definition of discrimination ''on the basis of sex.''

A number of commenters stated that the Department had proposed a new definition of ''sex'' for the Section 1557 rule. Some objected that any reinterpretation of ''sex'' should be addressed by Congress or left to the courts, rather than administrative agencies. Others stated that the proposed regulations realign the Department's interpretation with several decades of Federal court decisions and with the logical interpretation based on the statute's plain meaning of sex (namely sex in its biological meaning), which until 2017 had been the consistent consensus of the Federal courts.

Some commenters said that sex is a binary reality of male and female, and that Title IX and Section 1557 apply this historic understanding of sex. Some commenters stated that there is no evidence in the legislative history of either Title IX or the ACA that Congress intended to prohibit gender identity or sexual orientation discrimination in Section 1557, and that the purpose of Title IX is to ensure women (as biologically distinct from men) equal opportunities in Federally funded programs and activities.[65] Commenters said that the 2016 Rule exceeded the Department's authority by adopting a new, different, or expansive definition of prohibited sex discrimination in its Section 1557 regulation, although Congress declined to do so when presented with the opportunity and instead incorporated its meaning from Title IX which was passed in 1972. Some commenters noted that Congress has repeatedly considered adding gender identity and sexual orientation as protected categories in nondiscrimination laws related to education,[66] or to employment,[67] or in bills that would redefine discrimination ''on the basis of sex''[68] as the 2016 Rule attempted, but that Congress has chosen not to do so.[69] Where Congress has chosen to prohibit ''gender identity'' discrimination in other statutes, it added the term ''gender identity'' as a

[63] *See* 42 U.S.C. 300gg–1, 300gg.2.

[64] 45 CFR 90.14, 90.15.

[65] Commenters cited 118 Cong. Rec. 5808 (1972); 44 FR at 71423.

[66] See, *e.g., Student Non-Discrimination Act of 2018,* H.R. 5374, 115th Congress, 2nd sess.; online at: *https://www.congress.gov/115/bills/hr5374/BILLS-115hr5374ih.pdf*: ''No student shall, on the basis of actual or perceived sexual orientation or gender identity . . . be excluded from participation in, or be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.''

[67] *See, e.g., Employment Non-Discrimination Act of 2013,* S. 815, 113th Congress, 1st sess.; online at: *https://www.govtrack.us/congress/bills/113/s815/text*: ''It shall be an unlawful employment practice for an employer—(1) to fail or refuse to hire or to discharge any individual, or otherwise discriminate against any individual . . . because of such individual's actual or perceived sexual orientation or gender identity . . .''

[68] *See, e.g., Equality Act,* H.R. 5, 116th Congress, 1st sess.; online at: *https://www.congress.gov/116/bills/hr5/BILLS-116hr5rfs.pdf*; amends *Civil Rights Act of 1964* ''by striking 'sex,' each place it appears and inserting 'sex (including sexual orientation and gender identity)' . . .''

[69] *See* H.R. 1652, 113th Cong. (2013); S. 439, 114th Cong. (2015). H.R. 3185, 114th Cong. (2015); S. 1858, 114th Cong. (2015); H.R. 2015, 110th Cong. (2007); H.R. 2981, 111th Cong. (2009); S. 811, 112th Cong. (2011); *See* H.R. 4636, 103rd Cong. (1994).

new and separate category of prohibited grounds in addition to ''sex'' without redefining ''sex'' itself.[70] Other commenters said that reliance on legislative history is an improper method of statutory interpretation, and that the Supreme Court has deemed reliance on Congressional inaction to be inappropriate.

One commenter cited U.S. Supreme Court cases as setting forth the binding legal standard of sex discrimination as a binary biological concept. The commenter cited *Tuan Anh Nguyen* v. *I.N.S.* as rejecting an approach of ''[m]echanistic classification of all our differences as stereotypes'' because it obscures the reality that ''physical differences between men and women . . . are enduring,'' 533 U.S. 53, 73 (2001), as well as Justice Ginsburg's majority opinion in *United States* v. *Virginia,* which held that '' '[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.' '' 518 U.S. at 533 (1996).

Some commenters stated that changing cultural preferences should not be the standard for interpreting legal texts. Others analogized Title IX's lack of a definition of ''sex'' to the lack of a definition of ''race'' under the Civil Rights Act of 1964, where courts looked to the plain and ordinary meaning to interpret it as based on a person's ''family, tribe, people, or nation belonging to the same stock.'' Other commenters cited analyses of public meanings at the time of adoption, concluding that when ''gender'' was used, which was rare, it was used in contrast to sex: Gender referred to socially constructed roles, while sex, according to virtually every dictionary of the time, referred to biological differences between men and women.[71] Other commenters stated that use of the term ''gender'' (with regard to one's identity) as separate from ''sex'' (with regard to one's biology) is relatively new and is improperly interpreted today as evidence of support for gender-identity legal theories in prior legal precedents or decades-old statutes. Some commenters asserted that at the time of the passage of the underlying Federal civil rights statutes, ''sex'' and ''gender'' were commonly used identically under Title VII, Title IX, and the Equal Protection Clause to refer to biological sex.[72] However, other commenters disagreed, and stated that historical sources demonstrate the variability and complexity of the concept of sex to include ''[t]he sum of the morphological, physiological, and behavioral peculiarities of living beings.''

Some commenters stated that the terms male or female apply to everyone. Commenters stated that the ''sex'' of an organism is a clear, provable, objective, identifiable, biological, and binary reality according to relevant textbooks, studies, and articles from various specialties in the scientific community, including embryology, genomics, psychiatry, clinical anatomy, neuropsychology, developmental biology, genetics, endocrinology, neuropsychiatry, radiology, organismic and evolutionary biology, neuropharmacology, pediatrics, and pathology.[73] Healthcare providers stated that the reality of sex, as male or female, can be identified through advanced chromosomal testing such as karyotyping or simple genital identification at birth in roughly 99.98% of cases, leaving the remaining 0.02% as diagnoses with intersex or ambiguous conditions. Others stated that delineating a binary division on the basis of reproductive organs reflected an outdated paradigm and was not universally descriptive of transgender, transitioning, androgynous, intersex, two-spirit, or questioning individuals.

Some commenters stated that removal of a regulatory definition of ''sex'' leaves the regulation ambiguous, and the 2016 Rule was justified in clarifying by adding a definition that included gender identity and termination of pregnancy. Other commenters stated that the public widely understands the state of being either male or female, as determined by one's chromosomes or genetics, which leaves no ambiguity.

Response: Because Section 1557 incorporates Title IX's prohibition on discrimination ''on the basis of sex,'' it presupposes that the executive and judicial branches can recognize the meaning of the term ''sex.'' This final rule repeals the 2016 Rule's definition of ''on the basis of sex,'' but declines to replace it with a new regulatory definition. *See* 84 FR at 27857. Instead, the final rule reverts to, and relies upon, the plain meaning of the term in the statute.

''Sex'' according to its original and ordinary public meaning refers to the biological binary of male and female that human beings share with other mammals. As noted in briefs recently submitted by the Federal government to the Supreme Court, discrimination on the basis of sex means discrimination on the basis of the fact that an individual is biologically male or female.[74] Several commenters reference various sources of legislative history: That of Title IX, of Congress's decision to add protections on the basis of sexual orientation and gender identity to other statutes alongside protections on the basis of sex, and of Congress's repeated refusal to add those protections in other cases.[75] These sources support the plain

[70] 18 U.S.C. 249(a)(2).

[71] Commenters cited Joanne Meyerowitz, A History of ''Gender,'' 113 a.m. Hist. Rev. 1346, 1353 (2008); David Haig, The Inexorable Rise of Gender and the Decline of Sex: Social Change in Academic Titles, Archives of Sexual Behavior 1945–2001 (Apr. 2004); Sari L. Reisner, *et al.,* ''Counting'' Transgender and Gender-Nonconforming Adults in Health Research, *Transgender Studies* Quarterly 37 (Feb. 2015); New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010).

[72] *See Glenn* v. *Brumby,* 663 F.3d 1312, 1315 (11th Cir. 2011) (citing *City of Cleburne* v. *Cleburne Living Ctr., Inc.,* 473 U.S. 432, 440–41 (1985). (''In describing generally the contours of the Equal Protection Clause, the Supreme Court noted its application to this issue, referencing both gender and sex, using the terms *interchangeably* . . .'').

[73] Commenters cited texts including, *e.g.,* T.W. Sadler, Ph.D., *Langman's Medical Embryology* (Philadelphia: Lippincott Williams & Wilkins, 2004), 40; William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 519; Keith L. Moore, Ph.D., DSc, and T.V.N. Persaud, M.D., Ph.D. DSc, FRCPath., *The Developing Human: Clinically Oriented Embryology* (Philadelphia: Saunders/Elsevier, 2003), 35; Maureen L. Condic, Ph.D. and Samuel B. Condic, Ph.D., ''Defining Organisms by Organization,'' National Catholic Bioethics Quarterly 5, no. 2 (Summer 2005): 336; Lawrence S. Mayer, Ph.D., and Paul R. McHugh, M.D., ''Sexuality and Gender Findings from the Biological, Psychological, and Social Sciences,'' *New Atlantis* 50 (Fall 2016): 89; Scott F. Gilbert, Ph.D. *Developmental Biology* (Sunderland, Mass.: Sinauer Associates, 2016), 519–20; and William J. Larsen, Ph.D., *Human Embryology* (New York: Churchill Livingstone, 2001), 307; Nichole Rigby, M.A. and Rob J. Kulathinal, Ph.D., ''Genetic architecture of sexual dimorphism in humans,'' *J. of Cellular Physiology* 230, no. 10 (2015): 2305; Jonathan C.K. Wells, Ph.D., ''Sexual dimorphism of body composition,'' *Best Practice & Research: Clinical Endocrinology & Metabolism* 21 (2007): 415; Larry Cahill, Ph.D., ''His Brain, Her Brain,'' *Scientific American,* October 1, 2012; Larry Cahill, Ph.D. ''A Half-Truth Is a Whole Lie: On the Necessity of Investigating Sex Influences on the Brain,'' *Endocrinology* 153 (2012): 2542; Madhura Ingalhalikar, Ph.D., et al., ''Sex differences in the structural connectome of the human brain,'' *Proceedings of the National Academy of Sciences* 111 (January 2014): 823–28.

[74] *Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)); Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 4–5 (''When Congress enacted Title IX in 1972, the 'ordinary, contemporary, common meaning' of 'sex' was biological sex. . . . Title IX consistently uses 'sex' as a binary concept capturing only two categories: Male and female.'').

[75] Examples of bills where Congress chose not to enact prohibitions on discrimination on the basis of sexual orientation or gender identity include: The Employment Non-Discrimination Act (ENDA), which has been introduced ten times in the U.S. House of Representatives but has never proceeded out of committee: H.R. 4636 (103rd Cong. 1994); H.R. 1863 (104th Cong. 1995); H.R. 1858 (105th Cong. 1997); H.R. 2355 (106th Cong. 1999); H.R. 2692 (107th Cong. 2001); H.R. 3285 (108th Cong.

meaning of Title IX, but are not the only source of support for the Department's understanding of the meaning of the word ''sex.'' Contemporaneous dictionaries and common usage make clear that ''sex'' in Title IX means biological sex.[76] Even today, the article on gender dysphoria in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition defines ''sex'' to ''refer to the biological indicators of male and female (understood in the context of reproductive capacity), such as in sex chromosomes, gonads, sex hormones, and nonambiguous internal and external genitalia.'' [77] The term ''gender'' may sometimes be ambiguous. However, neither Title IX nor Section 1557 uses that term, and the ordinary public meaning of the term ''sex'' in Title IX is unambiguous. In order to avoid ambiguities associated with the term ''gender,'' the Department's regulations and guidance have, where relevant, distinguished sex (in its biological meaning) from gender, gender identity, or gender expression.[78]

Some commenters challenge the Department's approach by pointing to medical conditions that they refer to as ''intersex.'' The term refers to rare medical conditions that the medical literature, since 2006, has preferred to call ''disorders of sexual development'' (DSD).[79] DSD are estimated to be present in 0.0167%–0.022% of the population. More importantly, DSD are ''congenital conditions in which development of chromosomal, gonadal, or anatomic sex is atypical.'' [80] This medical definition refers to, and presupposes, the ordinary biological and binary meaning of ''sex,'' just as the definition of any medical disorder presupposes an understanding of healthy baseline functionality.

Title IX,[81] along with its implementing regulations,[82] consistently understands ''sex'' to refer to the biological binary categories of male and female only.[83] The Department of Justice has recently noted that ''[i]f the term 'sex' in Title IX included 'gender identity'—which, according to the American Psychiatric Association, may include 'an individual's identification as . . . some category *other than* male or female,' *Diagnostic and Statistical Manual of Mental Disorders Fifth Edition* 451 (2013) (emphasis added)—then multiple Title IX provisions would make little sense.'' [84] Many comments on the 2019 NPRM assume that Section 1557's protection against discrimination ''on the basis of sex'' covers women's health issues including pregnancy, uterine cancer, and prenatal and postpartum

2003); H.R. 2015 (110th Cong. 2007); H.R. 2981 (111th Cong. 2009); H.R. 1397 (112th Cong. 2011); H.R. 1755 (113th Cong. 2013). Similarly, the Equality Act has been introduced in three successive sessions of Congress; it did not proceed out of committee in the 114th and 115th Congresses, and it passed the House of Representatives on May 17, 2019. *See* H.R. 3185 (114th Cong. 2015); S. 1828 (114th Cong. 2015); H.R. 2282 (115th Cong. 2017); S. 1006 (115th Cong. 2017); H.R. 5 (116th Cong.) (introduced Mar. 3, 2019).

[76] *See* New Oxford Am. Dictionary 721–22, 1600 (3d ed. 2010). Some Federal courts have gone farther, using the legislative history to show that ''Congress never considered nor intended'' for sex under Title VII (which is often used to interpret Title IX) to apply to ''anything other than the traditional concept of sex,'' and that coverage for a concept such as transgender status ''surely'' would have been mentioned in the legislative history had Congress intended such an ''all-encompassing interpretation.'' The Department finds the analysis in these Court decisions persuasive, but declines to rely on their reasoning. *See Ulane* v. *Eastern Airlines Inc.,* 742 F. 2d 1081, 1085 (7th Cir. 1984) (analyzing ''The total lack of legislative history supporting the sex amendment coupled with the circumstances of the amendment's adoption''); *see also Voyles* v. *Ralph K. Davies Medical Center,* 403 F. Supp. 456, 457 (N.D. Cal. 1975), *aff'd,* 570 F.2d 354 (9th Cir. 1978) (finding a ''void'' in the legislative history and concluding that Congress's ''paramount, if not sole, purpose in banning employment practices predicated upon an individual's sex was to prohibit conduct which, had the victim been a member of the opposite sex, would not have otherwise occurred. Situations involving transsexuals, homosexuals or bi-sexuals were simply not considered.'').

[77] American Psychiatric Ass'n, *Diagnostic and Statistical Manual of Mental Disorders,* 5th ed. (Arlington, VA: American Psychiatric Ass'n, 2013), 451–59.

[78] *See* 45 CFR 411.5; *also* 79 FR 77771, 84 FR 27854. *See* NIH, Office of Research on Women's Health, ''Sex & Gender,'' *https://orwh.od.nih.gov/sex-gender* (''NIH is committed to improving health by supporting the rigorous science that drives medical advances. Sex/gender influence health and disease, and considering these factors in research informs the development of prevention strategies and treatment interventions for both men and women. 'Sex' refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. 'Gender' refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context and vary across societies and over time. . . . With continuous interaction between sex and gender, health is determined by both biology and the expression of gender.'').

For these reasons, in general throughout this document the Department prefers to use simply the term ''sex'' because the plain, ordinary meaning of ''sex'' is already biological, so it is generally redundant to use the term ''biological sex.'' Where the Department uses the term ''biological sex,'' or similarly ''biological male'' or ''biological female,'' it does so merely to emphasize this point and for the purposes of clarity in particular contexts, and not to imply that there is a distinction between biological sex and sex under the plain meaning of the term.

[79] R.L.P. Romao, J.L. Pippi Salle, and D.K. Wherett, ''Update on the Management of Disorders of Sex Development,'' *Pediatric Clinics of North America* 59 (2012), 853–69; I.A. Hughes, ''Disorders of Sex Development: A New Definition and Classification,'' *Best Practice & Research Clinical Endocrinology & Metabolism* 22:1 (2008), 119–34.

[80] A. Rawal and P. Austin, ''Concepts and Updates in the Evaluation and Diagnosis of Common Disorders of Sexual Development,'' *Current Urology Reports* 16:83 (2015), 1–9; I. Hughes et al., ''Consequences of the ESPE/LWPES guidelines for diagnosis and treatment of disorders of sex development,'' *Best Practice & Research Clinical Endocrinology & Metabolism* 21:3 (2007), 351–65; P.A. Lee et al., ''Consensus Statement on Management of Intersex Disorders,'' *Pediatrics* 118:2 (2006), e488–500.

[81] *See* 42 U.S.C. 1681(a)(2)(''both sexes''), (a)(2) (''one sex'' and ''other sex''), (a)(6)(B) (''Men's'' and ''Women's''), (a)(6)(B) (''Boy'' and ''Girl''); (a)(7)(A) (''Boys'' and ''Girls''), (a)(7)(B)(i) (''Boys'' and ''Girls''), (a)(8) (''father-son'' ''mother-daughter''), and (a)(8) (''one sex'' and ''other sex''). *See also* 42 U.S.C. 1681(a)(2)(6)(''fraternity'' and ''sorority'').

[82] *See* language such as ''male and female,'' ''both sexes,'' ''each sex,'' ''one sex . . . the other sex,'' and ''boys'' and ''girls,'' at 45 CFR 86.2(s), 86.7, 86.17(b)(2), 86.21(c)(4), 86.31(c), 86.32(b)(2) and (c)(2), 86.33, 86.37(a)(3), 86.41(b) and (c), 86.55(a), 86.58(a) and (b), 86.60(b), and 86.61. *See* similarly Department of Education Title IX regulation at 34 CFR 106.2(s), 106.7, 106.17(b)(2), 106.21(c)(4), 106.31(c), 106.32(b)(2) and (c)(2), 106.33, 106.37(a)(3), 106.41(b) and (c), 106.55(a), 106.58(a) and (b), 106.60(b), and 106.61; Department of Justice Title IX regulation at 28 CFR 54.105, 54.130, 54.230(b)(2), 54.235(b)(3), 54.300(c)(4), 54.400(c), 54.405(b)(2) and (c)(2), 54.410, 54.430(a)(3), 54.450(b) and (c)(2), 54.520(a), 54.535(a) and (b), 54.545(b), and 54.550. *See also* DOJ Coordination and Compliance Division, Title IX Regulations by Agency, *https://www.justice.gov/crt/fcs/Agency_Regulations#2.*

[83] Federal courts have also made this observation. *See, e.g., Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518, 522 (3d Cir. 2018) (''''Sex' is defined as 'the anatomical and physiological processes that lead to or denote male or female.' Typically, sex is determined at birth based on the appearance of external genitalia.''); *Hively* v. *Ivy Tech Cmty. Coll.,* 853 F.3d 339, 362 (7th Cir. 2017) (''[i]n common, ordinary usage in 1964—and now, for that matter—the word 'sex' means biologically *male* or *female.*'') (Sykes, J., dissenting) (emphasis in original); *cf. id.* at 357 (''we, who are judges rather than members of Congress, are imposing on a half-century-old statute a meaning of 'sex discrimination' [to include sexual orientation] that the Congress that enacted it would not have accepted.'') (Posner, J., concurring); *G.G. ex rel Grimm* v. *Gloucester Cnty. Sch. Bd.,* 822 F.3d 709, 736 (4th Cir. 2016) (''Title IX was enacted in 1972 and the regulations were promulgated in 1975 and readopted in 1980, and during that time period, virtually every dictionary definition of 'sex' referred to the physiological distinctions between males and females, particularly with respect to their reproductive functions.'') (Niemeyer, J., dissenting); Statement of Interest for DOJ, *Soule* v. *Connecticut Association of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5 (''Other provisions of Title IX employ ''sex'' as a binary term, and thus provide further confirmation that the prohibition on ''sex'' discrimination does not extend to discrimination on the basis of transgender status or gender identity.''); *Franciscan All., Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 687 (N.D. Tex. 2016) (''the meaning of sex unambiguously refers to the biological and anatomical differences between male and female students as determined at their birth,'' quoting *Texas* v. *United States,* 201 F. Supp. 3d 810, 833 (N.D. Tex. 2016)); *Johnston* v. *Univ. of Pittsburgh of Commw. Sys. of Higher Educ,* 97 F. Supp. 3d 657, 676 (W.D. Pa. 2015) (''[o]n a plain reading of the statute, the term 'on the basis of sex' in Title IX means nothing more than male and female, under the traditional binary conception of sex consistent with one's birth or biological sex'').

[84] Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5.

services. That assumption is correct: These issues are protected under Section 1557 because of the ordinary and biological meaning of ''sex.''

Prior to the ACA, OCR itself had always applied Title IX in its enforcement actions using the biological binary meaning of sex.[85] Recently, OCR has resolved a number of Section 1557/Title IX cases of discrimination against women in healthcare programs and activities funded by the Department, again relying on a biological understanding of sex.[86] The 2016 Rule itself presupposed the biological meaning of sex when it permitted ''sex-specific'' health programs that are ''restricted to members of one sex,'' when it incorporated ''termination of pregnancy'' into discrimination on the basis of sex, and when it referred repeatedly to ''sex assigned at birth.''[87]

Supreme Court case law on Title IX has consistently presupposed the biological and binary meaning of ''sex.''[88] Even when some lower courts have recently extended Title VII or Title IX protections ''on the basis of sex'' to encompass gender identity, they have done so only by presupposing the ordinary public meaning of ''sex'' as a biological binary reality. In *Whitaker* v. *Kenosha Unified Sch. Dist.,* for example, the Seventh Circuit stated: ''Here, the School District's policy cannot be stated without referencing sex, as the School District decides which bathroom a student may use based upon the sex listed on the student's birth certificate. This policy is inherently based upon a sex-classification and heightened review applies.''[89] Likewise, in *Harris Funeral Homes,* the Sixth Circuit stated: ''Here, we ask whether Stephens would have been fired if Stephens had been a woman who sought to comply with the women's dress code. The answer quite obviously is no. This, in and of itself, confirms that Stephens's sex impermissibly affected Rost's decision to fire Stephens.''[90] In other words, Stephens ''quite obviously'' is not ''a woman'' because ''Stephens's sex'' is male.[91]

The Department does not deny that some courts have caused confusion as to the meaning of sex in civil rights law. Conflicting views in the lower courts, however, do not preclude the Department, consistent with the position of the U.S. government, as set forth in briefs filed in the Supreme Court, from returning to its decades-long practice of conforming to the original and ordinary public meaning of ''sex'' in Title IX, a meaning that continues to be presupposed even in the same rulings that have caused this confusion.

Some lower courts have recently held that discrimination ''on the basis of sex'' encompasses gender identity or sexual orientation even when ''sex'' is understood in its ordinary, biological, and binary sense. These views will be addressed below in the relevant subsections.

Comment: Some commenters argued that the proposed rule would be inconsistent with the purposes of the ACA; that the weight of law recognizes sexual orientation and gender identity as forms of sex discrimination; and that the proposed rule would undermine Congress's intent to expand access to healthcare and healthcare coverage. Commenters emphasized that it is unacceptable for a healthcare facility to deny medical care to a patient based on the patient's sexual orientation or transgender status.

Response: The Department does not condone the unjustified denial of needed medical care to anyone, and believes that everyone, regardless of gender identity or sexual orientation, should be treated with dignity and respect. The Department must interpret Congress's purpose in passing the ACA by reading that statute's plain text. The ACA sought to expand access to healthcare and healthcare coverage through some means but not others: in particular, Congress saw fit to incorporate into the ACA certain nondiscrimination protections, and not others. For example, in the unlikely event that a healthcare provider were to deny services to someone based solely on his or her political affiliation, the Department would not be able to address such denial of care under Section 1557. Under this final rule, OCR is committed to no less than full enforcement of the prohibitions on discrimination that Congress included in Section 1557, without exceeding the statutory text. Unlike other bases of discrimination, the categories of gender identity and sexual orientation (as well as political affiliation) are not set forth in those statutes.[92]

Comment: Some insurers stated that they already took steps to come into compliance with prohibitions related to gender identity and termination of pregnancy in their plans under the 2016 Rule, and that they will incur burdens to change their plans. Other commenters stated that the 2016 Rule created burdens that, if unrelieved, would encumber their day-to-day affairs and limit their ability to provide healthcare services for their patients or healthcare coverage for their employees.

Response: As discussed in the Regulatory Impact Analysis below, this rule removes certain requirements, without requiring providers to incur new burdens related to those requirements. Whether or not the Department revises the regulation, the past expenditures incurred by insurers and other commenters to come into

[85] In the 2015 NPRM, the earliest record of the Department's new understanding of sex discrimination cited was an OCR letter dated 12 July 2012. 80 FR 54176.

[86] U.S. Department of Health and Human Services, ''HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination'' (2018), *https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html*; ''OCR works with DOJ to ensure Federally funded medical center provides communication services for deaf and hard of hearing patients'' (2018), *https://www.hhs.gov/about/news/2017/12/20/ocr-works-with-doj-to-ensure-Federally-funded-medical-center-provides-communication-services-for-deaf-and-hard-of-hearing-patients.html*; ''HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar'' (2019), *https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html* (requiring chaperone policies where patients can request a chaperone of the same sex, meaning biological sex, during sensitive physical examinations).

[87] *See* 81 FR 31384, 31387, 31406, 31408–09, 31428, 31429, 31435, 31436, 31467, 31470, 31471, 31472.

[88] *See, e.g., Nat'l Collegiate Athletic Ass'n* v. *Smith,* 525 U.S. 459, 464 (1999) (Title IX claim based on allegation ''that the NCAA discriminates on the basis of sex by granting more waivers from eligibility restrictions to male than female postgraduate student-athletes''); *Cannon* v. *Univ. of Chicago,* 441 U.S. 677, 680 (1979) (Title IX claim based on allegation that plaintiff's ''applications for admission to medical school were denied . . . because she is a woman'').

[89] 858 F.3d 1034, 1051 (7th Cir. 2017).

[90] *Equal Emp't Opportunity Comm'n* v. *R.G. & G.R. Harris Funeral Homes,* 884 F.3d 560 (6th Cir. 2018), 575. *See also* certain passages during oral argument on appeal at the U.S. Supreme Court, *e.g.:* ''here, Ms. Stephens, was being treated differently because of her sex. . . .Yes, if she had not been a—if she had not been assigned at birth the sex that she was assigned at birth, she would have been treated differently'' (Kagan, J., Transcript of Oral Argument at 41, *R.G. & G.R. Harris Funeral Homes, Inc.* v. *E.E.O.C.,* 139 S. Ct. 1599 (2019) (No. 18–107), *https://www.supremecourt.gov/oral_arguments/argument_transcripts/2019/18-107_4gcj.pdf*); *See also* Mr. Cole, counsel for respondents at oral argument, *Id.* at 4–5: ''None of [our] arguments ask this Court to redefine or, in Judge Posner's words, update sex. They assume, arguendo, that sex means at a minimum sex assigned at birth based on visible anatomy or biological sex.'' *Id.* at 28: ''[O]ur argument rests on text meaning, at a minimum, sex assigned at birth or biological sex, and everybody agrees— . . . [we are] asking you to interpret the statute as it is written and as everybody agrees it applies to sex assigned at birth.''

[91] *Harris* 884 F.3d at 575. It is true that the *Harris* court referred to Stephens with female pronouns throughout the rest of its ruling, but it appeared to do so based on its concept of gender identity, not of sex. Had the *Harris* court employed female pronouns in the quoted passage, it would have visibly undermined the basis of its Title IX analysis.

[92] The Department responds below to comments with respect to sexual orientation and gender identity specifically.

compliance with the 2016 Rule are ''sunk costs'' that cannot be recovered. With the finalization of this rule, insurers have the option—as they have had since December 31, 2016—of providing such coverage or not. Presumably some insurers will maintain coverage consistent with the 2016 Rule's requirements and some will not. The final rule also does not alter the status quo, and thus does not impose burdens in this regard, because, independent of the finalization of this rule, the 2016 Rule's provisions on gender identity and termination of pregnancy have been vacated by a final order and decision of a federal court.

Comment: Commenters expressed concern that the proposed rule would result in lack of information about gender transition-related services or termination of pregnancy, leaving patients without information about different surgical procedures and prescription options, and in danger of harm. Some argued that women, members of the LGBT community, people with disabilities, people with LEP, and racial minorities need additional specific protections because they will face greater burdens accessing healthcare due to ''intersectionality'' theories. Others, however, said it was not appropriate or reflective of current civil rights law to analogize sexual orientation or gender identity to race or other protected categories.

Some commenters argued that the 2016 Rule had decreased LGBT patients' fears of discrimination, that the proposed rule will lead to discrimination against them (including by States, providers, marketplaces, agents, and brokers), and that this will increase their health disparities, mainly via poorer quality of care, lack of access to willing providers especially in rural areas, postponed care including preventive care, increased healthcare and insurance costs, and impediments to HIV patients' access to medication. Commenters said the rule would undermine the President's goal of eradicating HIV. Commenters relied on national and statewide reports and studies highlighting harm faced by LGBT people due to inadequate healthcare, including an increase in substance abuse; worsening psychiatric disorders; untreated depression leading to suicide; and higher rates of AIDS, HIV and other STIs, cancer, and behavioral health issues. These commenters also argued the proposed rule would permit LGBT people to suffer discrimination and hence stigmatic injury, which could also deter them from disclosing their LGBT status to their physicians and seeking proper care. Commenters alleged high rates of mental conditions (*e.g.,* depression),[93] behavioral conditions (*e.g.,* substance use disorder),[94] developmental conditions (*e.g.,* autism, learning disabilities), and physical conditions (*e.g.,* HIV, heart disease) among the LGBT population. Commenters also expressed concerns about lack of communication and consent between providers and patients, and alleged that the risk of discrimination is heightened in vulnerable populations, including persons with developmental disabilities, persons with LEP, elderly patients with diminished capacity, and those who rely on surrogates or guardians for making medical decisions on their behalf. Others stated that OCR does not have authority to protect all forms of discrimination that may negatively impact people, but that it must act within its statutory authority.

Response: The Department is concerned with the health of all Americans. It acts to the fullest extent of its statutory authority in its efforts to improve the health and wellbeing of all. Under its civil rights authority, it enforces Federal laws requiring nondiscrimination on specified grounds, which in the case of Section 1557 are race, color, national origin, sex, age, and disability. When OCR receives a claim alleging multiple grounds of prohibited discrimination, the Department analyzes the elements of each claim according to the statute applicable to that ground.

Consistent with the text of the ACA and, in this case, the underlying civil rights statutes incorporated into the ACA, the Department seeks, wherever possible, to remove barriers to healthcare. Those barriers include regulations that impede providers' ability to offer healthcare by interfering with their conscientious medical judgments or imposing unnecessary cost burdens on them. By removing such provisions from the 2016 Rule, the Department hopes to increase the availability of healthcare to all populations.

As a matter of policy, the Department recognizes and works to address barriers to treatment caused by stigma about depression, anxiety, substance use disorder, and other comorbid mental and behavioral health conditions.[95] With regard to HIV, this final rule does not alter or affect the longstanding Federal protections against discrimination for individuals with HIV: Section 504, and hence also this final rule, prohibits discrimination on the basis that an individual has HIV.[96] OCR continues to pursue major enforcement actions under its authorities[97] and to provide the public guidance[98] to protect the rights of persons with HIV or AIDS. HHS remains committed to ensuring that those living with HIV or AIDS receive full protection under the law, in accordance with full implementation of the President's National HIV/AIDS Strategy.[99]

Regarding commenters' worries about informed consent, this final rule does not repeal any informed consent requirements. Besides many relevant State laws,[100] CMS regulations also

[93] Commenters cited Remafedi G, French S, Story M, et al., The Relationship Between Suicide Risk and Sexual Orientation: Results of a Population-Based Study. Am J Public Health. 1998;88(1):57–60; McLaughlin KA, Hatzenbuehler ML, Keyes KM. Responses to Discrimination and Psychiatric Disorders Among Black, Hispanic, Female, and Lesbian, Gay, and Bisexual Individuals. Am J Public Health. 2010;100(8):1477–84.

[94] Commenters cited Banez GE, Purcell DW, Stall R, et al., Sexual Risk, Substance Use, and Psychological Distress in HIV Positive Gay and Bisexual Men Who Also Inject Drugs. AIDS. 2005;19 (suppl. 1):49–55.

[95] *See, e.g.,* Pain Management Task Force, ''Pain Management Best Practices, Fact Sheet on Stigma'' (Aug. 13, 2019), *https://www.hhs.gov/sites/default/files/pmtf-fact-sheet-stigma_508-2019-08-13.pdf* (''Compassionate, empathetic care centered on a patient-clinician relationship is necessary to counter the suffering of patients . . . . Patients with painful conditions and comorbidities, such as anxiety, depression or substance use disorder (SUD) face additional barriers to treatment because of stigma.'').

[96] *See* 29 U.S.C. 705(20) (incorporating ADA definition of disability into Section 504); 42 U.S.C. 12102(1)–(3); 28 CFR 35.108(d)(2)(iii)(J).

[97] *See, e.g.,* ''HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination'' (Oct. 30, 2019), *https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html*; ''HHS Office for Civil Rights Enters Into Agreement with Oklahoma Nursing Home to Protect Patients with HIV/AIDS from Discrimination'' (Sept. 8, 2017), *https://www.hhs.gov/about/news/2017/09/08/hhs-office-for-civil-rights-enters-into-agreement-with-oklahoma-nursing-home.html.*

[98] *See* OCR, ''Know the Rights That Protect Individuals with HIV and AIDS,'' *https://www.hhs.gov/sites/default/files/ocr/civilrights/resources/factsheets/hivaids.pdf*; OCR, ''Protecting the Civil Rights and Health Information Privacy Rights of People Living with HIV/AIDS,'' *https://www.hhs.gov/civil-rights/for-individuals/special-topics/hiv/index.html.*

[99] *See* ''Ending the HIV Epidemic: A Plan for America,'' *https://www.hiv.gov/Federal-response/ending-the-hiv-epidemic/overview.*

[100] *See, e.g.,* Alaska Stat. § 09.55.556(a); Ark. Code Ann. § 16–114–206; Del. Code Ann. tit. 18, § 6852; Ga. Code Ann. § 31–9–6.1; Haw. Rev. Stat. § 671–3; Idaho Code Ann. § 39–4304; Ind. Code § 16–36–1.5–7; Ky. Rev. Stat. Ann. § 304.40–320; La. Rev. Stat. Ann. § 40:1299.40; Me. Rev. Stat. Ann. tit. 24 § 2905; Neb. Rev. Stat. § 44–2816; Nev. Rev. Stat. § 449.710; N.Y. Pub. Health Law § 2805–d; N.C. Gen. Stat. § 90–21.13; Or. Rev. Stat. § 677.097; 40 Pa. Cons. Stat. § 1303.504; Tenn. Code Ann. § 29–26–118; Tex. Rev. Civ. Stat. Ann. art. 4590i, § 6.02;

Continued

require, as a condition of participation in Medicare, that patients (or their legal surrogate) have the right to make informed decisions, the right to surgical informed consent policies,[101] and the right to properly executed informed consent forms.[102] Most States' malpractice laws address negligent failure to communicate risks and benefits of medical treatment options. Basic elements of informed consent with respect to participation in a clinical trial, for example, include: (1) Providing information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate.[103]

The Department knows of no data showing that the proper enforcement of Federal nondiscrimination law according to statutory text will disproportionately burden individuals on the basis of sexual orientation and/or gender identity. Because the 2016 Rule explicitly declined to make sexual orientation a protected category, and because the Rule's gender identity provision has been legally inoperative since December 31, 2016, to the extent that LGBT individuals suffer future harms, it cannot be attributed to the Department's finalizing this rule, as opposed to other causes.

Comment: Commenters raised concerns that, without the 2016 Rule's provisions, certain insurers, such as those offering short-term limited duration insurance plans, would not offer coverage for conditions that affect only women, such as uterine cancer. Some commenters stated that the underlying Title IX regulatory provisions are insufficient by themselves to address access to insurance coverage of procedures provided to a single sex in healthcare. Some commenters stated that, without the 2016 Rule, women would not be able to afford insurance for medical and hospital care.

Response: The Department is strongly committed to promoting women's health. The Department enforces or implements ACA provisions that protect patient access to obstetrical and gynecological care.[104] The Department also enforces other provisions, both within and outside the ACA, that, for example, provide for maternity and newborn care as essential health benefits,[105] require coverage of women's preventive health services,[106] establish (as a matter of statute) the HHS Office of Women's Health and the Pregnancy Assistance Fund,[107] and promote young women's breast health awareness.[108]

The Department's commitment to women's health also includes vigorous enforcement of Section 1557's prohibition on sex-based discrimination. Under HHS's Title IX regulations, which OCR will use for enforcing Section 1557, covered entities must provide medical insurance benefits, services, policies, and plans without discrimination on the basis of sex. This does not preclude a covered entity's providing a covered benefit or service that is used uniquely by individuals of one sex or the other, such as uterine cancer treatments. However, any plan that includes full-coverage health insurance or services must encompass gynecological care.[109] As discussed in the relevant section below, the Department is bound by applicable law in determining the extent to which Section 1557 covers short-term limited duration insurance.

Comment: Some commenters said that the Department was wrong to claim in the 2019 NPRM that State and local entities are better equipped to address issues of gender dysphoria or sexual orientation, because they say that fifty percent of the LGBT population lives in States without laws prohibiting insurance companies from discriminating based on LGBT status. Others said that, because States like New York explicitly protect persons who identify as LGBT, the new rule will cause confusion for providers and patients about people's rights under Federal and State law. Some commenters suggested that including gender identity and sexual orientation in the Final Rule would reduce ambiguity in its interpretation and implementation.

Response: States and localities do indeed manifest a range of different views on what specific protections should be accorded to the categories of sexual orientation and gender identity in civil rights law, including healthcare civil rights law. That is precisely why, under our Constitutional Federal system, it is appropriate not to preempt States' diverse views on these topics without a clear mandate from Congress to do so. This final rule complies with the federalism-related portions of Executive Orders 12866 and 13132 by avoiding undue interference with State, local, or tribal governments in the exercise of their governmental functions. It leaves them free to balance the multiple competing considerations involved in the contentious and fraught set of questions surrounding gender dysphoria and gender identity, and to adopt protections on the basis of sexual orientation or gender identity to the extent that they see fit (so long as they comply with Federal law).[110]

The Department notes, furthermore, that under the guaranteed issuance and renewal provisions of the ACA, health insurance issuers that offer health insurance coverage in the individual or group market in a state must accept every employer and every individual in that state that applies for such coverage, and must renew or continue in force such coverage at the option of the plan sponsor or the individual. *See* 42 U.S.C. 300gg–1 (guaranteed issuance), 300gg–2 (guaranteed renewability). Federal law similarly limits the bases on which a health insurance issuer can vary premium rates in the individual or small group market; such bases are limited to type of coverage (individual or family), rating area, age, and tobacco use. 42 U.S.C. 300gg. Thus, commenters' concern that LGBT individuals could be denied coverage if the Section 1557 rule does not include gender identity (or sexual orientation) is misplaced.

Comment: One commenter expressed concern that the proposed rule will have an effect beyond the United States by showing the international community that the United States Federal government does not recognize protections for individuals based on gender identity or sexual orientation in healthcare.

Response: The Department is not primarily responsible for the United States' foreign relations. Moreover, the Department has an obligation to implement the statutes according to the plain language of the text passed by Congress (unless unconstitutional), regardless of international implications.

Comment: Some commenters requested that the Department retain all guidance it had issued under the 2016 Rule. Other commenters stated that components of HHS continue to offer

Utah Code Ann. § 78–14–5; Vt. Stat. Ann. tit. 12, § 1909; Wash. Rev. Code Ann. § 7.70.050; Wis. Stat. Ann. § 448.30.

[101] 42 CFR 482.51(b)(2).

[102] 42 CFR 482.24(c)(4)(B)(v).

[103] 45 CFR 46.116–117 (HHS Office of Human Research Subject regulations).

[104] *See, e.g.,* 42 U.S.C. 300gg–19a(d).

[105] 42 U.S.C. 18022(b)(1)(D).

[106] 42 U.S.C. 300gg–13.

[107] 42 U.S.C. 237a; 42 U.S.C. 18202.

[108] 42 U.S.C. 280m.

[109] *See, e.g.,* 45 CFR 86.39.

[110] Ambiguity in the 2016 Rule's provisions regarding gender identity is addressed below. The Department further notes that sexual orientation was explicitly rejected as a protected category under the 2016 Rule. 81 FR 31390 (''OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination.'').

inconsistent guidance about the legal interpretation of the 2016 Rule.

Response: The Department stated in the preamble to the proposed rule that guidance under the 2016 Rule that conflicted with the proposed rule was suspended until further notice.[111] All such guidance is hereby withdrawn, effective upon publication of this final rule, and is in the process of being removed from the Department's website. Pursuant to Executive Order 13891, the Administration is also undertaking efforts to comprehensively review guidance documents ''to ensure that Americans are subject to only those binding rules imposed through duly enacted statutes or through regulations lawfully promulgated under them, and that Americans have fair notice of their obligations,'' [112] which also requires removal of inconsistent guidance from departmental websites.

ii. Gender Identity, Including Single-Sex Services Under § 92.206 of the 2016 Rule

The Department proposed to repeal the 2016 Rule's definition of ''on the basis of sex'' to encompass gender identity, which the 2016 Rule defined as ''an individual's internal sense of gender, which may be male, female, neither, or a combination of male and female, and which may be different from an individual's sex assigned at birth.'' [113] The Department also proposed to repeal § 92.206 of the 2016 Rule, which has three elements. First, the section required covered entities not to discriminate ''on the basis of sex'' (as defined in § 92.4 of the 2016 Rule) in providing access to health programs and activities. Second, it required them to ''treat individuals consistent with their gender identity.'' Third, it prohibited covered entities from ''deny[ing] or limit[ing] health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.'' [114]

Comment: Commenters offered varying views on the state of gender-identity nondiscrimination protections under current Federal law. Some commenters alleged that it is settled law that Section 1557 prohibits gender identity discrimination. Others stated that, in other Federal court decisions on Title VII and Title IX, the text of the Title IX statute and regulation are held to be ''at least susceptible to'' the interpretation that it prohibits anti-transgender bias.[115]

Other commenters disagreed, stating that the courts are not unanimous on the question and pointed to legal precedent saying that gender identity is not encompassed by sex discrimination under Federal civil rights statutes. Commenters stated that the 2016 Rule had departed from existing civil rights law by creating new prohibited conduct unsupported by the text of the statutes. Commenters stated that Title IX has been interpreted by the courts for decades to apply to biological women.[116] Other commenters stated that the fact that the Supreme Court has agreed to consider the legality of the general theory proposed in the 2016 Rule demonstrates it is a novel and contested legal issue.[117] Other commenters stated Congress clearly intended ''sex discrimination'' to be defined with reference to biological classification as male or female, and that is the only understanding that is reasonably supported by the text, history, or structure of the relevant law. Some criticized the 2016 Rule's reliance on the EEOC's opinion in *Macy* v. *Holder,* 2012 EEOPUB LEXIS 1181, 112 FEOR (LRP) 257 (2012) (Title VII).

Response: The Department disagrees with commenters who contend that Section 1557 or Title IX encompass gender identity discrimination within their prohibition on sex discrimination. Some of the cases referenced by such commenters were decided under the Equal Protection Clause of the Constitution,[118] under which courts have applied intermediate levels of scrutiny, permitting governments to adopt ''discriminatory means'' on the basis of sex only insofar as those means are substantially related to the achievement of important governmental objectives and are not ''used to create or perpetuate the legal, social, and economic inferiority of women.'' [119] The Department does not agree that the Equal Protection cases cited by these commenters require Title IX to include a prohibition on gender identity discrimination. Unlike the Equal Protection Clause, Title VII and Title IX broadly forbid covered entities from discriminating on the basis of sex, with limited exemptions expressly provided in statute. Title VII exempts covered entities from the prohibition on sex discrimination where sex is a ''bona fide occupational qualification.'' [120] Title IX exempts covered entities from the prohibition on sex discrimination for admissions to historically single-sex colleges, school father-son and mother-daughter activities (so long as reasonably comparable activities are provided for students of both sexes), beauty pageants, certain boys' or girls' conferences, single-sex voluntary youth service organizations, fraternities and sororities, and military training programs.[121]

The text of Title IX also demonstrates that it is not susceptible to an interpretation under which it would prohibit gender identity discrimination. The statute permits covered entities to maintain ''separate living facilities for the different sexes,'' and it expressly presents this, not as an exemption from the nondiscrimination requirements, but as an ''interpretation'' of them: Separate-sex living facilities are not, as such, discriminatory.[122] The Department's Title IX regulations likewise permit separate-sex housing, intimate facilities, physical education and human sexuality courses, and contact sports.[123] The statute presents these distinctions as being fully compatible with its nondiscrimination requirement. Nondiscrimination requires that separate-sex facilities and programs be (where relevant) comparable to one another, but the existence of separate-sex facilities and programs is not, as such, discriminatory under Title IX. Consequently, the Department does not believe an interpretation of Title IX that would prohibit gender identity discrimination is compatible with the statute's overall approach towards what

[111] 84 FR 27872 (''Upon publication of this notice of proposed rulemaking, the Department will, as a matter of enforcement discretion, suspend all subregulatory guidance issued before this proposed rule that interprets or implements Section 1557 (including FAQs, letters, and the preamble to [the 2016 Rule]) that is inconsistent with any provision in this proposed rule (including the preamble) or with the requirements of the underlying civil rights statutes cross-referenced by Section 1557 or their implementing regulations.'').

[112] ''Promoting the Rule of Law Through Improved Agency Guidance Documents,'' Exec. Order No. 13891, 84 FR 55235 (Oct. 9, 2019).

[113] 81 FR 31387–88, 31467.

[114] 81 FR 31471.

[115] *See G.G. ex rel. Grimm* v. *Gloucester Cty. Sch. Bd.,* 822 F.3d 709 (4th Cir. 2016), *recalling mandate & issuing stay,* 136 S. Ct. 2442 (2016).

[116] *See, e.g., N. Haven Bd. of Ed.* v. *Bell,* 456 U.S. 512, 517–20, (1982); *Cannon* v. *Univ. of Chi.,* 441 U.S. 677, 680 (1979).

[117] Order, *R.G. & G.R. Harris Funeral Homes* v. *EEOC,* No. 18–107 (U.S. Apr. 22, 2019) (granting certiorari).

[118] *See Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011).

[119] *United States* v. *Virginia,* 518 U.S. 515, 516 (1996).

[120] 42 U.S.C. 2000e–2(e)(1).

[121] 20 U.S.C. 1681.

[122] 20 U.S.C. 1686.

[123] 45 CFR 86.32–34, § 86.41.

does and does not constitute sex discrimination.

Case law under both Title VII and Title IX has likewise recognized that these statutes do not forbid reasonable and relevant distinctions between the sexes.[124] As the United States Solicitor General recently put it, ''Many commonplace practices that distinguish between the sexes do not violate [Title VII] because they account for real physiological differences between the sexes without treating either sex less favorably.'' [125] No express statutory carve-out is required in order for employers under Title VII to be permitted to impose a sex-specific dress code that burdens men and women equally, nor in order for educational institutions under Title IX to be permitted to require men and women to shower separately from each other. And as compared to the fields of employment and of education, the field of healthcare necessarily may contain many more ''commonplace practices that distinguish between the sexes . . . [by] account[ing] for real physiological differences between the sexes without treating either sex less favorably.'' As discussed in greater detail later in the subsection of this preamble on gender identity, reasonable distinctions between the sexes may be called for in numerous areas within the Department's expertise, including shared hospital rooms,[126] sex-specific protections for patients' modesty,[127] specialized medical practices related to gynecology,[128] and medical treatments or recommendations relying on sex-based generalizations,[129] and other research situations.[130] The biological differences between men and women are not irrelevant to employment law and education, and they are in many ways even more relevant in the health setting.

In general, a covered entity is permitted to make distinctions on the basis of sex that are ''not marked by misconception and prejudice, nor . . . show disrespect for either class.'' [131] In many cases, removing or weakening such reasonable sex-based distinctions could undermine the equality of the sexes by disproportionately harming women.[132] As discussed further below, case law is still developing as to whether covered entities' refusal to draw these distinctions could in some cases violate personal privacy interests and so create a hostile environment under Title IX.[133] ''[N]eutral terms can mask discrimination that is unlawful,'' while ''gender specific terms can mark a permissible distinction.'' [134] Where the ''[p]hysical differences between men and women'' are relevant, sex-neutral policies will in some cases ''undoubtedly require alterations'' to make them sex-specific, in order ''to afford members of each sex privacy from the other sex in living arrangements.'' [135]

Comment: Commenters stated that *Price Waterhouse* v. *Hopkins,* 490 U.S. 228 (1989), and *Oncale* v. *Sundowner Offshore Oil Services, Inc.,* 523 U.S. 75 (1998), fully support or even require the 2016 Rule's gender identity provisions or their equivalent. Commenters asked the Department to address specific court cases that they stated were contrary to the Department's view, such as *Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518 (3d Cir. 2018), *Whitaker* v. *Kenosha Unified Sch. Dist. No. 1 Bd. of Educ.,* 858 F.3d 1034 (7th Cir. 2017), and *Glenn* v. *Brumby,* 663 F.3d 1312 (11th Cir. 2011).

Response: For most of the history of Title IX case law, the ''commonplace practices that . . . account for real physiological differences between the sexes without treating either sex less favorably'' [136] were uncontroversial and not considered discriminatory. In the past five years, two circuit courts have begun to question this long-standing precedent in proceedings arising from motions for preliminary injunctions, although no circuit court has yet done so in a final ruling.[137]

These courts (and some district courts) draw on the Supreme Court's reasoning in *Price Waterhouse* in order to assert that otherwise permissible distinctions on the basis of sex must be applied (if at all) on the basis of an individual's subjective gender identity. But the novel legal theory advanced by these courts represents a serious misreading of *Price Waterhouse* and of Title IX, a reading that has been disputed by the decisions of other courts, including *Franciscan Alliance.*

Price Waterhouse is a Title VII case and establishes that, '' '[i]n forbidding employers to discriminate against individuals because of their sex, Congress intended to strike at the entire spectrum of disparate treatment of men and women resulting from sex stereotypes.' '' [138]

When courts have read *Price Waterhouse* as determining that ''on the basis of sex'' encompasses gender identity, they have done so on the ground that discrimination on the basis of gender identity is, as such, a form of sex stereotyping. But *Price Waterhouse* should be read in light of the Supreme Court definition of a ''stereotype'' about sex ''as a frame of mind resulting from

[124] *See Wittmer* v. *Phillips 66 Co.,* 915 F.3d 328, 334 (5th Cir. 2019) (Ho, J., concurring); *Jespersen* v. *Harrah's Operating Co.,* 444 F.3d 1104, 1109–10 (9th Cir. 2006) (en banc) (collecting cases).

[125] Brief for EEOC, *R.G. & G.R. Harris Funeral Homes* v. *EEOC,* No. 18–107 (U.S. filed Aug. 16, 2019), at 36.

[126] *See Cypress* v. *Newport News General and Nonsectarian Hospital Association,* 375 F.2d 648, 658 (4th Cir. 1967) (''Our holding is simply that race cannot be a factor in the admission, assignment, classification, or treatment of patients in an institution like this, which is state-supported and receives federal funds. Room assignments may be made with due regard to sex, age, type of illness, or other relevant factors, but racial distinctions are impermissible, since the law forbids the treatment of individuals differently or separately because of their race, color, or national origin.''); *cf.* similar statutory requirements at 10 U.S.C. 4319 (Army), 10 U.S.C. 6931 (Navy), and 10 U.S.C. * 9319 (Air Force) (requiring separation of sleeping and latrine areas for ''male'' and ''female'' recruits); 10 U.S.C. 4320 (Army), 10 U.S.C. 6932 (Navy), and 10 U.S.C. 9320 (Air Force) (limiting after-hours access by drill sergeants and training personnel to persons of the ''same sex as the recruits'').

[127] *See, e.g.,* OCR Voluntary Resolution Agreement with Michigan State University, *https://cms-drupal-hhs-prod.cloud.hhs.gov/sites/default/files/vra-between-msu-and-ocr.pdf,* at IV.D.1.d.iii, IV.D.1.d.v.

[128] *See, e.g.,* Women's Preventive Services Guidelines, Health Resources and Services Administration, Dec. 17, 2019 (HRSA) *https://www.hrsa.gov/womens-guidelines-2019.*

[129] *See* the Department's Office of Women's Health, *https://www.womenshealth.gov/.*

[130] *See* NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* (2017), *https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf*; NIH, Office of Research on Women's Health, ''Sex & Gender,'' *https://orwh.od.nih.gov/.*

[131] *See Tuan Anh Nguyen* v. *INS,* 533 U.S. 73.

[132] *See* Brief for EEOC, *Harris Funeral Homes,* at 37–38 (citing cases).

[133] *See, e.g., Doe* v. *Luzerne Cty.,* 660 F.3d 169, 176–77 (3d Cir. 2011) (recognizing that an individual has ''a constitutionally protected privacy interest in his or her partially clothed body'' and that this ''reasonable expectation of privacy'' exists ''particularly while in the presence of members of the opposite sex''); *Brannum* v. *Overton Cty. Sch. Bd.,* 516 F.3d 489, 494 (6th Cir. 2008) (''the constitutional right to privacy . . . includes the right to shield one's body from exposure to viewing by the opposite sex''); *Fortner* v. *Thomas,* 983 F.2d 1024, 1030 (11th Cir. 1993) (''[M]ost people have a special sense of privacy in their genitals, and involuntary exposure of them in the presence of people of the other sex may be especially demeaning or humiliating.''). *But see Parents for Privacy* v. *Barr,* No. 18–35708, (9th Cir. Feb. 12, 2020) (no title IX or constitutional privacy violation for school policy allowing student to use bathroom and locker rooms consistent with their gender identity).

[134] *Tuan Anh Nguyen* v. *INS,* 533 U.S. 64.

[135] *United States* v. *Virginia,* 518 U.S. 515, 550 n.19 (1996) (emphasis added) (brackets and citation omitted).

[136] Brief for EEOC, *Harris Funeral Homes,* at 36.

[137] *Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1039 (7th Cir. 2017); *Dodds* v. *United States Dep't of Educ.,* 845 F.3d 217 (6th Cir. 2016). The ruling in a third related case, *G.G.* v. *Gloucester Co. Sch. Bd.,* 822 F.3d 709 (4th Cir. 2016), was based on *Auer* deference to Department of Education subregulatory guidance and has since been vacated after that guidance was withdrawn.

[138] *Price Waterhouse* v. *Hopkins,* 490 U.S. 228, 251 (1989), quoting *Los Angeles Dept. of Water & Power* v. *Manhart,* 435 U. S. 702, 707, n. 13 (1978).

irrational or uncritical analysis.'' [139] Wherever ''stereotyping play[s] a motivating role in an employment decision,'' according to *Price Waterhouse,* the employer has demonstrated an ''impermissible motive,'' for stereotypes should not even ''play a part in the decisionmaking process.'' [140]

The Department believes that, unlike stereotypes, reasonable distinctions on the basis of sex, as the biological binary of male and female, may, and often must, ''play a part in the decisionmaking process''—especially in the field of health services. A covered entity such as a healthcare provider is not impermissibly stereotyping biological males (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as ''him''; limits access to lactation rooms and gynecological practices to female users and patients; or lists a male's sex as ''male'' on medical forms. Similarly, a covered health care entity is not impermissibly stereotyping biological females (notwithstanding their internal sense of gender) on the basis of sex if it uses pronouns such as ''her''; warns females that heart-attack symptoms are likely to be quite different than those a man may experience; advises women that certain medications tend to affect women differently than men; or lists a female's sex as ''female'' on medical forms. Finally, it is not stereotyping for covered entities to have bathrooms or changing rooms designated by reference to sex, or to group patients in shared hospital rooms by sex.[141] Such practices and actions are not rooted in stereotypes, but in real biological or physiological differences between the sexes. Moreover, none of these examples disadvantages one sex over another, and in fact the failure to take sex into account may in some cases have a disadvantageous effect.

As the Supreme Court has noted, ''to fail to acknowledge even our most basic biological differences . . . risks making the guarantee of equal protection superficial, and so disserving it. Mechanistic classification of all our differences as stereotypes would operate to obscure those misconceptions and prejudices that are real.'' [142] ''[T]here is nothing irrational or improper in the recognition'' of the social and other consequences of real physiological differences between the sexes; ''[t]his is not a stereotype.'' [143] Reasonable distinctions ''may be based on real differences between the sexes . . . so long as the distinctions are not based on stereotyped or generalized perceptions of differences.'' [144] ''Prohibition of harassment on the basis of sex requires neither asexuality nor androgyny.'' [145]

Justice Ginsburg's majority opinion in *U.S.* v. *Virginia* sharply distinguished sex from other protected classes in this regard: ''Supposed 'inherent differences' are no longer accepted as a ground for race or national origin classifications. Physical differences between men and women, however, are enduring: '[T]he two sexes are not fungible; a community made up exclusively of one [sex] is different from a community composed of both.' . . . 'Inherent differences' between men and women, we have come to appreciate, remain cause for celebration.'' [146] This recognition of physical (*i.e.,* biological) differences between men and women is not stereotyping and in some cases will ''undoubtedly require alterations'' to accommodated sex-specific differences.[147]

The lower court decisions referenced by commenters held that a covered entity which required transgender individuals to abide by otherwise permissible distinctions on the basis of sex, such as separate-sex bathrooms, would be impermissibly ''imposing its stereotypical notions of how sexual organs and gender identity ought to align.'' [148] A few lower courts have relied on these holdings in interpreting Section 1557 to require covered entities to override these reasonable distinctions based on sex, in deference to an individual's gender identity.[149] The notion that such distinctions on the basis of sex amount, as such, to impermissible stereotyping, would be lethal to countless reasonable and fully permissible healthcare practices, some of which have been identified above. No court has gone so far: These lower courts have questioned such distinctions only insofar as these distinctions come into conflict with an individual's stated gender identity. But *Price Waterhouse* offers no basis for this regime of individualized exceptions to otherwise reasonable distinctions. If it is impermissible stereotyping of a female employee to demand that she not ''behave aggressively,'' then *Price Waterhouse* (to the extent that it applies) requires companies to stop holding *all* female employees to such a stereotyped standard—not merely to grant exceptions for the occasional female employee who objects to that standard.[150] Similarly, if it is impermissible stereotyping to assume that ''sexual organs . . . ought to align'' with the sex listed on one's hospital bracelet, then *Price Waterhouse* (to the extent that it applies) would invalidate the existence of *all* sex markers on hospital bracelets, not merely of those to which a transgender individual has objected. Where a covered entity has not stereotyped but has only drawn a reasonable distinction, *Price Waterhouse* is irrelevant.

Distinctions based on real differences between men and women do not turn into discrimination merely because an individual objects to those distinctions. Title IX does not require covered entities to eliminate reasonable distinctions on the basis of sex whenever an individual identifies with the other sex, or with no sex at all, or with some combination of the two sexes

[139] *Tuan Anh Nguyen* v. *I.N.S.,* 533 U.S. 53, 68 (2001).

[140] *Price Waterhouse,* 490 U.S. 252–53, 254–55. The Civil Rights Act of 1991 amends the *Price Waterhouse* standard to say that ''an unlawful employment practice is established when the complaining party demonstrates that . . . sex . . . was a motivating factor for any employment practice, even though other factors also motivated the practice,'' but the employer may rebut this claim if he or she ''demonstrates that [the employer] would have taken the same action in the absence of the impermissible motivating factor.'' 42 U.S.C. 2000e–2(m), § 2000e–5(g)(2)(B).

[141] *See* 29 CFR 1910.141(c) (OSHA regulation requiring ''toilet rooms separate for each sex'').

[142] *Tuan Anh Nguyen,* 533 U.S. at 73. In *Sessions* v. *Morales-Santana,* 137 S. Ct. 1678 (2017), the Supreme Court struck down, on intermediate-scrutiny grounds, a statute that granted U.S. citizenship to children born abroad of unwed parents if the child's mother had been a U.S. citizen for one year before the birth, but required five years in the case of a U.S. citizen father. However, the Court did not reject the *Nguyen* analysis recognizing that sex distinctions are real, and that not all such distinctions are based on unlawful stereotypes.

[143] *Id.* at 68.

[144] *Faulkner* v. *Jones,* 10 F.3d 226, 232 (4th Cir. 1993).

[145] *Oncale* v. *Sundowner Offshore Oil Services, Inc.,* 523 U.S. 75, 81 (1998).

[146] *United States* v. *Virginia,* 518 U.S. 515, 533 (1996) (internal citations omitted).

[147] *Id.* at 550 n.19.

[148] *Equal Employment Opportunity Comm'n* v. *R.G. &. G.R. Harris Funeral Homes, Inc.,* 884 F.3d 560, 576 (6th Cir. 2018). *See also Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1051 (7th Cir. 2017) (''the School District treats transgender students like Ash, who fail to conform to the sex-based stereotypes associated with their assigned sex at birth, differently. These students are disciplined under the School District's bathroom policy if they choose to use a bathroom that conforms to their gender identity.''); *Glenn* v. *Brumby,* 663 F.3d 1312, 1316 (11th Cir. 2011) (''A person is defined as transgender precisely because of the perception that his or her behavior transgresses gender stereotypes.'').

[149] *See Rumble* v. *Fairview Health Servs.,* No. 14–cv–037 (SRN/FLN), 2017 WL 401940 (D. Minn. Jan. 30, 2017); *Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017)

[150] *See Price Waterhouse,* 490 U.S. at 235, 250–51.

(as under the 2016 Rule).[151] Rather, Title IX prohibits subjecting a person to less favorable treatment because of his or her sex. Thus, if a person claims to have been discriminated against on the basis of his or her sex, that claim is neither weakened nor strengthened by any allegations about his or her ''internal sense of gender.'' Numerous lower courts have held that, like any other man or woman, a transgender individual may sue under Title VII if he or she is harassed, assaulted, terminated, or otherwise discriminated against because of his or her sex.[152] Under Title IX, as under Title VII, ''[t]ranssexuals are not genderless, they are either male or female and are thus protected under Title VII to the extent that they are discriminated against on the basis of sex.'' [153] The Department will vigorously enforce Section 1557's prohibition on sex-based discrimination, but that prohibition cannot be construed as a prohibition on reasonable sex-based distinctions in the health field.

Comment: Commenters offered a variety of views on the role that a patient's sex and/or gender identity ought to play in medical decision-making.

Many commenters spoke of the importance of sex-reassignment surgeries and cited studies that they said show the value of these surgeries in alleviating gender dysphoria. Others cited different studies that they said show the opposite. Some clinicians expressed concerns about consent and medical appropriateness of pre-pubertal sex reassignment with lifelong physical and mental implications (including permanent sterility) when children and adolescents lack the requisite social, emotional, and intellectual maturity, or life experiences necessary for true consent. Commenters also were concerned about coercive, peer, adult, and ideological pressures on children and adolescents to seek cross-sex hormonal treatment, sex reassignment surgery, or other similar services. Some commenters, including parties to lawsuits against the Department on the ground that the 2016 Rule would require gender transition treatments and therapies for children, criticized the 2016 Rule for containing no age limitation. Commenters stated that the ''gender-affirming'' model is the most controversial form of counseling and, as such, is not used by the Dutch national transgender clinic, which they said is considered the international flagship of gender dysphoria treatment.

Some commenters noted that violations of the 2016 Rule are enforceable by termination of Federal financial assistance and that violations of State law with respect to healthcare may involve civil penalties for negligence or malpractice, etc. In light of this, they stated that the 2016 Rule placed providers in an impossible position, where compliance with one law means noncompliance with another, and either choice results in a steep penalty.

Other commenters said that the 2016 Rule's definition of ''on the basis of sex'' could prohibit the way OB/GYN practices specialize in treating females, and raised the concern that specializing in the treatment of female patients could be deemed prohibited discrimination against biological males who identify as women. Commenters stated that because these services are focused on and tailored to females as a single biological sex, they are able to provide a higher quality of care to those patients. They noted that it has long been a permissible sex-based distinction for OB/GYN doctors to not treat any biological males, and this distinction is recognized under HHS Title IX regulations. Such commenters found the 2016 Rule overbroad and inconsistent with day-to-day affairs in how they practice medicine. But other commenters stated that OB/GYNs are not affected by the transgender requirements under the 2016 Rule and that pre-existing OB/GYN practices are justified by reasonable scientific justifications.

Certain providers advocated for removal of the requirement to ''treat individuals consistent with their gender identity,'' as this provision would violate the conscience rights of healthcare providers, and the ethical and foundational convictions that underlie the entire way they practice medicine. Other commenters said that repeal of this provision leaves no clarity about whether such providers will actually provide treatment for transgender patients, and expressed the concern that affirming treatment consistent with gender identity is necessary for high-value transgender healthcare, as is required for all people in the practice of medicine.

Some commenters noted their concern that the 2016 Rule requires doctors to remove healthy reproductive tissue in sex-reassignment surgeries, even if it may be contrary to the patient's medical interest. For example, if a surgeon performs mastectomies as part of a medically necessary treatment for breast cancer, under the 2016 Rule, he or she could also have been required to perform mastectomies for sex-reassignment purposes when recommended by a psychologist, even if the surgeon believes such treatments are not medically indicated in his or her own professional judgment. Similarly, commentators argued that some doctors might be forced to perform hysterectomies not only against their medical judgment but also outside of their expertise. Other commenters contended that certain procedures are not meaningfully different when performed on a transgender versus non-transgender patient, because the mechanics of the procedures are substantially similar. Although genital reassignment surgery is considered a ''gender transition service,'' clinicians commented that somewhat similar procedures are used for genital reconstruction to repair damaged, diseased, or disfigured genital tissue, or in the treatment of disorders of sexual development.

Commenters also stated that the 2016 Rule would force them to provide services damaging to the health of patients, in conflict with their mission as a healthcare provider, instead of using these medical resources to help patients.[154]

Commenters stated that HHS does not have a compelling interest in requiring the medical provision of, or insurance

[151] *See Johnston* v. *Univ. of Pittsburgh of the Commonwealth Sys. of Higher Educ.,* 97 F. Supp. 3d 657 (W.D. Pa. 2015).

[152] *Barnes* v. *City of Cincinnati,* 401 F.3d 729 (6th Cir. 2005); *Smith* v. *City of Salem,* 378 F.3d 566 (6th Cir. 2004). These cases have been cited, by the 2016 Rule and in some recent court cases, in support of the view that sex discrimination encompasses discrimination on the basis of gender identity. This is a serious misreading pointed out at *Johnston* v. *Univ. of Pittsburgh of Com. Sys. of Higher Educ.,* 97 F. Supp. 3d 657, 675n17 (W.D. Pa. 2015) (''In *Smith* v. *City of Salem,* . . . the court did not conclude that ''transgender'' is a protected class under Title VII, but only that a male or female who is also transgender can assert a sex stereotyping claim under Title VII for adverse employment actions that result from the individual's conformity to their gender identity rather than their biological or birth sex. Indeed, the same year that the 6th Circuit issued its opinion in *Smith,* it affirmed, in an unpublished opinion, a district court decision holding that ''Title VII does not prohibit discrimination based on an individual's status as a transsexual,'' in an employment discrimination case involving a transgender women's use of a men's restroom. *Johnson* v. *Fresh Mark, Inc.,* 98 Fed. App'x. 461, 462 (6th Cir.2004).'').

[153] *Tronetti* v. *TLC HealthNet Lakeshore Hosp.,* No. 03–CV–0375E(SC), 2003 WL 22757935, at *4 (W.D.N.Y. Sept. 26, 2003). *See Rosa* v. *Park West Bank Trust Co.,* 214 F.3d 213, 215–16 (1st Cir. 2000) (discrimination against a cross-dressing man is sex-based discrimination if the entity would have treated a ''similarly situated'' woman differently, *i.e.,* if it treats ''a woman who dresses like a man differently than a man who dresses like a woman'').

[154] Commenters cited specific examples of coercion. *See Minton* v. *Dignity Health,* 2017 WL 7733922 (Cal. Super. Ct. Nov. 2017); *Robinson* v. *Dignity Health,* No. 16–cv–3035 YGR, 2016 WL 7102832 (N.D. Cal. Dec. 6, 2016) (on remand from U.S. Supreme Court).

for, gender transition services or procedures. Other commenters stated that access to such services for transgender patients constitutes a compelling interest. Some commenters challenged the idea that an individual born as one biological sex can in actuality be transformed into a person of the other sex, with or without surgeries or hormone treatments.

Response: The Department recognizes that certain single-sex medical procedures, treatments, or specializations are rooted in the binary and biological meaning of sex for valid scientific and medical reasons. The Department believes the 2016 Rule caused significant confusion and cast doubt as to whether such longstanding specialized practices remained lawful, as indicated, for example, by the fact that commenters had diverging views on how the 2016 Rule impacted OB/GYN practices. The Department declines to interfere in these practices, and repeals a mandate that was, at least, ambiguous and confusing.

The Department appreciates the many comments received on the issue of gender identity, gender dysphoria, and the appropriate care for individuals with gender dysphoria. The Department believes providers should be generally free to use their best medical judgment, consistent with their understanding of medical ethics, in providing healthcare to Americans. The wide variation in these comments confirms that the medical community is divided on many issues related to gender identity, including the value of various ''gender-affirming'' treatments for gender dysphoria (especially for minors), the relative importance of care based on the patient's sex, and the compatibility of gynecological practice with a requirement of nondiscrimination on the basis of gender identity.[155]

The Department is also reluctant to pretermit ongoing medical debate and study about the medical necessity of gender transition treatments. The 2016 Rule assumed that, if a covered entity offers a ''categorical coverage exclusion or limitation for all health services related to gender transition,'' then that entity must be relying on medical judgments that are ''outdated and not based on current standards of care.'' [156] But based on its review of the most recent evidence, the Department concludes that this was an erroneous assertion, and that there is, at a minimum, a lack of scientific and medical consensus to support this assertion, as the comments noted above demonstrate. This lack of scientific and medical consensus—and the lack of high-quality scientific evidence supporting such treatments—is borne out by other evidence. For example, on August 30, 2016, CMS declined to issue a National Coverage Determination (NCD) on sex-reassignment surgery for Medicare beneficiaries with gender dysphoria ''because the clinical evidence is inconclusive.'' [157] CMS determined, ''[b]ased on an extensive assessment of the clinical evidence,'' that ''there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes for Medicare beneficiaries with gender dysphoria and whether patients most likely to benefit from these types of surgical intervention can be identified prospectively.'' [158] Similarly, in a 2018 Department of Defense (DOD) report on the diagnosis of gender dysphoria, which included input from both transgender individuals and medical professionals with experience in the care and treatment of individuals with gender dysphoria, DOD found that there is ''considerable scientific uncertainty and overall lack of high quality scientific evidence demonstrating the extent to which transition-related treatments, such as cross-sex hormone therapy and sex reassignment surgery—interventions which are unique in psychiatry and medicine—remedy the multifaceted mental health problems associated with gender dysphoria.'' [159] Other research has found that children who socially transition in childhood faced dramatically increased likelihood of persistence of gender dysphoria into adolescence and adulthood.[160] The Department does not believe that the nondiscrimination requirements in Title IX, incorporated by reference into Section 1557, foreclose medical study or debate on these issues. And to the extent that a medical consensus develops on these issues, it is not clear that regulations of the sort encompassed in the 2016 Rule would be necessary to encourage medical professionals to follow such consensus.

The Department believes that its approach in the 2016 Rule inappropriately interfered with the ethical and medical judgment of health professionals. The preamble to the 2016 Rule stated that, under that Rule, ''a provider specializing in gynecological services that previously declined to provide a medically necessary hysterectomy for a transgender man would have to revise its policy to provide the procedure for transgender individuals in the same manner it provides the procedure for other individuals.'' [161] This statement raised the prospect of forcing a provider to perform irreversible, sterilizing, and endocrine-disrupting procedures on what may be, in the provider's view, non-diseased and properly functioning organs—including in children and youth.[162] A medical provider may rightly judge a hysterectomy due to the presence of malignant tumors to be different in kind from the removal of properly functioning and healthy reproductive tissue for psychological reasons, even if the instruments used are identical. For example, OB/GYNs competent and willing to perform dilation and curettage procedures to aid with recovery from a miscarriage should not, and legally cannot,[163] be forced to perform dilation and curettage procedures for abortions, because the regulatory, ethical, and medical frameworks that apply to abortions are radically different from those that apply to recovery from miscarriages. Moreover, commenters who offer transition services made clear that these often involve specialized cross-sex hormonal treatments before and after any sex-reassignment surgeries, and require coordination of care with urologists, psychiatrists, and a variety of other healthcare professionals in different specialized fields. A provider who routinely provides, for example, hysterectomies to address uterine cancer should be able reasonably to choose not to be involved in what may be the much more medically complicated set of procedures involved in sex reassignment.

[155] Comments referring specifically to providers' conscientious objections to certain forms of treatment are addressed below in the section on ''relation to other laws.''

[156] *Cf.* 81 FR 31472, 31429.

[157] CMS, ''Decision Memo for Gender Dysphoria and Gender Reassignment Surgery'' (CAG–00446N) (Aug. 30, 2016) *https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=282.*

[158] *Id.*

[159] Department of Defense, ''Report and Recommendations on Military Service by Transgender Persons'' (Feb. 22, 2018), 5.

[160] Thomas D. Steensma, Ph.D., Jenifer K. McGuire, Ph.D. M.P.H., et al. ''Factors Associated with Desistance and Persistence of Childhood Gender Dysphoria: A Quantitative Follow-Up Study,'' 52(6) Journal of the American Academy of Child & Adolescent Psychiatry 582–90 (2013).

[161] 81 FR 31455.

[162] In this regard, the Department distinguishes between the situation created by the requirements of 2016 Rule and the in-program requirements applied within federally funded grant programs where, for example, ''the general rule that the Government may choose not to subsidize speech applies with full force,'' even if the speech concerns what is allegedly required by medical ethics. *See, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 200 (1991).

[163] *See* Church Amendments, 42 U.S.C. 300a–7.

Upon reconsidering this issue, the Department now believes that the 2016 Rule did not offer a sufficient analysis to justify the serious effect of requiring providers to perform certain procedures or provide certain treatments contrary to their medical judgment. The Department does not and need not take a definitive view on any of the medical questions raised in these comments about treatments for gender dysphoria. The question is whether Title IX and Section 1557 require healthcare professionals, as a matter of nondiscrimination, to perform such procedures or provide such treatments. The answer is that they do not. This final rule does not presume to dictate to medical providers the degree to which sex matters in medical decision making, nor does it impose the 2016 Rule's vague and overbroad mandate that they ''treat individuals consistent with their gender identity.''

Nothing in this final rule prohibits a healthcare provider from offering or performing sex-reassignment treatments and surgeries, or an insurer from covering such treatments and procedures, either as a general matter or on a case-by-case basis. The large number of comments received from healthcare providers who perform such treatments and procedures suggests that there is no shortage of providers willing to do so, even without the 2016 Rule's provisions on gender identity (which had been enjoined for over two years by the time of the comment period).

Finally, the *Franciscan Alliance* court held that HHS had not demonstrated a compelling interest in requiring providers with sincerely held religious objections to gender transition services, notwithstanding their objections, to provide these services. The Department sees no compelling interest in forcing the provision, or coverage, of these medically controversial services by covered entities, much less in doing so without a statutory basis.

Comment: Some commenters stated that revising the rule to eliminate the court-vacated provisions on gender identity, in conjunction with other Federal actions related to gender transition-related services, is evidence of animus to transgender individuals, and that the free exercise of religion or conscience claims raised by medical professionals and insurers are merely ''pretext'' for invidious discrimination. Others contended that the proposed rule recognizes the human dignity of all because certain surgical procedures and medications related to gender identity and abortion do not actually serve the health or wellbeing of patients but violate their dignity and physical and psychological integrity, especially of children and women in crisis pregnancies, and that these providers act out of sincere beliefs both as to medical judgment and religious belief in pursuing the best interests of patients regardless of their background or stated identities.

Response: The Department respects the dignity of all individuals. It seeks to further the health and well-being of all, but it can do so only by implementing the laws as adopted by Congress.

Moreover, the Department notes that commenters have provided a number of bases for objections to being forced to provide or cover certain treatments or surgeries contrary to their sincere medical, economic, religious, scientific, ethical, or conscience-based reasons. To presume that religious beliefs on these issues are rooted in bigotry, animosity, or insincerity would risk unlawfully stereotyping people of faith. *See Masterpiece Cakeshop* v. *Colorado Civil Rights Comm'n,* 138 S. Ct. 1719, 1729 (2018) (''To describe a man's faith as 'one of the most despicable pieces of rhetoric that people can use' is to disparage his religion in at least two distinct ways: By describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.'').[164]

Comment: Commenters expressed various views on whether transgender patients should be treated in accord with their expressed gender identity and/or in accord with their sex.

Some commenters stated that transgender designations conceal real biological sex differences that are relevant to medical risk factors, recognition of which is important for effective diagnosis, treatment, and disease prevention—including effective treatment for patients who identify as transgender. Some added that biological sex differences remain present in numerous bodily systems even after a patient has undergone hormonal and/or surgical transition therapies, and that physicians must be permitted to take these differences into account. Healthcare providers commented that critical decisions are made in the practice of medicine on the basis of objective biological information concerning a person's sex as being male or female because, among other reasons, medications and treatments affect males and females differently, and only females can become pregnant, regardless of stated gender identity. These commenters were concerned that by requiring providers to treat patients consistent with gender identity instead of biological sex, the patients' health is endangered, with both short- and long-term consequences.[165]

Other commenters stated that the Department has not provided sufficient explanation or justification for removing § 92.206 of the 2016 Rule with respect to ensuring equal access to healthcare services without respect to sex, including prohibitions on discriminatory denials of services typically associated with one sex to persons who identify as transgender. The commenters stated that the Department ignored the text of § 92.206 when it asserted in the proposed rule that the 2016 Rule would ''require[e] healthcare entities to code as male all persons who self-identify as male, regardless of biology, [which] may lead to adverse health consequences.''[166] Commenters said § 92.206 properly prohibits, among other things, the arbitrary denial of care based not on clinical considerations but solely on the patient's ''sex as assigned at birth'' or as recorded in medical or insurance records. Others said that while the biological definition of ''sex'' may be appropriate for scientific contexts such as National Institutes of Health (''NIH'') studies, the Department's nondiscrimination provisions should define the term more broadly.

Some commenters commented on a case of a transgender patient with abdominal pains who, as a result of being treated according to a male gender identity, was not diagnosed as being pregnant as part of the triage process and had a stillborn child. Some commenters viewed this set of facts as evidence against the 2016 Rule while others claimed it was evidence for the 2016 Rule.

Response: The Department has long recognized that the practice of medicine and biomedical research routinely involves decisions and diagnoses that legitimately make distinctions based on sex, including decisions made at triage; research studies (including clinical trials); questions of medical history; and requests for a medical consultation. As discussed at length in the NPRM, substantial scientific literature published after the 2016 Rule indicates that sex-specific practices in medicine and research exist because biological

[164] Religious exemptions will be addressed further in the section discussing the final rule's relation to other laws.

[165] Commenters cited texts including William J. Malone, MD, Gender Dysphoria Resource for Providers (3rd Edition); and Michael Laidlaw, MD, ''The Gender Identity Phantom,'' International Discussion Space for Clinicians and Researchers (Oct. 24, 2018) *http://gdworkinggroup.org/2018/10/24/the-gender-identity-phantom.*

[166] *See* 84 FR 27885, n. 55.

(and, derivatively, genetic) differences between males and females are real and matter to health outcomes and research.[167] For example, NIH requires research grant applicants to consider sex as a biological variable ''defined by characteristics encoded in DNA, such as reproductive organs and other physiological and functional characteristics.'' [168] According to an NIH article,

> [s]ex as a biological variable (SABV) is a key part of the new National Institutes of Health (NIH) initiative to enhance reproducibility through rigor and transparency. The SABV policy requires researchers to factor sex into the design, analysis, and reporting of vertebrate animal and human studies. The policy was implemented as it has become increasingly clear that male/female differences extend well beyond reproductive and hormonal issues. Implementation of the policy is also meant to address inattention to sex influences in biomedical research. Sex affects: Cell physiology, metabolism, and many other biological functions; symptoms and manifestations of disease; and responses to treatment. For example, sex has profound influences in neuroscience, from circuitry to physiology to pain perception.[169]

Yet the 2016 Rule required covered entities to ''treat individuals consistent with their gender identity'' in virtually every respect. The 2016 Rule's definition of gender identity does not turn on any biological or external indicia of sex, and explicitly disavows any such reliance.[170] Under the 2016 Rule, one can identify as ''male, female, neither, or a combination of male and female.'' A person's gender identity under the 2016 Rule is determined ultimately by what a person says his or her gender identity is, and a covered entity is bound to treat all individuals ''consistent with their gender identity'' the moment it becomes aware of such a declaration (which must be allowed to change under the 2016 Rule). No other Federal statute, agency rule, or guidance has ever gone so far on this question.[171]

In this regard, the 2016 Rule risked masking clinically relevant, and sometimes vitally important, information by requiring providers and insurers to switch from a scientifically valid and biologically based system of tracking sex to one based on subjective self-identification according to gender identity. By eliminating the transgender provisions and definitions from the 2016 Rule, this final rule clarifies that sex, according to the Title IX's plain meaning, may be taken into account in the provision of healthcare, insurance (including insurance coverage), and health research, as was the practice before the 2016 Rule.

Section 92.206 of the 2016 Rule required covered entities to ''treat individuals consistent with their gender identity'' in every respect save one. Namely, ''a covered entity may not deny or limit health services that are ordinarily or exclusively available to individuals of one sex, to a transgender individual based on the fact that the individual's sex assigned at birth, gender identity, or gender otherwise recorded is different from the one to which such health services are ordinarily or exclusively available.'' This confusingly worded exception is premised on the fact that entities may provide specific services to ''one sex'' based on biology, yet must grant transgender individuals access to such single-sex services regardless of how they identify *and* regardless of their sex (''sex assigned at birth''). The 2016 Rule's mandate cannot answer, for example, how a provider is to determine whether or when a transgender individual is entitled by law to be referred to a women's mental health support group, a men's mental health support group, either group, or both at the same time.

Some providers choose to code and track patients according to their biology for some purposes and according to their gender identity for other purposes. Under the 2016 Rule, however, if a transgender patient self-identifies as male in the medical intake process, yet an examining doctor has reason to believe the patient is biologically female, the doctor could reasonably assume that he or she is *prohibited* from changing the person's chart to reflect female sex, because that would not be treating the person ''consistent with'' her stated gender identity.

In the 2019 NPRM, the Department cited a 2019 case from a medical journal article that concluded that a nurse had applied longstanding standards when triaging what the article called a ''man with abdominal pain,'' who identified as male and had been classified as such, but who was in fact a pregnant woman.[172] Because indications of pregnancy were not manifest, and because the patient was treated according to stated gender identity, her pregnancy was not diagnosed early, and the child was stillborn.

This provider was treating the patient according to her stated gender identity (male), just as the 2016 Rule demanded. Indeed, the provider risked liability under the 2016 Rule for not taking that step. The provider did not act unreasonably when, consistent with longstanding medical practice, it did not have a policy of asking every man with abdominal pain whether he is pregnant.

Unlike the many strained hypothetical objections offered in opposition to the proposed rule, this case is not based on speculation. Rather,

[167] *See, e.g.,* NIH Research Matters, Gene Linked to Sex Differences in Autism (Apr. 14, 2020), *https://www.nih.gov/news-events/nih-research-matters/gene-linked-sex-differences-autism;* Wei Yang, Nicole M. Warrington, *et al.,* Clinically Important Sex differences in GBM biology revealed by analysis of male and female imaging, transcriptome and survival data, Science Translational Medicine (Jan. 21, 2019), *https://www.ncbi.nlm.nih.gov/pubmed/30602536S* (identifying sex-specific molecular subtypes of glioblastoma); Ramona Stone and W. Brent Weber, Male-Female Differences in the Prevalence of Non-Hodgkin Lymphoma, 81 Journal of Environmental Health 16 (Oct. 2018); *https://www.ncbi.nlm.nih.gov/pubmed/28065609;* Anke Samulowitz, Ida Gremyr, et al., ''Brave Men'' and ''Emotional Women'': A Theory-Guided Literature Review on Gender Bias in Health Care and Gendered Norms towards Patients with Chronic Pain, Pain Research and Management (Feb. 25, 2018), *https://www.ncbi.nlm.nih.gov/pubmed/29682130* (stating that ''the response to opioid receptor antagonists may generate a difference between men's and women's experiences of pain''); Douglas C. Dean III, E.M. Planalp, *et al.,* Investigation of brain structure in the 1-month infant, Brain Structure and Function 1–18 (Jan. 5, 2018), *https://www.ncbi.nlm.nih.gov/pubmed/29305647* (finding differences between male and female infants at the age of 1 month); Stefan Ballestri, Fabio Nascimbeni, *et al.,* NAFLD as a Sexual Dimorphic Disease: Role of Gender and Reproductive Status in the Development and Progression of Nonalcoholic Fatty Liver Disease and Inherent Cardiovascular Risk, Advances in Therapy (May 19, 2017), *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5487879;* Susan Sullivan, Anna Campbell, *et al.,* What's good for the goose is not good for the gander: Age and gender differences in scanning emotion faces, 72:3 Journals of Gerontology 441 (May 1, 2017), *https://www.ncbi.nlm.nih.gov/pubmed/25969472;* Ester Serrano-Saiz, Meital Oren-Suissa, *et al.,* Sexually Dimorphic Differentiation of a C. Elegans Hub Neuron Is Cell Autonomously Controlled by a Conserved Transcription Factor, 27 Current Biology 199 (Jan. 5, 2017).

[168] NIH Guidance, *Consideration of Sex as a Biological Variable in NIH-funded Research* at 1 (2017), *https://orwh.od.nih.gov/sites/orwh/files/docs/NOT-OD-15-102_Guidance.pdf.*

[169] Janine Austin Clayton (Office of Research on Women's Health, NIH), ''Applying the new SABV (sex as a biological variable) policy to research and clinical care.'' *Physiology & Behavior* 187 (2018), 2.

[170] 81 FR 31467 (''Gender identity means an individual's internal sense of gender'' whose expression ''may or may not conform to social stereotypes associated with a particular gender''); 81 FR 31468 (''[sex] stereotypes can include the expectation that individuals will *consistently identify with only one gender* and that they will act in conformity with the gender-related expressions stereotypically associated with that gender.'') (emphasis added).

[171] *Cf.* 18 U.S.C. 249 (Shepard-Byrd Hate Crimes Act) (defining gender identity as ''actual or perceived gender-related characteristics'').

[172] *See* 84 FR 27855, n. 55, citing Daphne Stroumsa, Elizabeth F.S. Roberts, et al., ''The Power and Limits of Classification—A 32 Year Old Man with Abdominal Pain,'' New England Journal of Medicine (May 16, 2019), *https://www.ncbi.nlm.nih.gov/pubmed/31091369* (a patient with an electronic medical record classification as male did not receive care to treat ''labor, placental abruption, or preeclampsia—urgent conditions presenting a potential emergency'').

it involved the actual death of an unborn child and attendant trauma and anguish for those involved, all potentially because of a misdiagnosis resulting from a reliance on stated gender identity as opposed to sex. Given that life-and-death decisions are frequently made in healthcare settings and often in urgent circumstances, this story serves as an example of the consequences that could result from the confusion caused by the 2016 Rule and its mandate to treat individuals ''consistent with'' stated gender identity.

Comment: Commenters stated that it is clear that characteristics traditionally protected under antidiscrimination law are those inherent, immutable, and readily identifiable. They stated that a binary and biological definition of sex enables consistency and clarity about who is a member of the protected category, what the prohibited conduct is, how covered entities must comply both by inaction and action, and when government enforces a right against discrimination. Commenters stated that changing the definition of the protected category to an identity that is changeable and fluid results in a legal standard that is impractical if not impossible to apply to particular circumstances. Commenters found that those courts that recognize gender identity discrimination apply the prohibitions inconsistently.

Healthcare providers submitted comments stating that ''gender identity'' is a subjective psychological concept that cannot be anatomically located within the brain, and that no MRI or CT scan, autopsy, genetic testing, blood test, or pathology report can localize an ''internal sense'' and verify whether the gender identity of a patient is actually male, female, neither, or a combination of male or female.

Commenters stated that they did not understand the categories in the 2016 Rule's definition of gender identity which are not obviously limited in the number of possible permutations nor anchored in biology. Commenters were concerned that Title IX's prohibitions against disparate treatment of biological women as different from biological males may no longer be prohibited or even enforceable. When a protected category that was binary now becomes a subjective spectrum, commenters did not know what the substantive standard was to establish a facial violation, or how to apply it to particular facts. Some commenters stated that it contradicts Title IX to treat sex as a non-binary concept when the statute explicitly protects persons of either ''one sex'' or ''the other sex.'' Commenters stated the 2016 Rule retained the words male or female—two categories which have long formed the biological and binary concept of sex—but eliminated their substantive content. The breadth of the definition of gender identity included both exterior (''expression'') and interior (''internal'' sense) characteristics; mental (''identity'') and physical (''body characteristics''); variable over time (at birth vs. after birth), feminine or masculine (binary), both (''some combination''), and androgyny (''neither''). Commenters stated that they did not have clarity as to how to assess claims of ''either/or'' disparate treatment as well as ''both/and.'' Commenters also noted the text also included an expansive catchall provision stating that the definition of gender identity ''is not limited to'' what was in that enumerated list.

Response: The Department agrees that gender identity is difficult to define, in some cases difficult to categorize, and frequently very difficult to determine with objective certainty. For these and reasons stated elsewhere, the 2016 Rule's provisions on gender identity were confusing facially and in application. This final rule eliminates that confusion by returning to the plain meaning of the underlying statutes, relying as it does on the plain meaning of ''sex'' as biologically binary.

Comment: The Department received comments stating that the proposed rule would harm the privacy interests of children with gender dysphoria who seek to use restrooms according to gender identity and would otherwise encourage bullying. Commenters also alleged that in Federal court cases concerning gender identity unrelated to health services, courts have rejected arguments about competing privacy concerns of non-transgender individuals with respect to bathroom access for transgender individuals.

Response: These comments show that, although the preamble to the 2016 Rule had stated that it was not intended to overrule ''existing Federal, State and local laws, rules or regulations'' such as Title IX or its regulations, under which ''certain types of sex-specific facilities such as restrooms may be permitted'' such as bathrooms or intimate facilities,[173] even the 2016 Rule's supporters can reasonably interpret its provisions as doing precisely that.

The Department acknowledges that there is new and developing case law on the intersection of privacy concerns of non-transgender individuals and bathroom access for transgender individuals.[174] As commenters pointed out, there have been recent Title IX complaints regarding access to intimate facilities and associated case law. One complaint alleged a sexual assault by a male who identifies as female and had been granted access to a single-sex (female) facility based on stated gender identity.[175] Another incident involved dueling discrimination and privacy complaints concerning the use of communal shower facilities. After filing a complaint, a male who identifies as female was granted an exception to live as a female. A group of females filed complaints that their privacy rights were violated.[176] At least one Title IX complaint similar to these was denied by a court because of the specific facts of the case.[177] But the case law on such complaints is very new and still developing.

The Department notes that, regardless of whether Title IX *requires* covered entities to maintain sex-specific bathrooms, the Title IX regulations continue to *permit* policies that regulate intimate facilities based on sex. These regulations are consistent both with the ordinary, biological understanding of the word ''sex'' as reflected throughout the text of Title IX and the ordinary understanding of discrimination. Indeed, as the U.S. government has noted, the provisions in Title IX stating that nothing in that statute prohibits educational institutions from ''maintaining separate living facilities *for the different sexes*'' ''could not sensibly function if 'the term 'sex' includes 'gender identity,' which, unlike 'sex,' may not be limited to two categories.'' [178] Moreover, it has long been understood that, although ''separate bathrooms are obviously not blind to sex, they do not discriminate because of sex . . . so long as they do not treat men or women disadvantageously compared to the opposite sex.'' [179] In light of experience, including experience since the 2016 Rule was promulgated, the Department concludes that this final rule, by

[173] 81 FR 31409.

[174] *See, e.g., Soule* v. *Conn. Ass'n of Schools,* No. 3:20–cv–00201 (D. Conn. filed Feb. 12, 2020).

[175] Moriah Balingit, ''After Alleged Sexual Assault, Officials Open Investigation of Transgender Bathroom Policy,'' *The Washington Post* (Oct. 9, 2018), *https://www.washingtonpost.com/local/education/after-alleged-sexual-assault-officials-open-investigation-of-transgender-bathroom-policy/2018/10/09/431e7024-c7fd-11e8-9b1c-a90f1daae309_story.html.*

[176] *See* Department of Defense, ''Report and Recommendations,'' 37.

[177] *See Doe* v. *Boyertown Area Sch. Dist.,* 897 F.3d 518, 531–33 (3d Cir. 2018).

[178] Statement of Interest for DOJ, *Soule* v. *Conn. Ass'n of Schools,* 3:20–cv–00201–RNC (D. Conn., filed March 27, 2020) at 5.

[179] Brief for EEOC, *Harris Funeral Homes,* at 36.

removing the possibility that the Section 1557 regulations could be read as overruling Title IX's regulatory permission to maintain certain sex-segregated facilities (a permission consonant with Title IX's prohibition on sex discrimination, as explained above), will better permit covered entities to balance relevant privacy interests. The Department declines to retain a provision that could reasonably be read to prohibit covered entities from recognizing the difference between men and women or acting to protect men's and women's privacy interests in HHS-funded health programs or activities.[180]

Comment: Some commenters challenged the requirement under the 2016 Rule that medical professionals must use a patient's preferred pronouns based entirely on self-identification, regardless of biological sex or the presence or absence of surgery or the use of masculinizing or feminizing hormone treatments. Some commenters disagreed with any requirement that forces providers to treat patients in a manner other than according to their biological sex, including through coerced use of pronouns. Others stated that social transition treatment required providers to use the preferred pronouns or preferred names of patients, and to identify patients according to their preferred sex effectively at all times.

Response: The 2016 Rule preamble held out a provider's ''persistent and intentional refusal to use a transgender individual's preferred name and pronoun and insistence on using those corresponding to the individual's sex assigned at birth'' as a potential example of hostile-environment sex discrimination under Section 1557.[181] At least one district court has held similarly that when a provider allegedly ''continuously referred to'' a transgender patient ''with female pronouns'' in accordance with her sex, this could be sufficient grounds for a sex discrimination claim under Section 1557 in light of the *Price Waterhouse* ''stereotyping'' theory discussed above.[182] This view, again, rested on a misreading of Title IX.

Pronouns are not stereotypes. Pronouns reflect the most elementary sex-based classification in the English language. They are routinely used in scientific contexts to refer to humans as well as any other animals that are either male or female. They identify an individual's sex, which is an essential element of determining sex-based discrimination under Title IX. This final rule does not interfere with the medical judgment of any covered entity in treating gender dysphoria, but Title IX cannot be used to require covered entities to ignore or override the underlying distinctions of sex that Title IX itself is premised upon.

The Department thus does not believe that Title IX requires participants in covered entities to use a pronoun other than the one consistent with an individual's sex and does not believe it otherwise appropriate to dictate pronoun use or force covered entities to recognize a conception of sex or gender identity with which they disagree for medical, scientific, religious, and/or philosophical reasons. This final rule does not prevent covered entities from maintaining or adopting pronoun policies, or endorsing a variety of theories of gender identity, to the extent otherwise allowed by statutory and constitutional law. This rule also does not prevent State and local jurisdictions from imposing such policies to the extent allowed by statutory and constitutional law.

Comment: A commenter contended that the Department exceeded its authority by proposing to roll back protections for transgender individuals, noting that a 2012 letter from OCR stated that Section 1557 protections included gender identity.[183]

Response: Consistent with the position taken by the Executive Branch on Title IX since 2017, the Department has concluded that the position stated in the 2012 OCR letter reflected an incorrect understanding of Title IX, as incorporated into Section 1557. The Department indefinitely suspended the sub-regulatory guidance contained in the 2012 letter in light of the proposed changes to the rule. 84 FR 27872 n.175. Having considered the matters raised fully, the Department disavows the views expressed in the 2012 letter that concern the coverage of gender identity and sex discrimination under Section 1557. Similarly, the Department disavows the views expressed in a voluntary resolution agreement entered into with The Brooklyn Hospital Center in 2015 resolving allegations of gender identity discrimination under Section 1557.[184] To the extent that those views were integrated or incorporated into the 2016 Rule with respect to gender identity, they are rescinded in this final rule.

Comment: Many commenters asserted that the proposed rule removes legal protections for transgender individuals and would allow or encourage providers to deny basic healthcare to individuals who identify as transgender. Commenters pointed to what they said were instances of discrimination on the basis of the identity of the patient as a transgender individual, where providers allegedly used excessive precautions, avoided touching the patient, engaged in unnecessary physical roughness in pelvic examinations, made insensitive jokes, intentionally concealed information about options for different treatments, asked unnecessarily personal questions, referred to transgender patients by pronouns and terms of address based on their biological sex rather than their gender identity, and/or disclosed a patient's medical history without authorization. Others cited 15 closed cases handled by OCR of alleged discrimination against transgender individuals in which providers had refused sex-specific care or coverage on the basis of discrepancies between the individual's sex and stated gender identity.

Response: The Department believes that all people should be treated with dignity and respect, regardless of their characteristics including their gender identity, and they should be given every protection afforded by the Constitution and the laws passed by Congress. The Department is committed to fully and vigorously enforcing all of the nondiscrimination statutes entrusted to it by Congress. For reasons explained above, the term ''on the basis of . . . sex'' in Section 1557 does not encompass discrimination on the basis of gender identity. Unprofessional conduct such as inappropriate jokes or questions, excessive precautions, or concealment of treatment options, may be covered under State medical malpractice, tort, or battery laws.

Commenters' concern about denial of basic healthcare to transgender

[180] *See* OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center (requiring assignment of persons to shared patient rooms according to gender identity) (2015), sub-regulatory guidance contained therein since *abrogated,* as discussed above, *https://www.hhs.gov/sites/default/files/ocr/civilrights/activities/agreements/TBHC/vra.pdf.*

[181] 81 FR 31406.

[182] *See Prescott* v. *Rady Children's Hospital-San Diego,* 265 F. Supp. 3d 1090, 1098–100 (S.D. Cal. 2017) (''As other courts have recognized, '[b]y definition, a transgender individual does not conform to the sex-based stereotypes of the sex that he or she was assigned at birth. '. . . The Complaint alleges that the RCHSD staff discriminated against Kyler by continuously referring to him with female pronouns, despite knowing that he was a transgender boy and that it would cause him severe distress. . . . Accordingly, Ms. Prescott's claim on behalf of Kyler survives under [Section 1557 of] the ACA.'').

[183] *See* Letter from Leon Rodriguez, Director, U.S. Dep't of Health & Human Servs., Office for Civil Rights, to Maya Rupert, Federal Policy Director, National Center for Lesbian Rights (Jul. 12, 2012), *available at https://perma.cc/RB8V-ACZU.*

[184] *See* OCR Voluntary Resolution Agreement with The Brooklyn Hospital Center.

individuals appears to be based largely on unsubstantiated hypothetical scenarios. Although some rare instances have been reported, they are not recent, and the Department is unaware of a significant number of cases where a transgender individual who has accurately identified his or her (biological) sex to a provider has nonetheless been denied relevant, non-transition-related healthcare on the basis of his or her gender identity. The Department is not aware of any providers claiming that they see a need for or wish to make broad, identity-based denials of care. To the contrary, many providers who specifically object to the 2016 Rule's mandates with respect to sex-reassignment treatments and/or elective abortion procedures explicitly affirmed in comments their commitment to treat all patients without regard to self-identification, inclusive of gender identity or sexual orientation. In the anecdotes of discrimination reported by commenters, what is often being alleged is poor care or insensitive treatment rather than outright denial of care, and is often lacking documentation. This lack of substantial evidence supports the Department's understanding, in contrast to the allegations of some commenters, that denial of basic healthcare on the basis of gender identity is not a widespread problem in the U.S. Moreover, to the extent that the 2016 Rule provided against denial of basic healthcare on the basis of gender identity, those provisions of the rule have been preliminarily enjoined since December 2016 and have since been vacated; any future mistreatment hypothesized by commenters would not, then, be the result of this final rule.

Additionally, several of the behaviors alleged by commenters would be unlawful even if Title IX and Section 1557 had never been enacted. Unnecessary roughness in a pelvic examination, or any other medical procedure or examination without a medical basis or appropriate informed consent, may be a case of battery or malpractice, which should be reported to local law enforcement and/or licensing authorities. If such conduct willfully causes bodily injury because of gender identity, and is in or affecting interstate commerce, then it could be a Federal hate crime.[185] When OCR becomes aware of any crimes that may violate Federal law, it may be required to make a referral to the Department of Justice.[186] The Emergency Medical Treatment and Labor Act (EMTALA) also requires stabilization in certain emergency medical situations.

OCR also continues to enforce Federal health information privacy laws to ensure the confidentiality of all individuals' protected medical information, including information concerning gender dysphoria diagnosis or treatment, sexual orientation, or HIV status.[187]

The Department, through its Offices of Minority Health, supports outreach to diverse populations and those facing particularized or disproportionate health challenges.

Comment: Commenters alleged that removing the definitions of ''gender identity'' and ''on the basis of sex'' (which includes gender identity) from the rule would ''erase'' transgender individuals from the *Code of Federal Regulations.*

Response: The Department denies that removal of definitional terms in one regulation has the wide-ranging impact that commenters allege. Under this final rule, transgender individuals remain protected by the same civil rights laws as any other individual, and the Department will vigorously enforce their statutory and regulatory civil rights. This final rule also does not and cannot erase explicit statutory protections for individuals on the basis of gender identity, such as in hate crimes laws that bar violence committed on the basis of an individual's gender identity.[188]

iii. Termination of Pregnancy

Comment: Commenters reacted to the proposed rule's elimination of the 2016 Rule's language that had encompassed ''termination of pregnancy'' within the definition of ''on the basis of sex.'' Commenters stated that the Department's declining to take a position about the full scope of the meaning of ''termination of pregnancy'' in the 2019 NPRM was confusing, and that the point merited clarification. Some providers objected to the inclusion of ''termination of pregnancy'' under the 2016 Rule to the extent that it referred to elective abortions. Other providers interpreted ''termination of pregnancy'' to mean both elective abortion and natural termination of pregnancies. Others stated that all forms of termination of pregnancy should be encompassed in the prohibition on discrimination on the basis of sex.

Some commenters stated that removing the 2016 Rule's definition of ''on the basis of sex'' will allow discrimination against women based upon their abortion history. Commenters also identified a variety of other women's healthcare services related to pregnancy that may be implicated, including prenatal and postpartum services, tubal ligations, and birth control (both as a contraceptive and when used to treat other medical conditions). They also referred to infertility treatments including in vitro fertilization, and pointed to *Benitez* v. *North Coast Women's Care Medical Group, Inc.*[189] as a real-world example of discrimination in this regard. Commenters said that the proposed rule would or could permit discrimination against women through denial or restriction of access to treatments such as these, as well as treatments prior to, during, or after a miscarriage.

Response: Under this final rule, the Department will interpret Section 1557's prohibition on sex-based discrimination consistent with Title IX and its implementing regulations. This final rule ensures that the Department's Section 1557 regulations are implemented consistent with the abortion neutrality and statutory exemptions in Title IX. The regulations are subject to the text of the Title IX statute, so they cannot be ''construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion.'' 20 U.S.C. 1688. As explained below, this final rule also incorporates that statutory text explicitly into the Title IX regulations for the sake of clarity, to ensure those regulations are

[185] 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on ''actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability'').

[186] *See* 34 U.S.C. 41303 (''All departments and agencies within the Federal government . . . shall report details about crime within their respective jurisdiction to the Attorney General''); 28 U.S.C. 535(b) (''any information, allegation, or complaint received in a department or agency of the executive branch of government relating to violations of title 28 involving Government officers and employees shall be expeditiously reported to the Attorney General by the head of the department or agency'').

[187] *See* U.S. Department of Health and Human Services, ''Careless handling of HIV information jeopardizes patient's privacy, costs entity $387k'' (May 23, 2017), available at *https://www.hhs.gov/about/news/2017/05/23/careless-handling-hiv-information-costs-entity.html* (OCR enforcement under HIPAA); *see also* U.S. Department of Health and Human Services, ''HHS Office for Civil Rights Secures Corrective Action and Ensures Florida Orthopedic Practice Protects Patients with HIV from Discrimination'' (Oct. 30, 2019), *https://www.hhs.gov/about/news/2019/10/30/hhs-ocr-secures-corrective-action-and-ensures-fl-orthopedic-practice-protects-patients-with-hiv-from-discrimination.html* (OCR enforcement under Section 504 and Section 1557).

[188] *See* 18 U.S.C. 249(c)(4) (prohibiting hate crimes that are based on ''actual or perceived religion, national origin, gender, sexual orientation, gender identity, or disability'').

[189] *Benitez* v. *N. Coast Women's Care Med. Grp., Inc.,* 106 Cal. App. 4th 978 (Mar. 4, 2003).

implemented consistent with the statute.

The *Franciscan Alliance* court vacated the ''termination of pregnancy'' language in the 2016 Rule because it failed to incorporate the abortion-neutrality language from the Title IX statute.[190] The Court held that ''Congress intended to incorporate the entire statutory structure, including the abortion and religious exemptions,'' [191] and concluded that by failing to include these exemptions, the Department unlawfully ''expanded the 'ground prohibited under' Title IX that Section 1557 explicitly incorporated.'' [192]

The Department is committed to enforcing vigorously the prohibition on discrimination on the basis of sex, through its implementing regulations (which include provisions on termination of pregnancy), as interpreted consistent with the text of Title IX. OCR will fully enforce its statutory authorities concerning any discriminatory denial of access to women's health services, including those related to pregnancy. The Department, however, declines to speculate on particular hypotheticals related to termination of pregnancy, and will proceed based on the specific facts and circumstances of each case that may arise.

Comment: Some commenters stated that without the 2016 Rule, there would be serious and/or life-threatening results because hospitals would not provide abortion care on the basis of religious beliefs, referencing *ACLU* v. *Trinity Health Corporation,* 178 F. Supp. 3d 614 (E.D. Mich. 2016), and *Means* v. *U.S. Conference of Catholic Bishops,* No. 1:15–CV–353, 2015 WL 3970046 (W.D. Mich. 2015). Some alleged that the proposed rule does not comply with constitutional law regarding abortion or the applicable standard of scrutiny for sex discrimination and imposes undue burdens on women. Some stated that the proposed rule would hurt women's health by denying or encouraging denial of access to abortion.

Others submitted evidence challenging the idea that the termination of pregnancy provision, if retained (and not enjoined by a court), would materially increase abortion access for the average person. Specifically, they state that the overwhelming majority of abortions in America are performed at high-volume abortion clinics, and that there is no reason to suspect that retaining the 2016 Rule would lead to a significant increase in hospitals or other institutions willing to perform abortions when compared to abortion providers as a whole. According to commenters, this is in part because many hospitals and medical institutions that do not have a formal position objecting to abortion are free to engage in them now yet do not perform them or do so only to a limited extent.[193] Additionally, commenters said that the relative dearth of doctors willing to perform abortions at institutions appears largely to be a result of independent physician choices, not of the policies of institutions that object to abortions.

Some commenters were concerned that the 2016 Rule's provisions on termination of pregnancy devalue human life, both with respect to unborn children who lose their lives, and with respect to mothers, as many abortions are dangerous and lead to life-threatening complications for women. Other commenters stated that HHS has a compelling interest in defending the sanctity of innocent human life at all stages. Some institutional providers who object to abortion stated that they can and do treat women who have had miscarriages, even using techniques that are commonly used in abortion (such as dilation and curettage), so long as the procedure itself is not intended to and does not result in the taking of a human life.

Response: The Department appreciates all comments related to the highly controversial matter of abortion. The strong views that Americans hold on various sides of this question are an important policy reason supporting the Congressionally-enacted abortion-neutrality language in Federal statutes such as Title IX. Because Section 1557 expressly incorporated Title IX—therefore including the abortion-neutrality provision—the Department likewise incorporates that provision for purposes of the covered entities under Section 1557. This final rule also does not add any abortion-related conscience protections beyond those that Congress has set down in statute. Those statutes have not been held to be unconstitutional. The Department will vigorously enforce these and all other Federal civil rights statutes under its jurisdiction.

This final rule also does not abrogate other longstanding Federal laws that may apply to situations related to pregnancy, including EMTALA and the Pregnancy Nondiscrimination Act. The Department will read all applicable laws and exemptions harmoniously.[194] In addition, the termination of pregnancy provisions of the 2016 Rule have been enjoined since December 2016 and are now vacated. Finally, this rule does not change the legal ability of providers to offer abortions. The Department therefore disagrees with commenters who predict that the finalization of this rule will significantly reduce abortion access or cause resulting health consequences.

iv. Sexual Orientation

Comment: Some commenters stated that the 2016 Rule's § 92.209 should be removed because Title VII and Title IX do not include sexual orientation in their prohibition of sex discrimination. They used as an example the fact that the previous Administration treated sex, sexual orientation, and gender identity as different concepts in an executive order that prohibited discrimination on the basis of sex, sexual orientation, and gender identity in Federal hiring, contracting, and employment.[195] They added that Congress has rejected the sexual orientation and gender identity provisions in the Employment Non-Discrimination Act, the Equality Act, and the Student Non-Discrimination Act.

Others said that sexual orientation is a foundational trait of an individual and that cannot be separated and/or isolated from his or her being and that the proposed rule would enable discrimination based on sexual orientation. Other commenters cite a general fear of discrimination; abuse or neglect related to sexual orientation; a

[190] *Franciscan Alliance,* 227 F. Supp. 3d 660, 690–91 (N.D. Tex. 2016) (''Title IX prohibits discrimination on the basis of sex, but . . . . categorically exempts any application that would require a covered entity to provide abortion or abortion-related services. 20 U.S.C. 1688. . . . Failure to incorporate Title IX's religious and abortion exemptions nullifies Congress's specific direction to prohibit only the ground proscribed by Title IX. That is not permitted.''); *Franciscan Alliance,* 414 F. Supp. 3d 928, 945, 947 (N.D. Tex. 2019) (adopting reasoning from preliminary injunction and vacating the portions of the rule it deemed unlawful).

[191] *Franciscan Alliance,* 227 F. Supp. 3d at 690–91.

[192] *Id.* (citing *Corley* v. *U.S.,* 556 U.S. 303, 314 (2009)).

[193] As one commenter wrote, ''A 2018 study in the journal *Contraception* found that only 7% of obstetrician-gynecologists in private practice had performed an abortion in 2013 or 2014. An older study published in 2011 in *Obstetrics and Gynecology* found that 97% of practicing obstetrician-gynecologists encountered patients seeking an abortion, though only 14% performed them. Finally, a 2014 study published in *Perspectives on Sexual and Reproductive Health* found that just 5% of abortions take place in hospitals or physicians' offices, demonstrating that the vast majority of abortions are not performed by healthcare providers at hospitals or physicians' offices.''

[194] *See* 42 U.S.C. 13955dd(c)(1)(ii) (EMTALA); Public Law 95–555, 92 Stat. 2076 (Oct. 31, 1978) (Pregnancy Nondiscrimination Act).

[195] Exec. Order No. 13672, 79 FR 42971–72 (July 21, 2014), *https://www.govinfo.gov/content/pkg/FR-2014-07-23/pdf/2014-17522.pdf.*

lack of inclusive services; social isolation; a sense of invisibility; lack of educated providers; and distrust of the healthcare system. They argue that these burdens lead to inadequate care, including preventive care, and require a Federal response. In support of these claims, commenters cited a survey stating that 8% of lesbian, gay, and bisexual respondents allege they have been refused care from a healthcare provider due to their sexual orientation.[196] Other commenters, however, cited a survey showing that 97% of responding faith-based medical professionals attest that they ''care for all patients in need, regardless of sexual orientation, gender identification, or family makeup, with sensitivity and compassion, even when [they] cannot validate their choices.'' [197] Thus, some commenters argue, the issue is not one of refusing to care for certain patients based on identity, but instead a matter of declining to participate in a discrete set of morally controversial procedures and treatments that are available elsewhere.

Others said that discrimination because of an individual's sexual orientation is plainly a species of sex stereotyping that is impermissible under Section 1557's sex discrimination prohibition and cite *Baldwin* v. *Foxx,* an EEOC decision,[198] in support of the idea that the final rule should cover sexual orientation.

Response: OCR may only enforce laws that Congress has enacted and the regulations that were promulgated pursuant to that statutory authority. The plain meaning of ''sex'' under Title IX encompasses neither sexual orientation nor gender identity. Concerning commenters' discussion of Congress's failure to add sexual orientation and gender identity to contexts encompassed by Title IX or Title VII, the Department is guided primarily by its understanding of the plain meaning of the statute.[199] This final rule does not change the status quo with respect to sexual orientation, because, as the Department stated in the 2019 NPRM preamble, sexual orientation was not explicitly included in the 2016 Rule text,[200] and the Department has concluded that it is a category separate from sex and does not fall within the ambit of discrimination ''on the basis of sex.''

The U.S. Attorney General and Solicitor General have persuasively argued that *Price Waterhouse* does not elevate sexual orientation to a protected category using a sex stereotyping theory under Title VII, just as it fails to make gender identity a protected category under Title IX.[201] Much as the reasonable distinctions on the basis of sex discussed above (in the subsection on gender identity) are not illegitimate sex stereotypes, so too, distinctions on the basis of sexual orientation do not as such constitute sex stereotyping. As an initial matter, distinctions on the basis of sexual orientation may be sex-neutral and apply equally to both sexes, which would mean that they do not burden anyone on the basis of sex. The Eleventh Circuit has recently rejected the application of *Price Waterhouse* to expand ''sex'' to include ''sexual orientation,'' citing an abundance of case law in support.[202] Additionally, as the Solicitor General has argued, distinctions made on the basis of sexual orientation are not necessarily based on stereotypes, as they may instead be based on ''moral or religious beliefs about sexual, marital, and familial relationships.'' [203] ''There is nothing irrational or improper'' in such beliefs.[204]

The Department notes that in *Baldwin* v. *Foxx,* the EEOC reversed its long-held position that sexual orientation discrimination was not protected under Title VII.[205] The United States government has since rejected the

[196] *See* Shabab Ahmed Mirza and Caitlin Rooney, Discrimination Prevents LGBTQ People from Accessing Health Care, *Center for American Progress* (January 18, 2018), *https://www.americanprogress.org/issues/lgbt/news/2018/01/18/445130/discrimination-prevents-lgbtq-people-accessing-health-care/.*

[197] *See* Freedom2Care, ''Conscience in healthcare: 2019,'' *https://www.freedom2care.org/polling.*

[198] *Baldwin* v. *Foxx,* EEOC Appeal No. 0120133080, 2015 WL 4397641 (July 15, 2015).

[199] The Department agrees that Congressional inaction on this issue is supportive of the conclusion that Title IX does not encompass sexual orientation or gender identity, although it does not rely on this Congressional inaction in interpreting Title IX.

[200] 81 FR 31390 (''OCR has decided not to resolve in this rule whether discrimination on the basis of an individual's sexual orientation status alone is a form of sex discrimination.'').

[201] *See Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *26 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)) (''Title VII prohibits disparate treatment of men and women regardless of sexual orientation. Gay, lesbian, and bisexual employees, no less than straight employees, may invoke *Price Waterhouse* if they are subjected to gender-based stereotypes; a gay man who is fired for being too effeminate has just as strong a claim as a straight man who is fired for that reason.''). *See also Etsitty* v. *Utah Transit Authority,* 502 F.3d 1215, 1224–25 (10th Cir. 2007) (explaining that the legal issue ''is whether members of one sex are exposed to disadvantageous terms or conditions of employment to which members of the other sex are not exposed'').

[202] *Evans* v. *Georgia Reg'l Hosp.,* 850 F.3d 1248, 1256–57 (11th Cir. 2017) (''*Price Waterhouse* and *Oncale* are neither clearly on point nor contrary to *Blum* [v. *Gulf Oil Corp.,* 597 F.2d 936 (5th Cir. 1979) (''Discharge for homosexuality is not prohibited by Title VII. . . .'')]. These Supreme Court decisions do not squarely address whether sexual orientation discrimination is prohibited by Title VII.'') *Id.* at 1256–57 (''Finally, even though they disagree with the decisions, [the plaintiffs] acknowledge that other circuits have held that sexual orientation discrimination is not actionable under Title VII. *See, e.g., Higgins* v. *New Balance Athletic Shoe, Inc.,* 194 F.3d 252, 259 (1st Cir. 1999) (''Title VII does not proscribe harassment simply because of sexual orientation.''); *Simonton* v. *Runyon,* 232 F.3d 33, 36 (2d Cir. 2000) (''Simonton has alleged that he was discriminated against not because he was a man, but because of his sexual orientation. Such a claim remains non-cognizable under Title VII.''); *Bibby* v. *Phila. Coca Cola Bottling Co.,* 260 F.3d 257, 261 (3d Cir. 2001) (''Title VII does not prohibit discrimination based on sexual orientation.''); *Wrightson* v. *Pizza Hut of Am.,* 99 F.3d 138, 143 (4th Cir. 1996), *abrogated on other grounds by Oncale* v. *Sundowner Offshore Servs.,* 523 U.S. 75, 118 S. Ct. 998, 140 L.Ed.2d 201 (1998) (''Title VII does not afford a cause of action for discrimination based upon sexual orientation. . . .''); *Vickers* v. *Fairfield Med. Ctr.,* 453 F.3d 757, 762 (6th Cir. 2006) (''[S]exual orientation is not a prohibited basis for discriminatory acts under Title VII.''); *Hamner* v. *St. Vincent Hosp. & Health Care Ctr., Inc.,* 224 F.3d 701, 704 (7th Cir. 2000) (''[H]arassment based solely upon a person's sexual preference or orientation (and not on one's sex) is not an unlawful employment practice under Title VII.''); *Williamson* v. *A.G. Edwards & Sons, Inc.,* 876 F.2d 69, 70 (8th Cir. 1989) (''Title VII does not prohibit discrimination against homosexuals.''); *Rene* v. *MGM Grand Hotel, Inc.,* 305 F.3d 1061, 1063–64 (9th Cir. 2002) (''[A]n employee's sexual orientation is irrelevant for purposes of Title VII. It neither provides nor precludes a cause of action for sexual harassment. That the harasser is, or may be, motivated by hostility based on sexual orientation is similarly irrelevant, and neither provides nor precludes a cause of action.''); *Medina* v. *Income Support Div.,* 413 F.3d 1131, 1135 (10th Cir. 2005) (''Title VII's protections, however, do not extend to harassment due to a person's sexuality. . . . Congress has repeatedly rejected legislation that would have extended Title VII to cover sexual orientation.'') (internal quotations omitted). *Evans* and the EEOC question these decisions, in part, because of *Price Waterhouse* and *Oncale.* Whether those Supreme Court cases impact other circuit's decisions, many of which were decided after *Price Waterhouse* and *Oncale,* does not change our analysis that *Blum* is binding precedent that has not been overruled by a clearly contrary opinion of the Supreme Court or of this Court sitting *en banc.*'').

[203] *Bostock* v. *Clayton Cty. Bd. of Commissioners,* 2019 WL 4014070 at *25 (U.S. 2019) (Brief for the United States as *Amicus Curiae* Supporting Affirmance in No. 17–1618 (*Bostock* v. *Clayton Cty. Bd. of Commissioners*) and Reversal in No. 17–1623 (*Altitude Express Inc.* v. *Zarda*)).

[204] *See Tuan Anh Nguyen* v. *INS,* 533 U.S. 68. *See also Obergefell* v. *Hodges,* 135 S. Ct. 2585, 2602 (2015) (referring to opinions that are ''based on decent and honorable religious or philosophical premises'' and are therefore not ''disparaged here''); *See Masterpiece Cakeshop* v. *Colorado Civil Rights Comm'n,* 138 S. Ct. 1719, 1729 (2018) (''To describe a man's faith as 'one of the most despicable pieces of rhetoric that people can use' is to disparage his religion in at least two distinct ways: by describing it as despicable, and also by characterizing it as merely rhetorical—something insubstantial and even insincere.'').

[205] *See e.g., Angle* v. *Veneman,* EEOC Decision No. 01A32644, 2004 WL 764265, at *2 (Apr. 5, 2004) (recognizing that the EEOC had ''consistently held that discrimination based on sexual orientation is not actionable under Title VII''), *Marucci* v. *Caldera,* EEOC Decision No. 01982644, 2000 WL 1637387, at *2–*3 (Oct. 27, 2000).

EEOC's novel position.[206] Given Congress's decision not to extend civil rights protections on the basis of sexual orientation in the field of health and human services, the Department believes that State and local governments are best equipped to balance the multiple competing considerations involved in what remain a contentious and fraught set of questions.

v. Scrutiny for Sex-Based Classifications (Repeal of § 92.101(b)(3)(iv) of the 2016 Rule)

The Department proposed to repeal 92.101(b)(3)(iv) of the 2016 Rule, which forbids covered entities from operating a health program or activity restricted to members of one sex unless they can ''demonstrate an exceedingly persuasive justification, that is, that the sex-specific health program or activity is substantially related to the achievement of an important health-related or scientific objective.'' [207]

Comment: Commenters stated that the 2016 Rule's provisions would pose an unjustified burden on, and lead to excessive scrutiny of, entities operating single-sex facilities in healthcare, as well as entities or persons who would claim religious or abortion exemptions under Title IX.

Response: The Department agrees that the 2016 Rule placed an unjustified burden on sex-specific health programs and activities conducted by private entities. The ''exceedingly persuasive justification'' legal standard under Equal Protection jurisprudence sets a limit to *governmental* actions that discriminate on the basis of sex, such as the military draft.[208] This standard is foreign to Title IX jurisprudence.[209] The 2016 Rule cited no case law in support of its decision to import a significantly modified version of this standard from constitutional law into its interpretation of ''on the basis of sex'' as defined by Title IX.[210] The express statutory exemptions to Title IX's nondiscrimination provisions, such as for fraternities and sororities, do not require individual covered entities to provide an ''exceedingly persuasive justification'' before being able to benefit from the exemption. Title IX also does not require religious entities to provide such a justification to qualify for the religious exemption from Title IX nondiscrimination provisions. To require such a justification in the enforcement of Section 1557 would be to impose a significant burden on private entities that the statutory text does not contemplate. Government actors are routinely subjected to levels of judicial scrutiny that private parties (even private parties receiving Federal funds) are not, such as where constitutional provisions restrict government action, or where statutes allow civil rights actions against State actors. *See, e.g.,* 1st Am., U.S. Const.; 42 U.S.C. 1983; 42 U.S.C. 2000bb, *et seq.* It would be inappropriate to constrain medical professionals' best judgment by requiring them to meet the governmental burden of proof every time they seek to draw a reasonable distinction on the basis of sex in providing healthcare or separate programs or activities for the two sexes.[211] As stated above, such distinctions are not inherently discriminatory: It is not discriminating against men to exclude them from, for example, gynecological services, because men are not similarly situated to women for purposes of such services. Providers accordingly should not be required to present an ''exceedingly persuasive justification'' for providing gynecological services only to women. OCR will, however, evaluate, and respond appropriately to, any allegations that a covered entity's sex-specific health programs or activities have in fact discriminated unlawfully on the basis of sex, including sexual harassment.[212]

vi. Disparate Impact Under § 92.101(b)(3)(iii) of the 2016 Rule

The Department proposed to repeal 92.101(b)(iii) of the 2016 Rule, which prohibited selection of sites or facilities that have an effect of discriminating on the basis of sex.[213]

Comment: Some commenters opposed repealing language that affirmed a disparate impact theory under grounds of nondiscrimination encompassed by Section 1557, contending that the civil rights statutes cited in Section 1557 authorize disparate impact claims.

One commenter asserted that the very existence of Section 1557 indicates that the ACA intends to extend protections against disparate impact discrimination to private rights of action: Title VI already applied in the context of healthcare programs and activities, so Section 1557 would have been meaningless if it did not also allow for private rights of action for disparate impact discrimination. The same commenter also took issue with the proposed rule's elimination of monetary damages for disparate impact claims.

Response: Case law has indicated that certain civil rights statutes incorporated by Section 1557 do authorize disparate impact claims: Namely, claims with respect to discrimination on the basis of race, color, national origin, and disability.[214] Title IX, however, authorizes no such claims regarding discrimination on the basis of sex. Similarly, provisions relating to site or facility selection based on race, color, national origin, or disability are found in HHS's Title VI and Section 504 regulations, but are not found in HHS's Title IX regulations.[215] Insofar as the 2016 Rule added new grounds of prohibited discrimination not found in the statute, the Department believes it is necessary to revert to the underlying statutes and their implementing regulations. As a result, to the extent any of the underlying statutes authorize disparate impact claims, this final rule will recognize such claims by virtue of its reliance on the governing statutes, regulations, guidance and case law applicable to such claims, without needing to delineate the availability or lack of availability of all possible claims in this final rule. In reviewing all complaints that raise a disparate impact claim, the Department will consider the circumstances of each complaint and will independently apply each statute and underlying regulation, according to its text and any applicable court precedents, to the health context under Section 1557.[216]

Comment: Some commenters stated that that the proposed rule's removal of protections against disparate impact discrimination, especially concerning race, color, and national origin, will lead to more instances of discrimination and fewer means of recourse.

[206] *See* Brief for United States, *Bostock* v. *Clayton Cty. Bd. of Commissioners,* No. 17–1618 (U.S. filed Aug. 23, 2019).

[207] 81 FR 31470.

[208] *See Rostker* v. *Goldberg,* 453 U.S. 57, 69–70 (1981).

[209] *See, e.g.,* the clear distinction at *Whitaker* v. *Kenosha Unified Sch. Dist.,* 858 F.3d 1034, 1046–50 (7th Cir. 2017) (''Title IX Claim''), and 1050–54 (''Equal Protection Claim,'' encompassing the ''exceedingly persuasive justification'' test).

[210] *Cf.* 81 FR 31408–09.

[211] *See* 2016 Rule, 81 FR 31409 (''In all cases, . . . OCR will expect a covered entity to supply objective evidence, and empirical data if available, to justify the need to restrict participation in the program to only one sex.'').

[212] *See* U.S. Department of Health and Human Services, ''HHS OCR Secures Agreement with MSU to Resolve Investigation into Sexual Abuse by Larry Nassar'' (2019), *https://www.hhs.gov/about/news/2019/08/12/hhs-ocr-secures-agreement-msu-resolve-investigation-sexual-abuse-larry-nassar.html.*

[213] 81 FR 31470.

[214] *See* 45 CFR 84.4(b)(4) (Title VI); 80.3(b)(2) (Section 504).

[215] *See* 45 CFR 80.3(b)(3) (Title VI); 84.4(b)(5) (Section 504).

[216] The Department responds to comments on private rights of action and damages below in the section on the enforcement mechanisms of the 2016 Rule.

Commenters cited data about health disparities in LGBT and female populations that they asserted were caused by discrimination on the basis of gender identity or termination of pregnancy, and stated that disparate impact analysis under the 2016 Rule is the appropriate way to address such discrimination. Another commenter questioned the persuasiveness of assessing the relative proportion of health disparities between racial, transgender, and/or female populations and other populations. The commenter stated that the available data did not provide conclusive evidence that the health disparities were caused by discriminatory conduct against LGBT persons and individuals seeking abortions, because correlations are not definite evidence of causation. The commenter contended that the proposed rule's approach causes ambiguity by blurring the distinctions between the two.

Response: As an initial matter, the Department wishes to reiterate that it will enforce Section 1557 in light of its regulations that already protect against disparate impact on the basis of race, color, or national origin. With respect to concerns regarding disparate impact on LGBT and abortion-seeking populations, the Department notes that this final rule conforms the Section 1557 Rule to HHS's Title IX regulations, under which the disparate impact standard does not apply. This conformity provides a clearer standard for covered entities, which are no longer required to have legally sufficient knowledge of the causes of statistically disproportionate health disparities on the basis of sex or gender identity.

vii. Insurance Coverage in § 92.207 of the 2016 Rule

The 2016 Rule prohibited insurers from ''hav[ing] or implement[ing] a categorical coverage exclusion or limitation for all health services related to gender transition.'' [217] Its preamble explained that this encompasses a ''range of transition-related services'' to treat gender dysphoria that are ''not limited to surgical treatments and may include, but [are] not limited to, services such as hormone therapy and psychotherapy, which may occur over the lifetime of the individual,'' and that may be required even if not ''strictly identified as medically necessary or appropriate'' insofar as the entity covers other types of similarly ''elective'' procedures.[218]

Comment: Commenters indicated support for the 2016 Rule's insurance coverage requirements, claiming that the Rule has led to increased access to gender transition services for transgender patients, and that these services will be lost if the proposed rule is finalized. In comments, clinicians provided information about the specific procedures, services, or treatments they perform or offer with respect to gender identity. Among those who offer medical interventions under the category of ''gender transition,'' there was a consensus that such interventions included genital sex reassignment surgeries, cross-sex hormonal treatment, counseling, and often psychological or psychiatric support. Some clinicians stated that only patients with longstanding identification as the opposite sex and distress with their biological sex sought these services. Beyond these, some (but not all) clinicians indicated that gender transition procedures could also include surgery for feminization or masculinization of the entire body, which could include reduction, augmentation, removal, or transplant of tissue, skin, hair, or body fat, as well as ''social transition'' services such as voice training.[219]

Some commenters regard transition services (which they said may include counseling, hormone therapy, and/or a variety of possible surgical treatments) as the governing standard of care. They directed the Department to studies on the matter including those cited in the 2016 Rule preamble, and cited what they said is a consensus of major American medical associations [220] about sex-reassignment surgery, cross-sex hormones, and affirmation counseling. Commenters urged the Department to follow the 2016 Rule in relying on the standards promulgated by the World Professional Association for Transgender Health (WPATH).[221]

Commenters stated that, under the WPATH standards and other protocols, treatment for gender dysphoria may require transition-related care.[222] Commenters asserted specific benefits from transition-related care in treating gender dysphoria.[223] For example, commenters said that access to transition services leads to decreased health disparities, such as lower levels of depression and suicide attempts.[224]

With respect to adolescents, some commenters promoted approaches that affirm or encourage gender identity variation, including sex reassignment, citing data that they said showed it resulted in fewer mental health concerns.[225] Some medical professionals also stated in comments that hormone blockers are a safe and reversible way to delay puberty, noting

[217] 81 FR 31472, 31435–36.

[218] *Id.*

[219] Examples of procedures identified were rhinoplasty, blepharoplasty, septoplasty, rhytidoplasty, abdominoplasty, electrolysis, liposuction, jawline modifications, scalp advancement, cheek and chin contouring, fat transfer, pectoral implants, forehead or brow lifts, or breast, buttocks, breast, waist, or lip augmentation/reduction. *See* Whitman-Walker Health; Philadelphia Transgender Center. HHS–OCR–2019–0007–138335 (Whitman-Walker Health). *http://www.thetransgendercenter.com/index.php/femaletomale1/ftm-price-list.html; http://www.thetransgendercenter.com/index.php/maletofemale1/mtf-price-list.html.*

[220] Commenters cited Jason Rafferty, ''Ensuring Comprehensive Care and Support for Transgender and Gender-Diverse Children and Adolescents,'' 142 *Pediatrics* no. 4 (Oct. 2018) (American Academy of Pediatrics policy statement), and noted that the American Medical Association, the American College of Physicians, the American Psychological Association, the American Psychiatric Association, the American Academy of Family Physicians, the Endocrine Society the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics, among others, support transition-related treatments.

[221] *See* 81 FR 31429.

[222] Commenters cited, for example, Wylie C. Hembree et al., *Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline,* 102 The Journal of Clinical Endocrinology & Metabolism 3869 (2017); Am. Medical Ass'n, *AMA Policies on GLBT Issues, Patient-Centered Policy H–185.950, Removing Financial Barriers to Care for Transgender Patients* (2008), *http://www.imatyfa.org/assets/ama122.pdf;* and Am. Psychiatric Ass'n, *Position Statement on Discrimination Against Transgender and Gender Variant Individuals* (2012); *http://www.dhcs.ca.gov/services/MH/Documents/2013_04_AC_06d_APA_ps2012_Transgen_Disc.pdf* (citing WPATH *Standards*); Am. Psychological Ass'n, *Policy on Transgender, Gender Identity & Gender Expression Non-Discrimination* (2008), *http://www.apa.org/about/policy/transgender.aspx.*

[223] Commenters cited, for example, Ashli A. Owen-Smith, et al., *Association Between Gender Confirmation Treatments and Perceived Gender Congruence, Body Image Satisfaction, and Mental Health in a Cohort of Transgender Individuals.* J Sexual Medicine (Jan. 17, 2018); Gemma L. Witcomb et al., *Levels of Depression in Transgender People and its Predictors: Results of a Large Matched Control Study with Transgender People Accessing Clinical Services,* J. Affective Disorders (Feb. 2018); and Cecilia Dhejne et al., *Mental Health and Gender Dysphoria: A Review of the Literature,* 28 Int'l Rev. Psychiatry 44 (2016).

[224] Commenters cited, for example, Lily Durwood, Katie A. McLaughlin, & Kristina R. Olson, *Mental Health and Self-Worth in Socially Transitioned Transgender Youth,* 56 J. Am. Acad. Child Adoles. Pyschiatry 116 (2017); Kristina R. Olson et al., *Mental Health of Transgender Children Who Are Supported in Their Identities,* 137 Pediatrics (2016); and Stephen T. Russel et al., *Chosen Name Use Is Linked to Reduced Depressive Symptoms, Suicidal Ideation, and Suicidal Behaviors Among Transgender Youth,* 64 J. Adolescent Health 503 (2018), *https://www.jahonline.org/article/S1054-139X(18)30085-5/fulltext.*

[225] Commenters cited Hill DB, Menvielle E, Sica KM, Johnson A. *An affirmative intervention for families with gender variant children: parental ratings of child mental health and gender.* J Sex Marital Ther. 36(1):6–23 (2010).

they have been used historically for children experiencing precocious puberty, or puberty at a younger age.

Other commenters disagreed as to whether sex reassignment treatments or surgeries, or gender-affirming therapies, are the proper care for gender dysphoria, or even whether they are ever medically indicated. Instead of surgery, hormones, or cross-sex affirmation counseling, some healthcare providers recommended watchful waiting, talk therapy that affirms a person's biological sex, or psychological or psychiatric treatment of comorbid conditions, as distinct from permanent surgical or hormonal interventions.[226] These providers explained that patients with gender dysphoria can work with a psychiatrist or counselor to better understand their feelings and emotions, and how the incongruence between their psychological identity and biological sex causes them distress. Some clinicians stated that reinforcing a patient's perception that there is something wrong with their body is damaging both to mental and physical health of transgender patients.

Some medical professionals discussed the long-term and irreversible physical effects of cross-sex hormones and puberty blockers, pointing to permanent deepening of voice, clitoromegaly, jaw enlargement, permanent sterility, and sexual dysfunction.[227] Doctors also commented that clinical data have not shown that such hormonal treatments improve the long-term psychological functioning of gender dysphoric persons. Clinicians stated that certain hormone treatments given to persons with gender dysphoria result in glucose and lipid metabolism disorders and cardiovascular conditions. Some clinicians were critical of the research supporting transition services, stating that it does not adequately assess such long-term health consequences and ignores a particularly vulnerable population of patients, namely the growing population of transitioned individuals who wish to transition back but are being ignored or impeded from receiving services affirming their biology.[228] They cited research indicating that patients did not need surgical or hormonal transition services when less drastic interventions would have been effective.[229] Clinicians stated that transition services were burdensome on these patients on several levels—financially, physically, and psychologically. Commenters concluded that repeal of the 2016 Rule would relieve the burden on these transgender individuals by letting providers decide, based on their assessment of individuals, what surgeries or treatments are appropriate according to their medical judgment and without coercive regulatory pressure.

Some medical providers raised concerns that prescription of sex-reassignment procedures and treatments had risked the health of young patients under their care due to lack of capacity at young ages to fully consent to treatments, difficulties with proper diagnosis during changes undergone in adolescence, and the negative impacts on bone mass and growth, emotional development, and sexual function.[230] Some clinicians stated that gender dysphoria is not an immutable mental health condition and, as such, the appropriate treatment is not physical and permanent. Some clinicians stated that current care for gender dysphoria includes accommodation counseling, the ''wait and see'' approach, and (where indicated) detransition therapy, because dysphoria, particularly in children, has a high rates of resolving without other interventions. They said that in their medical judgment, sex reassignment, cross-sex hormones, and affirming counseling are new and controversial treatments with known permanent and negative health consequences. Some medical clinicians criticized the WPATH standards [231] for coming to policy conclusions without adequate clinical evidence and recommending treatments that are still experimental.[232] Other commenters criticized the 2016 Rule for relying on the policy recommendations of an international advocacy group to

[226] Commenters cited sources including Monique Robles, ''Observations in a Gender Diversity Clinic,'' 44 Ethics & Medics 2 (Feb. 2019); and Devita Singh, Ph.D., ''A Follow-up Study of Boys with Gender Identity Disorder,'' Department of Human Development and Applied Psychology, Ontario Institute for Studies in Education, University of Toronto (2012).

[227] Commenters cited sources including Talal Alzahrani, M.D., et al., ''Cardiovascular Disease Risk Factors and Myocardial Infarction in the Transgender Population,'' *Circulation: Cardiovascular Quality and Outcomes* 12:4 (Apr. 2019), *https://www.ncbi.nlm.nih.gov/pubmed/30950651;* and Darios Getahun, M.D., et al., Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons, *Annals of Internal Medicine* (July 10, 2018), *https://www.ncbi.nlm.nih.gov/pubmed/29987313.*

[228] Commenters cited, for example, Miroslav L. Djordjevic et al., Reversal Surgery in Regretful Male-to-Female Transsexuals After Sex Reassignment Surgery, 13 J. of Sexual Med., 1000, 1006 (2016).

[229] Commenters cited, for example, Joe Shute, ''Sex change regret: Gender reversal surgery is on the rise, so why aren't we talking about it?'' *The Telegraph* (Oct. 1, 2017), *https://www.telegraph.co.uk/health-fitness/body/gender-reversal-surgery-rise-arent-talking.*

[230] Commenters cited, for example, Lieke Josephina Jeanne Johanna Vrouenraets, M.Sc., *et al.,* ''Early Medical Treatment of Children and Adolescents With Gender Dysphoria: An Empirical Ethical Study,'' *Journal of Adolescent Health* (Jan. 12, 2015), *https://www.ncbi.nlm.nih.gov/pubmed/26119518;* and Guido Giovanardi, ''Buying time or arresting development? The dilemma of administering hormone blockers in trans children and adolescents,'' *Porto Biomedical Journal* (2017).

[231] *See* Standards of Care for the Health of Transsexual, Transgender, and Gender Nonconforming People 16 (7th ed. 2011), *https://www.wpath.org/publications/soc.*

[232] Clinicians stated that the WPATH Standards ignored research evidence in support of a ''wait and see'' approach that gender dysphoria during childhood has a desistance rate, without drastic surgical or medical intervention for sex-reassignment or affirmation for social transition. They cited studies including Singh, D., ''A Follow Up Study of Boys with Gender Identity Disorder,'' doctoral dissertation submitted at University of Toronto (2012); Drummond, K. D., Bradley, S. J., Badali-Peterson, M., & Zucker, K. J., ''A follow-up study of girls with gender identity disorder,'' *Developmental Psychology* 44:1 (2008), 34–45; Wallien, M. S. C., & Cohen-Kettenis, P. T., ''Prediction of adult GID: A follow-up study of gender-dysphoric children,'' paper presented at the meeting of the World Professional Association of Transgender Health, Chicago, IL (2007); and Smith, Y.L., Van Goozen, S.H., & Cohen-Kettenis, P. T., ''Adolescents with gender identity disorder who were accepted or rejected for sex reassignment surgery: A prospective follow-up,'' *Journal of the American Academy of Child & Adolescent Psychiatry,* 40:4 (2001), 472–81.

interpret U.S. nondiscrimination laws and develop policy in the American healthcare sector. Other commenters disputed the conclusions of medical professional associations referenced above, stating that they had mischaracterized the medical data, and that life-altering transition interventions are not medically necessary, effective, or safe.[233]

Several commenters who expressed objections to the 2016 Rule clarified that they do not exclude patients from access to healthcare on the basis of the patient's gender identity, but rather objected to the rule requiring that they provide treatment that would be detrimental to the health and well-being of their patients. Part of their medical profession involves recommendations on which treatments will appropriately treat medical conditions to improve the health of their patients, and the choice not to provide transition surgery or abortion is part of those judgments. Some providers indicated that the options for treatment they recommend for patients with gender dysphoria are therapeutic and accommodative counseling to improve long-term health outcomes, particularly of young patients.

Other commenters said the Department should rely on the recent reviews of the clinical data on sex-reassignment surgery and cross-sex hormonal treatment by science and healthcare professionals at HHS and DOD.

Response: These comments further reinforce the Department's conclusion, discussed above in the section on gender identity, that there is no medical consensus to support one or another form of treatment for gender dysphoria. In the Department's current view, the 2016 Rule did not give sufficient evidence to justify, as a matter of policy, its prohibition on blanket exclusions of coverage for sex-reassignment procedures. The Department shares commenters' judgment that the 2016 Rule relied excessively on the conclusions of an advocacy group (WPATH) rather than on independent scientific fact-finding—such as the fact-finding that CMS undertook in deciding to not issue a National Coverage Determination with respect to sex-reassignment surgeries (as discussed above) due to insufficient proof of medical necessity. In addition, commenters identify a lack of clarity in the 2016 Rule's mandate, because of the lack of medical consensus as to what is even encompassed within ''gender transition procedures'' (*e.g.,* whether they include facial reconstruction or hair transplants). All these are further reasons why, as a matter of policy, Federal civil rights law should not be used to override providers' medical judgments regarding treatments for gender dysphoria. But as stated above, even if it were appropriate policy, such an end could not be achieved through application of Section 1557 and Title IX. There is no statutory authority to require the provision or coverage of such procedures under Title IX protections from discrimination on the basis of sex.

Comment: Some commenters state that the provisions in § 92.207(b)(3) through (5) of the 2016 Rule were confusing, overbroad, unclear, and inconsistent. Commenters stated that specificity in this area is necessary for efficient and transparent operation of the health insurance coverage to work for all involved. Commenters expressed concerns that the 2016 Rule did not address whether insurers are required to pay for all such surgeries, including without prior approval; approve them absent some standard of medical necessity; or approve them even over concerns of later malpractice lawsuits by the patient. A commenter reiterated his comments on the 2015 NPRM that the 2016 Rule's requirements related to gender transition were confusing for covered entities. The commenter said the regulatory requirement did not address which healthcare providers must provide these surgeries: *e.g.,* plastic surgeons, thoracic surgeons, general surgeons, or physicians whether or not they ordinarily perform major surgery. Others stated that although the 2016 Rule preamble characterized the categorical exclusion provision as a ''limited'' exception, the provisions on gender transition-related services were very broad and could include facial feminization or masculinization surgeries. Some commenters interpreted ''gender dysphoria'' as only affecting transgender individuals who seek sex re-assignment services, but other commenters cited clinical data indicating that men who had genital combat injuries and women who had removal of cancerous tissue in breasts and have received the diagnosis may also experience body dysmorphia.[234]

Other commenters stated that surgical sex reassignment (which may also include cross-sex hormonal treatment) may cost up to $22,025 on average for those covered by insurers. Still others said that the definition of ''gender dysphoria'' itself has changed rapidly and unpredictably over the years, leading to confusion, and point to its shifting conception as an experience of distress or a personal characteristic, to different and changing terms used for diagnosis of gender dysphoria in the DSM, and to the varied use of both clinical medical terms and sociological identity terms concerning the topic. The American Psychiatric Association justified the abandonment of the term ''gender identity disorder'' and its replacement with ''gender dysphoria'' in the Diagnostic and Statistical Manual of Mental Disorders to reduce stigmatization of the particular mental condition, but commenters noted that the DSM–5 made no changes to remove the classification of ''disorder'' for suicidal ideation, other body dysmorphias, or substance use disorder, which mental health advocates commented are also stigmatizing and may be comorbid with gender dysphoria.

Response: The Department agrees that the 2016 Rule made confusing and overbroad demands on covered entities, including insurance providers, and left unclear to what extent it was requiring providers to provide, or health insurance issuers to cover, treatments such as facial feminization, Adam's apple reduction, and hair transplants as part of ''health services related to gender transition.'' This final rule seeks to handle issues involving the exercise of legitimate medical judgment (including determinations relating to medical necessity and coverage decisions) with greater care, and to provide covered entities with greater clarity regarding their regulatory obligations.

Comment: Some commenters who identified as transgender patients opposed the proposed rule on the grounds that they had budgeted and planned with the expectation that there would be a limited or no cost for transition services due to the 2016 Rule, but they were surprised when they had an out-of-pocket cost not covered by their selected insurance company or plan. A much higher cost for these services resulted in the inability to receive or delay in receiving such services. They described surprise billing at multiple steps of the process, from reviewing health insurance coverage plans to waiting for reimbursements. These commenters stated that they anticipated and relied on OCR's 2016

[233] *See* Michelle Cretella, ''Gender Dysphoria in Children'' (November 2018) (American College of Pediatricians policy statement); *see also* James Cantor, ''American Academy of Pediatrics Policy and Trans- Kids: Fact-Checking,'' *Sexology* (Oct. 2018).

[234] Commenters cited M. Jocelyn Elders, et al., ''Medical Aspects of Transgender Military Service,'' Armed Forces and Society 41(2) (Mar. 2014): 199–220.

Rule as guaranteeing them insurance coverage because it is provided to other patients, and that this was their understanding of the Affordable Care Act and their civil rights protections. Other commenters contended that the 2016 Rule had caused the reduction of blanket exclusions for gender transition in health insurance coverage over the past three years.[235] Others stated that short-term limited duration insurance plans do not provide coverage of gender transition-related services, and therefore if transgender individuals are covered by such plans, they would not be able afford medically necessary services.

Response: With respect to coverage for gender transition services, the Department notes that this final rule makes no changes to what has been the status quo since December 2016, when the Department was enjoined from enforcement of the gender identity provisions of the 2016 Rule; such provisions have now been vacated by a court. Any recent decrease in blanket exclusions for sex-reassignment coverage is therefore more likely to be attributable to health insurance issuer or plan sponsor choice. State-level legal requirements concerning gender identity coverage have also come into effect in recent years, such as State statutes, regulations, guidance,[236] and court orders [237]—this final rule does not affect those changes in any way. But to the extent that provisions in the 2016 Rule did pressure any insurers to cover services on the basis of gender identity that they previously had not covered, such provisions did so without statutory authority, which is why they were preliminarily enjoined and vacated.

As a policy matter, the Department recognizes that surprise billing is a serious problem, but that topic is not a subject of this rulemaking. As for short-term limited duration insurance, for reasons discussed below, it is generally not regulated under this final rule and so is generally not affected by the rule's nondiscrimination requirements in any case.

e. Discrimination on the Basis of Association, Repeal of § 92.209 of the 2016 Rule

The Department proposed to repeal § 92.209 of the 2016 Rule, which included a prohibition on discrimination against an individual or entity on the basis of being known to or believed to have a relationship or association.

Comment: Commenters opposed the repeal of prohibitions against discrimination based on association with a protected category. These commenters contended that removing such protections would cause confusion, both for covered entities who will be unsure of their responsibilities and for individuals who will be unsure of their rights, especially in light of other Federal nondiscrimination laws that the Department enforces. For example, the Department enforces Title II of the ADA and its implementing regulation, which prohibits discrimination against an individual based on his or her association with another individual with a disability, as do Titles I and III of the ADA.[238] Commenters said that this also shows that it would defy Congressional intent, and cause inconsistency among different regulations that covered entities are subject to, if the Department were to withdraw associational discrimination protections from patients seeking healthcare. Commenters also expressed concern that the proposed rule would make it more difficult for those experiencing discrimination by association to enforce their rights. Other commenters stated that the lack of reference to associational discrimination in the proposed rule is inconsistent with existing case law that validates prohibitions on associational discrimination, particularly in employment discrimination cases brought under Title VII pertaining to race, sex, and religion. Others argued that it is incorrect to assume that by referencing the grounds protected under previous civil rights laws, Section 1557 automatically incorporates the limitations found in those laws.

Some commenters contended that specific protected populations are more susceptible to associational discrimination. In particular, commenters stated that deaf and hard-of-hearing patients frequently use hearing companions, especially in hospital settings, and may be subject to associational discrimination. Commenters also identified potential instances of associational discrimination, including an entity's refusing to provide medical services to a white individual due to association with an African American individual, refusing to provide medical services to a child because his parents speak a different language, or refusing to provide services to an individual because her family members have a specific disability.

Response: This final rule neither abrogates nor withdraws any protections available under the incorporated civil rights statutes or their implementing regulations. It simply declines to use the Section 1557 regulation to identify protections beyond those specifically identified in the text of the relevant statutes and regulations. Protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under those statutes and regulations. As stated above, the Department regards this as the best way to decrease confusion. As the *Franciscan Alliance* court noted, the executive branch is obligated to implement Section 1557, with the civil rights statutes it incorporates, by ''giving the statutory text its plain and ordinary meaning, construing the statute as a whole, and giving effect to every word of the statute.'' [239] Courts have held that Section 1557 incorporates the limitations of the civil rights statutes referenced in Section 1557.[240]

Some instances discussed by commenters would appear to constitute discrimination against a person under the underlying civil rights statutes even without the 2016 Rule's prohibition on associational discrimination. For example, if a covered entity refused to provide meaningful access for LEP parents who are legally entitled to make medical decisions on behalf of their child, it could constitute discrimination on the basis of national origin.

f. Multiple Protected Statuses

The Department received many comments about individuals who may have protected status or face discrimination on multiple grounds.

[235] Commenters cited sources including, *e.g.,* Out2Enroll, Summary of Findings: 2019 Marketplace Plan Compliance with Section 1557 (finding that 18.5% of insurers in 2017, 28% of insurers in 2018, and 94% of the insurers did not include blanket exclusions in their plans).

[236] *See, e.g.,* Calif. Health and Safety Code 1365.5; Colo. Insurance Bulletin No. B–3.49; Conn. Insurance Bulletin IC–34; 79 Del. Laws Ch. 47; DC Code 31–2231.11; Haw. Rev. Stat. 431:10A–118.3, 432:1–607.3, 432D–26.3; 50 Ill. Adm. Code 2603.35; Mass. Insurance Bulletin 2014–03; Nev. Rev. Stat. 651.070; Nev. Admin. Code 686A.140(7); 11 New York Codes Rules and Regulations 52.16; New York Insurance Code 2607, 3243, 4330; Ore. Rev. Stat. 746.015; Ore. Admin. Rules 836–080–0055; 46 Pa. Bulletin 2251; Rhode Island Health Insurance Bulletin 2015–3; 8 Va. Stat. Ann. 4724; Vt. Insurance Bulletin 174; Wash. Rev. Code 48.30.300.

[237] *See, e.g., Outfront* v. *Piper,* No. 62–cv–15–7501 (Minn. D. Ct. Nov. 14, 2016) (interpreting the state Constitution as applied to MinnesotaCare); *Good* v. *Iowa Dept. of Human Services,* No. 18–1158 (Iowa S. Ct. Mar. 8, 2019) (interpreting the Iowa Civil Rights Act as applied medical assistance).

[238] 28 CFR 35.130(g) (Title II); 42 U.S.C. 12112(b)(4) (Title I); 42 U.S.C. 12182(b)(1)(E) (Title III).

[239] *Franciscan Alliance, Inc.* v. *Burwell,* 227 F. Supp. 3d 660, 690 (N.D. Tex. 2016).

[240] *See, e.g., Condry* v. *UnitedHealth Group,* 2018 WL 3203046 (N.D. Cal. Jun 27, 2018) (''disparate impact claims on the basis of sex are not cognizable under section 1557'').

Comment: One commenter stated that because the 2016 Rule covers discrimination based on multiple protected statuses, the proposed rule would create a confusing mix of legal standards and available remedies and therefore could limit claims of intentional discrimination, while the 2016 Rule makes it easier for members of the public to file complaints of intersectional discrimination in one place.

Response: OCR has long accepted complaints alleging discrimination based on more than one protected status. OCR has handled those complaints, and will continue to handle them, under the implementing regulations of each of its applicable civil rights laws. Nothing in this final rule changes that. OCR's complaint form provides the public with the option to select multiple forms of prohibited discriminatory practices, such as both race and disability. OCR continues to encourage the public to file complaints about potentially unlawful discrimination, whether on one prohibited basis or on multiple prohibited bases.

Comment: Commenters stated that the proposed rule would compound discrimination faced by individuals with multiple protected characteristics, such as people of color who are also LEP or disabled. Some commenters said that African Americans are more likely to live with disabilities and chronic conditions, and thus would be disproportionately affected by relaxing discrimination restrictions for health insurance plans.

Response: The Department commits itself, in this final rule, to fully enforce Section 1557 according to its text and the text of the underlying statutes, as well as under the Department's implementing regulations for those statutes, as applied to the health context. Although the Department is proposing to repeal the nondiscrimination provision of the 2016 Rule at § 92.101, this final rule replaces it with a general provisions section at § 92.2. The new section will maintain the nondiscrimination requirements required by Title VI, Title IX, the Age Act, and Section 504. As such, individuals with multiple protected characteristics, such as race and disability, would be protected under the Department's enforcement of Section 1557 to the extent those statutes and regulations apply. Those statutes and regulations explain which characteristics are protected.

With respect to LEP and disability, this final rule additionally contains specific sections clarifying those protections. The underlying regulations and guidance for enforcing these statutes establish standards that are well-known by covered entities. The Department will continue to robustly enforce these statutes, and believes this final rule provides appropriate language to ensure that enforcement occurs.

Comment: Commenters contend that African American, Asian American and Pacific Islander, and Native American women are more likely to die from pregnancy-related complications and will be disproportionately affected by changes to the interpretation of sex discrimination in the proposed rule. Others contend that LGBT people of color will be harmed by the proposed regulation; they also state that LGBT people of specific national origins, including Native American and Middle Eastern, experience high rates of negative experiences in healthcare settings related to gender identity. Commenters alleged the proposed rule would disproportionately harm Native American women, women of color, and transgender individuals who are minorities.

Response: As discussed above, the 2016 Rule's definition of ''on the basis of sex'' is not included in this final rule because it exceeded the Department's statutory authority. In addition, with respect to gender identity and termination of pregnancy, the court's longstanding preliminary injunction and eventual *vacatur* of that language means that the results some commenters fear from removing such language would not be the result of this final rule. The Department is not aware of data supporting commenters' assertion that this change will have a disparate impact on the basis of race or national origin, although even if it did, that disparate impact would be attributable to the statutes rather than to this final rule. To the extent that the Department learns that individuals suffer barriers to healthcare on the basis of race, national origin, or any other protected characteristic, it will work to address those barriers within the limits of its statutory authority.

g. Examples of Discriminatory Practices (Repeal of § 92.207 of the 2016 Rule)

The Department proposed to repeal § 92.207 of the 2016 Rule, which stipulated that covered entities must not discriminate on the prohibited bases in providing or administering health-related insurance or other health-related coverage, and listed examples of such prohibited discrimination. Comments pertaining to § 92.207(b)(3)–(5) related to gender identity are discussed above in the section on discrimination on the basis of sex.

Comment: Commenters opposed repealing the explicit provisions of § 92.207 that prohibit covered entities from discriminating in health insurance or other health coverage. Commenters argued that the proposed rule did not provide any reasoned legal or policy basis for the repeal, which precluded the opportunity to provide public comment on the Department's justifications and so violated the APA. While the proposed rule discussed repealing provisions that may be duplicative, inconsistent, or confusing, commenters argued that the Department did not explain under which of these grounds it was repealing § 92.207, and that the proposed rule's supporting footnote [241] listed comparator regulatory citations that did not duplicate or contradict the provisions of § 92.207.

Commenters also expressed concern that repealing this section would allow health insurance issuers to discriminate, particularly with regard to benefit design, and could make it harder for people who experience discrimination to enforce their rights through administrative and judicial complaints. Commenters asserted that, prior to the ACA, health insurance issuers avoided covering costly individuals by employing the discriminatory practices prohibited by § 92.207, and that repealing these explicit prohibitions would allow health insurance issuers to again discriminate in a variety of ways, including by excluding or denying benefits, applying age limits, increasing costs for sicker enrollees, imposing utilization management limitations, and designing discriminatory prescription drug formularies. Commenters also argued that the ACA was intended to increase administrative oversight of private health insurance plans and to prevent discrimination in health insurance, particularly in light of the underlying civil rights laws' historically limited application to private health insurance and benefit design prior to the ACA.

Several commenters argued that the removal of specific nondiscrimination provisions under § 92.207 would make the regulation vague, eliminate guidance for covered entities, and create confusion about what is prohibited conduct, thereby increasing legal

[241] 84 FR at 27869 n.147 (comparing 45 CFR 92.207 with ''45 CFR 80.5 (health benefits under Title VI), 84.43 (health insurance under Section 504), 84.52 (health benefits under Section 504), 84.33 (rule of construction of Section 504 vis-à-vis validly obligated payments from health insurer); 86.39 (health insurance benefits and services under Title IX).'').

uncertainty and risk. This argument was reiterated by some State government regulators, who said that the specificity in the law provides clarity for both covered entities and the State, with State regulators often relying upon the standards in the 2016 Rule to ensure nondiscrimination in health insurance. Other commenters said that the repeal of § 92.207, compounded with the repeal of language access and taglines requirements, would open the door to discrimination based on national origin by healthcare providers.

Response: The number, breadth, and depth of comments received and discussed in this preamble indicate that the public was given an adequate opportunity to provide comment on the Department's justifications for this final rule.

Commenters are correct to note that the ACA has significantly expanded the applicability of Federal civil rights laws to private health insurance plans. That is why, under this final rule, all health insurance programs that remain covered by Section 1557 remain prohibited from discriminating on the grounds specified by the statute. This final rule has a section on scope at § 92.3, and the Department does not believe the rule needs an additional or separate section on health insurance in order to make this clear. OCR will examine carefully any allegations of discrimination by health insurance issuers, including through benefit design, and will vigorously enforce Section 1557's prohibitions. The Department also notes that certain health insurance issuers remain subject to similar nondiscrimination requirements under statutory provisions implemented and the regulations issued by CMS's Center for Consumer Information and Insurance Oversight (CCIIO). Commenters' specific concerns about national origin discrimination are addressed above and below in the relevant sections.

The 2019 NPRM listed § 92.207 among passages of the 2016 Rule that ''are duplicative of, inconsistent with, or may be confusing in relation to the Department's preexisting Title VI, Section 504, Title IX, and the Age Act regulations.'' [242] As the footnote referenced by commenters shows, the Department specifically pointed there to preexisting HHS regulations under those statutes regarding health benefits and health insurance.[243] The substantive overlap between these regulations and § 92.207 is sufficient to show that the latter either duplicates them, or is inconsistent with them, or may be confusing as to whether it is duplicating them or contradicting them. Because Section 1557 does not require a regulation, the Department prefers to enforce the relevant statutes, to the extent possible, through their existing regulations. The changes in the 1557 regulation made by this final rule advance the Administration's goal of reducing the regulatory burden of the ACA and of administrative action in general.[244]

The 2016 Rule's list of examples of prohibited conduct by insurers at § 92.207(b) was followed by a catchall provision at § 92.207(c) stipulating that the enumeration of those specific forms of discrimination was no limitation on the general prohibition on insurers' discriminating on the prohibited grounds. That catchall provision made § 92.207 no less vague, and gave it no less potential to cause confusion, than this final rule's general prohibition on discrimination by covered entities. The Department declines in this preamble to give guidance of this kind to State regulators, who must each work within their own State's regulatory framework for health insurance. The Department notes that State regulators may also rely upon regulations issued by CCIIO, as applicable.

h. Summary of Regulatory Changes

For the reasons discussed herein, and considering the comments received, the Department finalizes its proposed new § 92.2 without change, its repeal of § 92.4 without change, its repeal of the notice requirement in § 92.8(d) and Appendix B without change, and its repeal of § 92.101, 92.206–92.207, and 92.209 without change.

(5) Assurances in Proposed § 92.4, and Repeal of § 92.5 of the 2016 Rule

The Department proposed that the 2016 Rule's provision at § 92.3 requiring an assurance of compliance with Section 1557 be retained and redesignated § 92.4. 84 FR at 27863. Here, as throughout the proposed rule, the Department also updated the 2016 Rule's term ''State-based Marketplace℠'' to read ''State Exchange,'' in conformity with current CMS regulations. 84 FR at 27871.

Comment: Comments contended it is unclear whether submitting assurances required under this provision at § 92.4 would also fulfill the assurance requirements of Section 504 at 45 CFR 84.5.

Response: As under the 2016 Rule, the application package for all HHS grant-making agencies continues to include a requirement that the applying entity submit a signed assurance form (Form 690), which specifically references Section 1557 along with Title VI, Title IX, Section 504, and the Age Act. That form is available at *https://www.hhs.gov/sites/default/files/forms/hhs-690.pdf.* All recipients of Federal financial assistance from HHS are required to submit the consolidated form that satisfies the assurance requirements for both Section 1557 and these four other civil rights statutes.

The Department requested comment on whether this proposal struck the proper balance by retaining the assurance provisions from the 2016 Rule, and whether the benefits of these provisions exceed the burdens imposed by them.

Comment: Some commenters expressed their support for maintaining the current assurance of compliance requirement, noting that an assurance of compliance is an important step towards ensuring that covered entities know their obligations under Section 1557 and remain compliant. Additionally, questions were raised regarding which entity would be responsible for oversight, enforcement, and corrective action should a covered entity violate Section 1557 despite assuring its compliance.

Response: OCR is responsible for enforcing Section 1557 and will provide oversight, enforcement, and corrective action should a covered entity violate its obligations under Section 1557. The Department agrees that assurances of compliance provide valuable services by alerting covered entities of their obligations, and will retain these provisions under § 92.4 of this final rule.

Summary of Regulatory Changes: For the reasons given in the proposed rule, and having considered comments received, the Department finalizes its proposed § 92.4, and repeal of § 92.5 of the 2016 Rule, without change.

(6) Enforcement Mechanisms in Proposed § 92.5, and Repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule

The Department proposed provisions on enforcement of Section 1557 at the new § 92.5, 84 FR at 27863, and proposed to repeal §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and

[242] 84 FR 27869.

[243] *See* 84 FR at 27869 n.147.

[244] Executive Order 13765 on Minimizing the Economic Burden of the Patient Protection and Affordable Care Act Pending Repeal, 82 FR 8351 (Jan. 20, 2017); Executive Order 13771 on Reducing Regulation and Controlling Costs (Jan. 30, 2017); Executive Order 13777 on Enforcing the Regulatory Reform Agenda (Feb. 24, 2017); Executive Order 12866 on Regulatory Planning and Review, 58 FR 190 (Oct. 4, 1993), at § 1(b)(10).

Appendices A and C of the 2016 Rule, which also provided for enforcement mechanisms and notices.

a. Enforcement Procedures and Underlying Regulations in § 92.5(a) (Repeal of § 92.302 and § 92.6(a) of the 2016 Rule)

Proposed § 92.5(a) applies the enforcement mechanisms provided for, and available under, Title VI of the Civil Rights Act of 1964, Title IX of the Education Amendments of 1972, the Age Discrimination Act of 1975, or Section 504 of the Rehabilitation Act of 1973, with their respective implementing regulations, to Section 1557.

Comment: Various commenters expressed opposition to the Department's proposal to replace § 92.301 with § 92.5, and requested that the Department retain § 92.301. Others expressed the view that by adopting § 92.5, the Department would be incorrectly limiting the remedies available under Section 1557. Several commenters asserted that enforcement would be more difficult under the proposed rule because, they said, it creates a patchwork of legal standards—unlike the 2016 Rule, which used a single standard that permitted disparate impact claims. They said this would create confusion, hamper enforcement, and dilute the protections provided to individuals.

Response: This final rule properly limits the remedies available under Section 1557. The text of the 2016 Rule, at § 92.301(a), stated that the enforcement mechanisms available and provided for under Title VI, Title IX, Section 504 and the Age Act shall apply for the purposes of Section 1557.[245] But upon reconsideration of these issues, the Department concludes the 2016 Rule applied these mechanisms in a confusing and inconsistent manner. For certain covered entities, it applied Title VI mechanisms, not only to grounds of discrimination prohibited under Title VI, but also to those prohibited under Title IX and Section 504, while leaving Age Act mechanisms in place for the grounds of discrimination it prohibits; for other covered entities, it applied Section 504 mechanisms, not only to grounds of discrimination prohibited under Section 504, but also to those prohibited under Title VI, Title IX, and the Age Act.[246] The 2016 Rule's regulatory structure blended new standards and preexisting standards from underlying civil rights regulations, and imposed those standards alongside the underlying regulations, which were left in place. In contrast, this final rule adopts the enforcement mechanisms for these four statutes and their implementing regulations *respectively,* each for its own statute. The Department believes this minimizes the patchwork effect of the 2016 Rule by using a familiar regulatory regime under those four statutes. The Department also believes this approach is what the statutory text contemplates. Moreover, because OCR has significant experience enforcing civil rights claims using these civil rights statutes' regulations, the Department expects this change to improve enforcement of Section 1557 and, by removing possible confusion, to make it easier for both individuals and covered entities to know their rights and responsibilities.

Comment: One commenter said that the Department's proposal to remove the 2016 Rule's single standard for enforcing claims is inconsistent with the Minnesota District Court's finding in *Rumble* v. *Fairview Health Services* that ''Congress intended to create a new, health-specific, anti-discrimination cause of action that is subject to a singular standard, regardless of a plaintiff's protected class status.'' [247]

Response: The Department disagrees with this commenter's suggestion that it is inappropriate to finalize the proposed rule's repeal of provisions containing certain enforcement mechanisms. The Minnesota District Court found the language of the Section 1557 statute to be ''ambiguous, insofar as each of the four statutes utilize[s] different standards for determining liability, causation, and a plaintiff's burden of proof,'' [248] and concluded that the Department's interpretation of Section 1557 was permissible. However, the Minnesota District Court view is the minority view and has subsequently been rejected by multiple other court rulings that postdate the 2016 Rule.[249] The Department agrees with these latter courts' reasoning. To the extent that the statutory language could be ambiguous, as the Minnesota district court concluded, the Department believes that its new interpretation is a better and reasonable interpretation of the statute, and is at least an equally permissible statutory interpretation, and therefore is entitled to *Chevron* deference, *Chevron U.S.A., Inc.* v. *NRDC,* 467 U.S. 837 (1984). That the Department's interpretation represents a break with a previous interpretation does not preclude the Department from reinterpreting the statute and receiving *Chevron* deference for its new interpretation, *see, e.g., Rust* v. *Sullivan,* 500 U.S. 173, 186–87 (1991). Here, the Department believes that this final rule's approach is the one best suited to reducing confusion and robustly enforcing Section 1557's nondiscrimination provisions.

b. Compensatory Damages (Repeal of § 92.301(b) of the 2016 Rule)

The Department proposed to repeal § 92.301(b) of the 2016 Rule, which provided for compensatory damages for any and all claims under Section 1557.

Comment: Some commenters opposed the changes to the enforcement mechanisms under the proposed rule and asserted that Section 1557 makes available to all individuals any of the enforcement mechanisms available under any of the four civil rights statutes, including but not limited to compensatory damages.

Response: Although the 2016 Rule stated that compensatory damages are available in appropriate administrative and judicial actions under the Section 1557 regulation, the Department has concluded that its enforcement of Section 1557 should conform to the Department of Justice's Title VI Manual. 84 FR at 27851. The manual states that, under applicable Federal case law, compensatory damages are generally unavailable for claims based solely on a Federal agency's disparate impact regulations.[250] Consequently, the Department considers it most appropriate to finalize this rule by eliminating § 92.301(b) and reverting to enforcement under the regulations applicable to Title VI, Title IX, the Age Act, or Section 504. To the extent compensatory damages are, or are not,

[245] 81 FR 31472.

[246] *Id.*

[247] 2015 WL 1197415, at *11 (D. Minn. Mar. 16, 2015).

[248] *Id.* at *10.

[249] *See Briscoe* v. *Health Care Svc. Corp.,* 281 F. Supp. 3d 725, 738 (N.D. Ill. 2017) (''Taken together, the first two sentences of § 1557 unambiguously demonstrate Congress's intent 'to import the various different standards and burdens of proof into a Section 1557 claim, depending upon the protected class at issue.'''), quoting *Southeastern Pennsylvania Transp. Auth.* v. *Gilead Sciences Inc.,* 698–99 (E.D. Pa. 2015); *York* v. *Wellmark, Inc.,* 2017 WL 11261026, at *18 (S.D. Iowa Sept. 6, 2017) (''Congress clearly intended to incorporate the statutes' specific enforcement mechanisms rather than create a general catch-all standard applicable to all discrimination claims.''). *See also Galuten on Behalf of Estate of Galuten* v. *Williamson Med. Ctr.,* 2019 WL 1546940, at *5. (M.D. Tenn. Apr. 9, 2019) (same); *E.S. by and through R.S.* v. *Regence BlueShield,* 2018 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *Doe* v. *BlueCross BlueShield of Tennessee, Inc.,* 2018 WL 3625012, at *6 (W.D. Tenn. July 30, 2018).

[250] *See* DOJ Title VI Manual, *https://www.justice.gov/crt/fcs/T6Manual9* (citing *Alexander* v. *Sandoval,* 532 U.S. 275, 282–83 (2001), *Barnes* v. *Gorman,* 536 U.S. 181, 187 (2002), and *Gebser* v. *Lago Vista Indep. Sch.,* 524 U.S. 274, 87 (1998)).

available under those regulations, the regulations will provide for enforcement of Section 1557 in applicable circumstances in the same way.

This approach is consistent with both the best interpretation of the text and the court decisions (cited above) indicating that Section 1557 does not impose a single standard but instead incorporates the distinct enforcement mechanisms of each of the four civil rights statutes described in Section 1557.[251]

c. Implied Private Rights of Action (Repeal of § 92.302(d) of the 2016 Rule)

The Department proposed to repeal § 92.302(d) of the 2016 Rule, which stated that an individual or entity may bring a civil action in a United States District Court to challenge a violation of Section 1557 or the 2016 Rule.

Comment: Some commenters opposed repeal of this language. Several commenters argued that the existence of a private right of action is clear from the statutory language in Section 1557, which they say explicitly references and incorporates the enforcement mechanisms of the four civil rights laws listed, including a private right of action. They cited cases that allow for Section 1557 to include enforcement mechanisms separate from the mechanisms in underlying statutes.[252] Commenters said that the creation of a private right of action within Section 1557 is consistent with Congress's intent that civil rights laws be broadly interpreted to effectuate the remedial purposes of those laws, and that removing Section 1557's private right of action is inconsistent with precedent of the United States Supreme Court, which has upheld private rights of action under the preexisting civil rights laws.

Response: Upon reconsideration of this issue, the Department no longer intends to take a position in its regulations on the issue of whether Section 1557 provides a private right of action. To the extent that Section 1557 permits private rights of action, plaintiffs can assert claims under Section 1557 itself rather than under the Department's Section 1557 regulation.

Comment: Commenters requested that the Department adopt a regulatory framework for Section 1557 where there is a requirement for exhaustion of administrative remedies before a party can bring a private right of action.

Response: Because the Department is eliminating the language specifying a right to sue, the Department does not consider it necessary to establish a framework and a requirement for exhaustion of administrative remedies before filing suit in court.

d. Voluntary Action (Repeal of § 92.302(c) and § 92.6(b) of the 2016 Rule)

The Department proposed to repeal § 92.302(c) of the 2016 Rule, as well as § 92.6(b), which set forth provisions concerning voluntary cooperation with requests for information, and voluntary action beyond the requirements of Section 1557. These provisions have parallels in the regulations implementing Title VI, Section 504, Title IX, and the Age Act,[253] which the Department will use to enforce Section 1557.

The Department did not receive comments specific to these sections.

e. Access to Records of Compliance (Repeal of § 92.303(c) of the 2016 Rule)

The Department proposed to repeal § 92.303(c) of the 2016 Rule, which set forth the Department's obligations to permit access by OCR to review records and sources of information, and to otherwise comply with OCR investigations under the 2016 Rule.

Comment: Commenters expressed concern that the proposed rule undermines the Department's enforcement authority concerning compliance with Section 1557 by programs and activities administered by the Department.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions addressing access to review of covered entities' records of compliance.[254] The language in the 2016 Rule to this effect was unnecessary, as OCR has the tools to review records and sources of information under existing regulations.

f. Prohibitions on Intimidation and Retaliation (Repeal of § 92.303(d) of the 2016 Rule)

The Department proposed to repeal § 92.303(d) of the 2016 Rule, which concerns intimidation and retaliation provisions that pertain to the Department.

Comment: Several commenters contended that under the proposed rule, those bringing Section 1557 claims would no longer be explicitly protected from retaliation and discrimination.

Response: The regulations implementing Section 1557's four underlying statutes already contain provisions against intimidation and retaliation as appropriate.[255] The language in the 2016 Rule to this effect was unnecessary. Moreover, OCR ensures the confidentiality of complainants under all the statutes it enforces, to the extent permitted by law and consistent with OCR's investigative needs. In some cases, the Freedom of Information Act, the APA, or other laws may require disclosure of certain information provided by complainants.

g. Perpetuating Discrimination by Assistance and Utilizing Criteria or Methods of Administration (Repeal of § 92.101(b)(1)(ii), (b)(3)(ii), and (b)(4)(ii) of the 2016 Rule)

The Department proposed to repeal § 92.101(b)(1)(ii) and § 92.101(b)(4)(ii), which prohibited significant assistance to any agency, organization, or person that discriminates on the basis of race, color, national origin, or age. The Department also proposed to repeal § 92.101(b)(3)(ii), which prohibited utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex.

Comment: One commenter objected to repealing the prohibition on the utilization of criteria or methods of administration that have the effect of subjecting individuals to discrimination on the basis of sex. Arguing that Section 1557 is its own authority, the commenter stated that it is irrelevant that the Title IX regulations do not

[251] *See Galuten,* 2019 WL 1546940, at *5 n.8 (because ''the Age Discrimination Act would not authorize [ ] compensatory damages,'' ''it appears that a Federal court with jurisdiction would be constrained to dismiss Plaintiff's claims for compensatory . . . damages under the ACA'').

[252] Commenters cited *Edmo* v. *Idaho Dep't of Corr.,* No. 1:17–cv–00151–BLW, 2018 WL 2745898, at *9 (D. Idaho June 7, 2018) (''[C]ross-referencing the statutes and the express incorporation of the enforcement mechanisms from those statutes is probative of Congressional intent to provide both a private right and a private remedy for violations of Section 1557.''); *Esparza* v. *Univ. Med. Ctr. Mgmt. Corp.,* No. 17–4803, 2017 WL 4791185, at *5 (E.D. La. Oct. 24, 2017) (concluding it was ''abundantly clear to the Court that Congress intended to create a private right of action to enforce § 1557''); *Doe One* v. *CVS Pharmacy, Inc.,* 348 F. Supp. 3d 967, 982 (N.D. Cal. 2018) (finding plaintiffs had not sufficiently alleged disparate impact); *see also Cannon* v. *Univ. of Chi.,* 441 U.S. 677, 703 (1979) (recognizing that Congress intended to create Title IX remedies comparable to those available under Title VI, including a private cause of action for victims of the prohibited discrimination, and finding that age and advanced degrees criteria had a disparate impact on women); *Rumble* v. *Fairview Health Servs.,* 2015 WL 1197415.

[253] *See* 45 CFR 80.7(d), § 80.8(c)(1) (Title VI); § 84.6(b) (Section 504); proposed § 86.71 (Title IX incorporating 45 CFR 80.7(d)); § 90.49(c) (Age).

[254] *See* 45 CFR 90.45, § 91.31 (Age Act) and § 80.6(c) (Title VI); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.6(c)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.6(c)).

[255] *See* 45 CFR 80.7(e) (Title VI); § 91.45 (Age Act); 45 CFR 84.61 (Section 504 incorporating 45 CFR 80.7(e)); § 86.71, as finalized here (Title IX incorporating 45 CFR 80.7(e)).

contain a disparate impact provision. Some commenters also contended that removing the ''significant assistance'' provision would undermine enforcement.

Response: The prohibition on perpetuating discrimination by providing significant assistance to any agency, organization, or person that discriminates is identified only in the Title IX and Section 504 regulations, as applied to sex and disability discrimination claims;[256] the 2016 Rule applied it also to claims on the basis of race, color, national origin, or age. Similarly, as discussed above in the section on discrimination on the basis of sex, there is no disparate impact language in the Department's Title IX regulations, but the 2016 Rule made such language applicable to sex discrimination claims brought under Section 1557. For the reasons given earlier in this section, the Department considers it appropriate to rely on the enforcement mechanisms appropriate to each underlying civil rights statute, rather than to create a new and confusing civil rights regulatory framework specific to the enforcement of Section 1557.

h. Notices of Nondiscrimination Rights and Statement of Nondiscrimination Under the 2016 Rule (Repeal of § 92.8 of the 2016 Rule)

The Department proposed to repeal § 92.8 of the 2016 Rule, which required a notice informing individuals about nondiscrimination and accessibility requirements, such as the sample notice and nondiscrimination statement at Appendix A to Part 92.

Comment: Some commenters contended that HHS did not consider how the removal of the 2016 Rule's notice provisions may result in decreased access to, and utilization of, healthcare by people with disabilities, people with LEP, older adults, people who are LGBT, and other vulnerable populations. These commenters argued that with the notice provision's removal, these protected populations will be limited in knowing their rights under Federal civil rights laws, and in knowing how to file complaints with OCR if faced with discrimination in a healthcare setting. Others stated that the Department did not provide an evidentiary basis for what it deemed would be a ''negligible'' impact on people with LEP or ''additional societal costs'' as a result of removing the notice provisions. Commenters proposed that instead of eliminating the notice provision, the Department should consider requiring covered entities to provide notice on an annual basis, when updated, and upon request, in order to harmonize with the Health Insurance Portability and Accountability Act (HIPAA)'s annual notice requirements. Other commenters similarly proposed that the Department should consider specifying a number of times that a covered entity should send notice to individuals over the course of a year.

Response: The regulations implementing Section 1557's four underlying statutes already contain notice provisions.[257] The language in the 2016 Rule to this effect was unnecessary.

Individuals belonging to any protected category under Section 1557, including those with disabilities or LEP, remain covered under existing standards regarding notice. The Department is unaware of data suggesting that those regulations have been or are inadequate to their purpose of making individuals aware of their civil rights. To the extent that it discovered such data, it would consider revising each regulation as appropriate.

Each of the relevant underlying regulations has its own unique standards on providing notice, tailored to the purposes of each civil rights statute.[258] Compressing these into a single standard under the 2016 Rule has led to an unjustifiable burden and understandable confusion. The Department's estimates of regulatory burden are discussed in the RIA.

Comment: Some commenters stated the Department should clarify when the notice and taglines requirements will no longer be effective with respect to timeframes such as open enrollment for Exchanges, employer-sponsored plans, and Medicare. Most of these communications are subject to the current notice and taglines requirements under the 2016 Rule. Commenters sought clarification from the Department as to whether OCR will enforce the notice and taglines requirement against any covered entity from the date of the proposed rule (June 14, 2019).

Response: The changes made in this final rule will be effective 60 days from the publication of this final rule in the **Federal Register**. The 2016 Rule is in effect until that time, except as enjoined or vacated by courts.

Comment: Several commenters requested that the Department retain parts of § 92.8 of the 2016 Rule that require the designation of a responsible employee and grievance procedures, and the text of sample grievance procedures in Appendix C to Part 92. They said that retaining these provisions would increase access to healthcare and retain uniform responsible employee and grievance procedures.

Response: The Department believes it is appropriate to rely on the regulatory framework that has already been set forth for Section 1557's four underlying statutes. To the extent that those implementing regulations have responsible employee and grievance procedures, they are sufficient for enforcement of Section 1557.

i. Summary of Regulatory Changes

For the reasons described in the proposed rule and considering the comments received, the Department finalizes § 92.5, and the proposed repeal of §§ 92.6, 92.7, 92.8, 92.101, 92.301, 92.302, 92.303, and Appendices A and C of the 2016 Rule, without change.

(7) Relationship to Other Laws in Proposed § 92.6, and Repeal of § 92.2(b) and 92.3 of the 2016 Rule

The Department proposed to repeal §§ 92.2(b) and 92.3 of the 2016 Rule, which addressed the application and relationship of Section 1557 and the 2016 Rule to other laws. The Department proposed instead a new § 92.6. The new § 92.6(a) states that nothing in the 1557 regulations shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards applicable under Title VI, Title VII, Title IX, the Age Act, or Section 504, or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2. The new § 92.6(b) states that insofar as the application of any requirement under the Section 1557 regulations would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided

[256] *See* 45 CFR 84.4(b)(1)(v) (Section 504); § 86.31(b)(6), as finalized here (Title IX).

[257] *See* 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act).

[258] Title VI, 45 CFR 80.6(d), and the Age Act, 45 CFR 91.32, contain general requirements to provide notice. Section 504 requires more: A covered entity must ''take appropriate initial and continuing steps to notify [individuals] that it does not discriminate on the basis of [disability]'' and include this information in its ''recruitment materials and publications.'' 45 CFR 84.8. Title IX goes even further: A covered entity must ''prominently'' display its notice of nondiscrimination in ''each announcement, bulletin, catalog, or application form which it makes available to any [covered person], or which is otherwise used in connection with the recruitment of students or employees'' and not ''distribute a publication . . . which suggests, by text or illustration, that such [covered entity] treats applicants, students, or employees differently on the basis of sex except as such treatment is permitted by [Title IX].'' 45 CFR 86.9.

by the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*); the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 *et seq.*); Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d); the Coats-Snowe Amendment (42 U.S.C. 238n); the Church Amendments (42 U.S.C. 300a–7); the Religious Freedom Restoration Act (42 U.S.C. 2000bb *et seq.*); Section 1553 of the Patient Protection and Affordable Care Act (42 U.S.C. 18113); Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023); the Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)); or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.

a. Conscience Laws

Comment: Some commenters supported revising the Section 1557 Rule to explicitly identify the Federal public consensus that conscience statutes reflect, in order to ensure appropriate protection for all civil rights. Some noted that the Coats-Snowe and Church Amendments were passed by Congress and signed into law on a bipartisan basis, reflecting explicit protections from discrimination on the Federal, State, or local level if healthcare providers or hospitals seek to be exempted from participation in the performance or training for abortions.

Some commenters supported including references to conscience and religious freedom laws in § 92.6(b), stating that protecting the conscience rights of healthcare providers also protects patients by protecting trust between patients and providers, and allowing providers who entered healthcare on the basis of moral convictions to serve those who are ill consistent with that ethic. They also stated that providers must exercise professional judgment as to what constitutes the best interest of the patient. Commenters stated that respect for the autonomy of the patient should not be misconstrued to create coercive obligations on providers overriding the best interest of the patient. Some stated that the 2016 Rule resulted in a ''Hobson's choice'' of options for certain providers, who were required under the rule to either violate their ethical pledges to Do No Harm or their longstanding oaths as physicians, or comply with the 2016 Rule and be forced to perform abortions. Some commenters also suggested that if those providers complied with laws like Title VII and conscience laws that require religious accommodation, they could risk noncompliance with the 2016 Rule, or vice versa. Some of those commenters contended that coercing providers to compromise their moral integrity negatively impacts both provider and patient, and ultimately hurts the provider's ability to provide patient care. If facing the threat of coercion, such commenters said, providers will continually face escalating moral dilemmas in the practice of their job, resulting in stress and burnout in a time when physician shortages are already increasing.

Other commenters opposed the language in § 92.6(b), saying that the proposed rule construes the Federal conscience protections more broadly than existing law allows. They contended conscience protections and religious liberty are meant for individuals, not entities, and that healthcare systems and entities cannot have the right of conscience, because the notion of conscience is limited to individuals. Some commenters also recommended that instead of removing gender identity and termination of pregnancy language and having the language in § 92.6(b) concerning conscience and religious freedom statutes, the Department should merely insert a narrow religious exemption, for they asserted that preventing discrimination on the basis of gender identity or termination of pregnancy is more critical than religious freedom rights, which should be more heavily scrutinized for pretextual discrimination. Other commenters stated that conscience and religious protections under the current statutes are sufficient and incorporating conscience or religious exemptions is unnecessary. Some opposed referring to the Coats-Snowe Amendment in § 92.6(b), saying that it would allow healthcare providers to decline to make medical care available to any patient based on personal beliefs. Some added that the Department does not have the authority to interpret statutes such as the Coats-Snowe Amendment to limit or supersede Section 1557, which should be seen as controlling law. One commenter stated that Federal conscience statutes are not applicable to the ACA because they are not mentioned in the ACA.

Response: Section 1557 and the ACA did not repeal any Federal conscience law. Indeed, ACA § 1303 specifically provides that ''[n]othing in [the ACA] shall be construed to have any effect on Federal laws regarding—(i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.'' 42 U.S.C. 8023(c)(2). At the time of its passage, the President stated that ''[u]nder the [ACA], longstanding Federal laws to protect conscience (such as the Church Amendment, 42 U.S.C. 300a–7, and the Weldon Amendment, section 508(d)(1) of Pub. L. 111–8) remain intact and new protections prohibit discrimination against healthcare facilities and healthcare providers because of an unwillingness to provide, pay for, provide coverage of, or refer for abortions.'' [259] New law is to be interpreted consistently with existing law wherever possible, and the Department sees no conflict between Section 1557 and preexisting Federal conscience statutes.

This final rule emphasizes that the Section 1557 regulation will be implemented consistent with various statutes enacted by Congress, including conscience and religious freedom statutes. This should not be a controversial statement, nor should it even be necessary to add, as the Department is always obligated to comply with relevant Federal statutes. But the fact that so many commenters found this provision objectionable is itself a reminder of why such a provision is needed. The fact that the 2016 Rule was the subject of litigation and injunctive relief, in part because of plaintiffs' claim that the 2016 Rule did not clearly state that it would be enforced consistent with conscience and religious freedom statutes, is also a reason the Department believes it is appropriate to make the issue clearer in this final rule. This final rule does not purport to construe the statutes referenced in this section, so it cannot be construing them too broadly (or too narrowly). It would be inappropriate to replace § 92.6(b)'s language with a religious exemption, whether narrow or broad, because § 92.6(b) neither adds to nor takes away from the conscience and religious freedom statutory language that Congress has enacted.

Commenters who discuss the gender identity and termination of pregnancy provisions of the 2016 Rule in this context are confusing two different issues. As stated above, this final rule eliminates the 2016 Rule's provisions related to gender identity for numerous

[259] Executive Order 13535, ''Patient Protection and Affordable Care Act's Consistency with Longstanding Restrictions on the Use of Federal Funds for Abortion'' (March 24, 2010).

legal and policy reasons that have nothing to do with conscience protection, and it eliminates the 2016 Rule's provisions on termination of pregnancy because they failed to incorporate Title IX's abortion-neutrality language (which goes much farther than any mere protection for individual conscientious objectors). In neither case could the Department's concerns have been adequately addressed by permitting individuals to claim a conscientious exemption from those objectionable provisions.

Comment: Many providers with conscientious or religious concerns stated that their medical judgment is based upon a review of the clinical evidence, and that medical ethics requires that they act in accordance with their best medical judgment. For example, some commenters contended that they have practices, such as in the obstetrics and gynecology field, which are specialized to the biological sex of females based on a binary distinction between males and females. Others had objections because of their moral and religious convictions concerning specific procedures that they sincerely believed, both in their medical judgment and ethically, would endanger the health and wellbeing of a person.

Response: By respecting medical professionals' judgment, the Department protects their right and responsibility to follow medical ethics in treating patients to the best of their ability. In their objections to abortion, sex-reassignment procedures, or other treatments covered by the 2016 Rule, some providers assert that not only their medical judgment but also their conscientious or religious beliefs would be burdened by such procedures. The Department believes that the best way to avoid such burdens on conscience is, instead of requiring individual objectors to assert claims under RFRA or other applicable laws, to avoid regulatory requirements that would have forced them to provide such procedures in the first place, as well as to ensure that remaining requirements are interpreted consonant with the applicable Federal conscience statutes.[260] This will protect both providers' medical judgment and their consciences, thus helping to ensure that patients receive the high-quality and conscientious care that they deserve.

Comment: Some commenters argued that religious or conscience exemptions were used as a pretext to conceal animus against LGBT individuals. Commenters expressed concerns that the proposed rule would improperly prioritize conscience and religious freedom rights over LGBT rights or civil rights in general. However, others, such as hospital associations that expressed support for care regardless of gender identity and sexual orientation, explained that they also support appropriate protections for the reasonable accommodation of a nurse or other provider who may assert a sincere conscientious objection to participating in a particular medical procedure. Other providers stated that the exemption they seek is from providing certain treatments, not from treating certain patients. Some submitted their hospital nondiscrimination policies, contending those policies do not include blanket denial of healthcare treatment for LGBT individuals, and in many cases expressly prohibit discrimination on the basis of gender identity or sexual orientation, but that they nonetheless seek limited exemptions on the basis of sincerely held religious and moral convictions. Some individual, institutional, and religious groups affiliated with healthcare providers also provided comments stating that both in policy and in practice, they have never refused to care for a patient on the grounds of their identity as an LGBT individual. They stated that they object to being required to perform services that violate sound medical judgment, ethical convictions, or religious beliefs about the dignity of human beings. Commenters also submitted surveys finding healthcare professionals experienced pressure, coercion or punishment for not participating in training, performing a procedure, or writing a prescription when they had medical or scientific objections.

Response: The Department recognizes that members of the public hold different opinions concerning conscience and religious freedom laws and their interplay with various health contexts, including with respect to LGBT concerns. This final rule does not, however, create any new conscience or religious freedom exemptions beyond what Congress has already enacted.

Comment: Some commenters contend that women of color are more likely to rely on religious hospitals to receive care, and thus women of color will be more likely to be affected by religious exemptions that allow religious hospitals to deny certain reproductive care. Others opposed inclusion of references to conscience and religious freedom laws, stating that the danger of losing Federal funds is the only incentive for covered entities to offer more abortion, contraception, sterilization, gender identity affirming, or sex reassignment services. Other commenters stated that conscience laws were intended to protect health professionals from precisely that form of government coercion.

Some commenters stated that the proposed rule, in particular concerning the Church Amendments, 42 U.S.C. 300a–7, is inconsistent with EMTALA, because the conscience exemptions would deny emergency and stabilizing care, including with respect to abortion or sterilization. Other commenters stated that the rule is consistent with EMTALA, because EMTALA requires protection of the ''unborn child.''

Response: The Department is not aware of any instance to date where a facility required to provide emergency care under EMTALA was unable to do so because of objections protected by the Church Amendments. This final rule does not adopt any stance on how hypothetical conflicts between the Church Amendments and EMTALA ought to be resolved. The Department intends to read every law passed by Congress in harmony to the fullest extent possible, so that all laws are given their fullest possible effect. Commenters' other policy concerns about the possible healthcare effects of the conscience laws are among the many complicated factors that Congress had to balance in the texts of the separate statutes, and it is not the Department's job to overturn the results of that legislative process.

Comment: One commenter compared the proposed rule with the 2019 Conscience Rule and alleged that the Department's recent actions of decreasing protections for patients and increasing protections for providers run contrary to actual public sentiment. The commenter alleged that between 2008 and January 2018, the Department received fewer than 50 complaints regarding violations of Federal religious or conscience statutes while receiving 30,000 complaints of other civil rights discrimination in 2017 alone. Other commenters stated that the 2019 Conscience Rule violates EMTALA, and results in the denial of transition-related surgeries or abortion services in emergencies, because conscience statutes allow exemptions from performance of sterilizations or abortions. Commenters also recommended that the Department delay finalizing the proposed rule pending the outcome of litigation challenging the 2019 Conscience Rule, in order to provide clarity and finality, and to reduce litigation risk as regards the construction of Section 1557 with conscience statutes.

[260] *See California* v. *Azar,* at *24 (''HHS acted well within its authority in deciding how best to avoid conflict with the Federal conscience laws.'').

Response: This final rule is separate from the 2019 Conscience Rule. It does not implement that rule, and it does not implement the statutes implemented by that rule. Several courts have vacated the 2019 Conscience Rule before its effective date, but none of those courts issued any order against the conscience statutes themselves,[261] which the Conscience Rule sought to implement and which this final rule references. Because this final rule does not refer to or rely on the 2019 Conscience Rule, there is no reason to delay finalization of this rule pending further litigation over the 2019 Conscience Rule.

b. Religious Freedom Restoration Act

Comment: Some commenters said that the proposed rule's inclusion of the Religious Freedom Restoration Act (''RFRA'') in § 92.6(b) was unclear and confusing. Others said that it should be excluded because it would allow providers to deny needed healthcare. Other commenters supported inclusion of RFRA, agreeing that it is an important protection for religious conscience from government-imposed burdens. Commenters also pointed out that the Federal government has clearly articulated its commitment to RFRA and religious freedom laws under a recent executive order [262] and the subsequent Attorney General Memorandum [263] to executive departments and agencies that ''Congress has taken special care with respect to programs touching on abortion, sterilization, and other procedures that may raise religious conscience protections.'' [264] One commenter supported the Department's explicit acknowledgment that Section 1557 is subject to RFRA, stating that religious organizations have had to repeatedly go to court to vindicate their conscience rights against the Department's enforcement of the 2016 Rule. Others said that referring to RFRA accurately reflects statutory text and Congressional intent, and would correct a legal misinterpretation of Section 1557 that has been recognized as such by the *Franciscan Alliance* court.

Response: Congress explicitly stated that RFRA applies to ''all Federal law, and the implementation of that law, whether statutory or otherwise, and whether adopted before or after November 16, 1993 . . . unless such law explicitly excludes such application by reference to this chapter.'' [265] Section 1557 does not explicitly exclude such application, so the Department is bound to enforce Section 1557 in compliance with RFRA. The Department agrees with the court in *Franciscan Alliance* that particular provisions in the 2016 Rule violated RFRA as applied to private plaintiffs.[266] In order to ensure that Section 1557 regulations are now interpreted consistently with, and implemented in compliance with, RFRA, the Department considers it appropriate to specify this explicitly.

Comment: Some commenters stated that the text of the Section 1557 statute does not contain a religious exemption, and therefore asked the Department not to include a religious exemption, either explicitly or by reference in § 92.6(b). Other commenters stated that exemptions on religious bases should be blanket exemptions, not case-by-case exemptions as outlined in RFRA.

Response: This final rule does not craft a religious exemption to Section 1557. Congress has already created various religious and conscience protections in healthcare by enacting several statutes, including RFRA, healthcare conscience statutes, and the religious organization exception in Title IX. This final rule simply states that the Section 1557 regulation will be implemented consistent with those statutes.

c. Title IX

Comment: Some commenters opposed including reference to the Title IX statutory religious exemption in § 92.6(b). They said that Section 1557 does not require or authorize Title IX religious or abortion exemptions, because these are limited to educational institutions, and are improper in the healthcare context. Others expressed concern that Section 1557 and Title IX would be subject to exemptions that HHS does not apply to its rules enforcing Title VI.

Other commenters stated that it is unnecessary and unwise to change the standard for the religious exemption under Title IX, and pointed to the legislative history of Title IX, where the Conference Committee rejected an amendment proposed by Senator Hatch to loosen the standard for the religious exemption. Commenters stated that § 92.101(c) of the 2016 Rule took an inconsistent analysis by failing to incorporate Title IX's religious and abortion exemptions, despite incorporating exemptions from the other three Federal civil rights laws referenced in Section 1557.

Still other commenters stated that the Title IX exemption should not apply broadly to large religious institutional healthcare facilities, or that conscience protections and religious liberty cannot apply to institutions like hospitals or healthcare systems because they cannot have the right of conscience: They suggested that conscience is limited to individuals and that an institution is not a person. Other commenters disagreed and pointed to legislative history to recognize that the protections under Title IX's religious exemption are not just for individuals but for institutions.

Response: The text of Title IX applies its religious exemption to institutions, so there should be no question that religious exemptions can apply to institutions as well as individuals.[267] As discussed above regarding termination of pregnancy, the *Franciscan Alliance* court vacated portions of the 2016 Rule for failing to incorporate Title IX's exemption for religious institutions. More generally, the Supreme Court in *Burwell* v. *Hobby Lobby* held that RFRA can apply to for-profit corporations. 573 U.S. 682 (2014). And that holding parallels other Supreme Court precedent making clear that organizations may engage in exercises of religion protected by the First Amendment. *See, e.g., Masterpiece Cakeshop, Ltd.* v. *Colo. Civil Rights Comm'n,* 138 S. Ct. 1719, 1732 (2018); *Hosanna-Tabor Evangelical Lutheran Church & Sch.* v. *EEOC,* 565 U.S. 171, 199 (2012); *Church of the Lukumi Babalu Aye, Inc.* v. *City of Hialeah,* 508 U.S. 520, 525–26, 547 (1993).

Under the Civil Rights Restoration Act amendments to Title IX, the Title IX religious exemption is no longer limited to educational institutions controlled by religious organizations: Any educational operation of an entity may be exempt from Title IX due to control by a religious organization.[268] Section 1557

[261] *See New York* v. *United States Dep't of Health & Human Servs.,* 414 F. Supp. 3d 475 (S.D.N.Y. 2019); *City & Cty. of San Francisco* v. *Azar,* 411 F. Supp. 3d 1001 (N.D. Cal. 2019); *Washington* v. *Azar,* No. 2:19–CV–00183–SAB, 2019 WL 6219541 (E.D. Wash. Nov. 21, 2019).

[262] Executive Order 13798 on Promoting Free Speech and Religious Liberty, 82 FR 21675 (May 4, 2017).

[263] Memorandum of the Attorney General (Oct. 6, 2017), *https://www.justice.gov/opa/press-release/file/1001891/download.*

[264] *Id.*

[265] 42 U.S.C. 2000bb–3.

[266] *Franciscan Alliance,* 2019 WL 5157100 at *9 (''[T]he Court holds that the Rule, which expressly prohibits religious exemptions, substantially burdens Private Plaintiffs' religious exercise in violation of RFRA.'')

[267] *See* 20 U.S.C. 1681(a)(3) (''this section shall not apply to an educational institution which is controlled by a religious organization if the application of this subsection would not be consistent with the religious tenets of such organization''); 20 U.S.C. 1687(4) (excluding ''any operation of an entity which is controlled by a religious organization if the application of section 1681 of this title to such operation would not be consistent with the religious tenets of such organization'').

[268] *Id.*

incorporates the statutory scope of Title IX, so it is appropriate for this rule to incorporate the Title IX statutory language concerning religious institutions and abortion neutrality. Although much of Title VI case law can be applied to Title IX situations, the parallel is not perfect because Title IX contains several important statutory exemptions that are absent from Title VI. These are mentioned above in the section on discrimination on the basis of sex.[269]

Comment: Commenters stated that adding the Title IX exemption for religious entities violates the Establishment Clause, because it would force third parties to subsidize or bear the costs of religious exercise, citing *Cutter* v. *Wilkson,* 544 U.S. 709 (2005), *Lee* v. *Weisman,* 505 U.S. 577 (1992), and *Estate of Thornton* v. *Caldor, Inc.* 472 U.S. 703 (1985). Commenters indicated that religious exemptions must take an adequate account of the burdens a requested accommodation may impose on nonbeneficiaries. Commenters similarly suggested that the rule's requirement that the Section 1557 rule be implemented consistent with RFRA would violate the Establishment Clause and should be limited to instances where no third party is harmed by application of RFRA.

Response: Neither RFRA (as applied to Federal government actions), nor Title IX's statutory exemptions, have ever been held unconstitutional by the Supreme Court. The Court has upheld Title VII's statutory exemption for religious organizations,[270] and has denied that statutory exemptions of this type violate the Establishment Clause.[271] The Department will comply with all relevant court rulings.

d. Other Laws and Cases

Comment: The Department received comments supporting the express mention of Section 1303 of the ACA[272] in proposed § 92.6. These commenters contended that this helps clarify the prohibition on mandating QHPs to provide abortions, and that it could not have been Congress's intent to mandate abortion coverage in Section 1557. Section 1303 expressly leaves it up to issuers of health plans to decide not to cover abortion. Other comments stated that Section 1303 should not be expressly mentioned in this rule and that termination of pregnancy should remain as a prohibited basis of discrimination under the Section 1557 rule, notwithstanding Section 1303.

Response: In Section 1303, Congress specified that nothing in the ACA (therefore including Section 1557) ''shall be construed to have *any effect* on Federal laws regarding (i) conscience protection; (ii) willingness or refusal to provide abortion; and (iii) discrimination on the basis of willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion'' (emphasis added). The Department considers it appropriate to finalize § 92.6 to indicate that the Section 1557 regulation will be implemented consistent with Section 1303, as that provision is relevant to the interpretation of the Federal laws that Section 1557 incorporates by reference.

Comment: The Department received comments from State public officials raising concerns about the 2016 Rule's constitutionality. State public officials contended that the 2016 Rule violated the Spending Clause because the Federal government did not provide adequate notice by clear statement and opportunity to agree to the Section 1557 Rule's new conditions on receipt of Federal financial assistance. States also raised objections under the Eleventh Amendment to the Department-initiated Section 1557 enforcement actions. States identified their obligation to protect the First Amendment rights to free exercise of religion of their citizenry. However, these State commenters noted that the proposed rule's removal of the definition of ''on the basis of sex,'' and the addition of the religious and abortion exemptions, would address these concerns.

Other commenters stated that when the Department said in the 2019 NPRM that State and local entities are better suited than the Federal government to address gender identity discrimination, this was contrary to constitutional law principles and undermined the right to be free from discrimination.

Response: The Department is not aware of any Supreme Court precedent that would call into question the constitutionality of its reasoning about federalism as laid out in the 2019 NPRM.[273] The Department believes that this final rule resolves the concerns States had about the 2016 Rule's constitutionality.

Comment: Some comments from State public officials stated that the 2016 Rule conflicted with State laws on religious accommodations and independent medical judgment of healthcare providers. A different group of State public officials submitted a separate joint comment stating that their States' civil rights legislation and/or regulations prohibited discrimination on the basis of gender identity or sexual orientation, and that the proposed rule would remove the consistency of their laws with the 2016 Rule. They argued that State insurance agencies acted first to promulgate regulations after passage of Section 1557 in 2010, assuming that Section 1557 prohibited gender identity discrimination. Some States also said that the proposed rule's incorporation of Federal conscience statutes would result in conflict with State laws, or with other Department rules requiring covered entities to provide care to all (*e.g.,* vaccination care).

Some States said that as employers they had difficulty resolving religious accommodation laws with Section 1557. Others stated they had no difficulties resolving consumer complaints of discrimination on the basis of gender identity.

Response: The Department agrees that States have a public interest in enforcement of their statutes, including conscience and religious freedom statutes. This final rule respects Federalism: It neither interferes with State laws on conscience protections and medical judgment, nor does it interfere with State laws that provide additional protections (so long as these do not violate other Federal statutes). The rule also explicitly provides that Section 1557 will not be taken to supersede State laws that provide additional protections against discrimination on the enumerated grounds. The Department is not aware of actual, as opposed to hypothetical, conflicts between the statutes incorporated here and other laws or

[269] 20 U.S.C. 1681(a)(6)(B); 34 CFR 106 *et seq.*

[270] *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* 483 U.S. 327, 338–40 (1987); *see also Walz* v. *Tax Commn. of City of New York,* 397 U.S. 664 (1970) (upholding the constitutionality of a state's statutory property tax exemption for religious organizations); *Id.* at 675 (''The grant of a tax exemption is not sponsorship since the government does not transfer part of its revenue to churches but simply abstains from demanding that the church support the state. No one has ever suggested that tax exemption has converted libraries, art galleries, or hospitals into arms of the state or put employees 'on the public payroll.' There is no genuine nexus between tax exemption and establishment of religion.'').

[271] *Corporation of the Presiding Bishop of the Church of Jesus Christ of Latter-Day Saints* v. *Amos,* at 336–37 (''We agree with the District Court that this purpose does not violate the Establishment Clause. . . . A law is not unconstitutional simply because it allows churches to advance religion, which is their very purpose.''); *Id.* at 339 (''It cannot be seriously contended that [Title VII's statutory exemption] impermissibly entangles church and state; the statute effectuates a more complete separation of the two and avoids the kind of intrusive inquiry into religious belief that the District Court engaged in in this case.'').

[272] 42 U.S.C. 18023.

[273] *See* 84 at 27857 (2019 NPRM discussion of ''Sensitive Balancing of Competing Interests at the Local Level'' at Part g).

regulations that the Department enforces.

Comment: A commenter supported including the reference to Section 1553 of the ACA in § 92.6 in order to protect nurses who have objections to participating in assisted suicide, promote trust in the nurse-patient relationship, and keep the profession open to candidates who want to serve as nurses but object to participation in assisted suicide.

Commenters supported the proposal's specification that the proposed regulation not be applied in a manner that conflicts with or supersedes exemptions, rights, or protections contained in several civil rights statutes, such as the Architectural Barriers Act of 1968, the Americans with Disabilities Act of 1990 (as amended by the Americans with Disabilities Act Amendments Act of 2008), and Section 508 of the Rehabilitation Act of 1973.

Some commenters requested that the word ''obligations'' be added in order to specify that the proposed regulation not be applied in a manner that conflicts with or supersedes the exemptions, rights, protections or obligations contained in several civil rights statutes. This addition would help clarify that this consideration is intended to help reduce redundancy, compliance burdens, and confusion for healthcare providers.

Response: The Department appreciates all these comments in support of the proposed rule. The Department declines to add the word ''obligations,'' as the final rule's language adequately addresses its interaction with other civil rights statutes.

Comment: One commenter noted that a number of provisions in the proposed rule seem to contradict portions of the recent Conscience Rule published by the Department.[274] In particular, this proposed rule eliminates and narrows definitions advanced by the 2016 Rule, while the Conscience Rule expands definitions and protections. This proposed rule seeks to drastically cut costs of enforcement by eliminating notice and taglines requirements and other costs for providers, while the Conscience Rule will impose new costs on providers and individuals. Finally, this proposed rule and the Conscience Rule use different definitions to define health programs and activities.

Response: The 2019 Conscience Rule and this final rule rely on different statutes, and different underlying regulations for those statutes, so it is not surprising that there should be differences between their respective definitions and protections. The four civil rights statutes underlying Section 1557 have implementing regulations containing appropriate definitions, protections, and enforcement mechanisms. As explained herein, the Department has now deemed most of the parallel provisions in the 2016 Rule to be unnecessary, superfluous, or unduly burdensome. Therefore the Department considers it appropriate to finalize a Section 1557 rule that is shorter than the 2016 Rule and relies more substantially on those underlying regulations. In contrast, the 2019 Conscience Rule (which has been vacated and is subject to pending litigation) modified previous regulations that are only three sentences long, and that lack the kinds of definitions and enforcement mechanisms found in regulations implementing other civil rights laws enforced by the Department. In promulgating the 2019 Conscience Rule, the Department concluded more extensive regulations were needed in the absence of existing regulations containing such provisions.

Comment: One commenter stated that the proposed rule's changes to the relationship to other laws section at § 92.6 are contrary to the requirements of Section 1557, because the 2016 Rule stated that neither it nor Section 1557 would apply a lesser standard than Title VI, Title IX, Section 504, or the Age Act. In contrast, the proposed rule expressly states that application of the proposed rule will not be required if the proposed rule violates, departs from, or contradicts a number of other Federal civil rights laws.

Response: The Department seeks to give all laws their fullest possible effect. It does not believe that the other laws referenced at § 92.6 are generally in conflict with Title VI, Title IX, Section 504, or the Age Act, except to the extent that some of them (*e.g.,* RFRA) may be specifically designed to limit the applicability of other Federal laws and governmental actions.

e. Summary of Regulatory Changes

For the reasons described in the proposed rule and having considered the comments received, the Department finalizes § 92.6 and repeals §§ 92.2(b) and 92.3 of the 2016 Rule without change.

C. Section 1557 Regulation, Subpart B: Specific Applications to Health Programs or Activities (Sections 92.201–92.205 of the 2016 Rule)

The Department requested comment on the proposed retention and modification of the provisions in Subpart B of the Section 1557 regulation, which imposes specific requirements on covered entities as regards individuals with LEP or disabilities.

(1) Meaningful Access for Individuals With Limited English Proficiency (45 CFR 92.101)

The Department proposed § 92.101(a), which states that any entity operating or administering a health program or activity subject to the Section 1557 regulation is obligated to take reasonable steps to ensure meaningful access to such programs or activities by LEP individuals. It also proposed § 92.101(b), which states that OCR may assess how an entity balances the following four factors:

(1) The number or proportion of LEP individuals eligible to be served or likely to be encountered in the eligible service population;

(2) the frequency with which LEP individuals come in contact with the entity's health program, activity, or service;

(3) the nature and importance of the entity's health program, activity, or service; and

(4) the resources available to the entity and costs.

Section § 92.101(b) retains many of the 2016 Rule's provisions related to access for LEP individuals. It removes definitions of the terms ''qualified bilingual/multilingual staff'' and ''individual with limited English proficiency,'' but the 2019 NPRM expressed the Department's commitment to interpreting those terms naturally and consistently with the 2016 Rule.[275] It also repeals the 2016 Rule's definition of ''national origin.''

The Department requested comment on whether the proposed retention of some provisions that impose requirements on covered entities under the Section 1557 Regulation (which govern health programs or activities), but not on entities that only receive HHS funding for human services, would cause problems or confusion, and (if so) whether this might warrant amendments to the Department's Title VI regulation.

Comment: In response to the Department's request for comment concerning possible amendments to the underlying civil rights regulations, some commenters said that they were unable to provide meaningful comments without HHS first providing explanations and rationale for any proposed changes, and that unanticipated changes could not be

[274] 45 CFR part 88.

[275] 85 FR 27860–61, 27866.

made in a final rule without first giving the public an opportunity to comment on those proposed changes.

Response: The Department did not propose changes to regulations other than those finalized here, but simply invited comment on whether to consider doing so. In this final rule, the Department does not implement any such changes, and in this respect finalizes the proposed rule without change. The Department here finalizes only those changes proposed in the 2019 NPRM (with minor and primarily technical changes to these).

Comment: Some commenters opposed the proposed rule's revisions to the requirements for meaningful access for LEP individuals, arguing that they weaken nondiscrimination requirements. These commenters noted that instead of requiring covered entities to take reasonable steps to provide meaningful access for *each* ''LEP individual eligible to be served or likely to be encountered,'' the proposed rule only requires covered entities to take steps to ensure meaningful access for ''LEP individuals'' generally. These commenters contend that this change will result in a number of LEP individuals unable to access healthcare, and will contribute to discrimination and to healthcare disparities for LEP individuals. Many commenters stated that lack of understanding in a medical setting could cause harm and possibly death to patients with LEP. One commenter emphasized the facilitative role that interpreters play to decrease risk associated with miscommunication between patients and providers. A commenter expressed concerns that healthcare services would dramatically decrease for individuals with LEP who are unable to access an interpreter. Another commenter objected to the notion that oral interpretation for patients would not be required. Some commenters also oppose the replacement of the 2016 Rule's two-factor test with a four-factor test. One commenter recommended replacing the term ''reasonable'' in the Department's LEP Guidance meaningful access standard with the term ''all,'' saying that the word ''reasonable'' leaves too much room for ambiguity in its application.

Response: The 2016 Rule imposed a stringent requirement on covered entities to take reasonable steps to provide meaningful access to each LEP individual eligible to be served or likely to be encountered. This provision could potentially be interpreted to require a covered entity to provide language assistance services to every LEP individual it comes into contact with. This final rule instead follows DOJ's longstanding LEP guidance (under Executive Order 13166), and HHS's corresponding LEP guidance from 2003, by saying that a covered entity under Title VI must take reasonable steps to ensure meaningful access to its programs or activities by LEP individuals.[276] Adopting this language would apply the same standard to both health and human services programs within the Department, and would conform to the other Federal agencies that follow DOJ's LEP Guidance, consistent with its civil-rights coordinating authority. Because Section 1557 incorporates the enforcement mechanisms available under Title VI (which encompasses LEP status under *Lau* v. *Nichols*),[277] it is appropriate for this final rule to adopt the Title VI standard requiring reasonable steps to ensure meaningful access.

This final rule also incorporates the four-factor test found in the DOJ LEP Guidance and reiterated in the Department's own 2003 LEP Guidance. That test is ''designed to be a flexible and fact-dependent standard,'' [278] and is meant to strike a balance that ensures meaningful access by LEP individuals to critical services while not imposing undue burdens on small businesses, small local governments, or small nonprofits. As the 2019 NPRM made clear, an individualized case-by-case assessment of the four factors is the starting point for exercising the Department's enforcement discretion in language access cases.[279]

This final rule retains, and the Department will vigorously enforce, the underlying legal standard of Title VI: Recipients are prohibited from utilizing criteria or methods of administration which have the effect of subjecting individuals to discrimination on the basis of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the program with respect to individuals on the basis of their race, color, or national origin. Entities that utilize such criteria or methods of administration have failed to take reasonable steps to ensure meaningful access to their programs by individuals with LEP and are operating their programs in violation of this final rule's prohibition against discrimination on the basis of national origin. All covered entities remain obligated to submit assurances that they will comply with Title VI and all other relevant civil rights law.[280]

The language access provisions in this final rule are consistent with Title VI enforcement mechanisms and with the Department's longstanding guidance. Title VI enforcement mechanisms are broadly known to the regulated community, and the HHS LEP Guidance has been effective in helping covered entities comply with the statute and implementing regulations. The Department regards the four-factor test, employed since 2003, as the best way of balancing the relevant factors in ensuring nondiscrimination on the basis of national origin. Under this final rule, the Department's LEP Guidance will help covered entities assess their programs using the four factors to ensure meaningful access to their programs by individuals with LEP. By eliminating confusion, inconsistency, redundancy, and unnecessarily burdensome compliance costs, this final rule applies proven enforcement mechanisms and guidance to ensure access to covered programs by individuals with LEP.

Comment: Commenters stated that the proposed rule significantly reduces the administrative burden placed on providers. For example, the proposed rule will allow retail pharmacies to provide patients with better quality of care in a more efficient manner. Another comment emphasized that under the 2016 Rule, providers are required to physically post the information at their facilities, on their websites, and in any ''significant'' publications and communications. This example underscored that the term ''significant'' has never been defined by OCR, which has resulted in providers using taglines notices in nearly every document provided to patients. This practice was described as administratively burdensome and counterproductive, because patients already receive numerous notices mandated by the Department. Another commenter expressed support for the proposed rule's empowerment of individual entities to take reasonable steps to ensure meaningful access.

Response: The Department agrees, and recognizes the burdens imposed by the 2016 Rule's requirement to post notices and taglines in all significant communications and publications, as well as by the difficulty of determining the meaning of ''significant'' with

[276] *See* 67 FR 41455 (June 18, 2002) (DOJ Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

[277] 414 U.S. 563 (1974).

[278] 68 FR 47314 (Aug. 8, 2003) (HHS Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons).

[279] 84 FR 27865 (June 14, 2019).

[280] *See* 84 FR 27860.

respect to the numerous and diverse types of programs covered by this final rule. These requirements were difficult for covered entities to implement due to different and overlapping language access requirements imposed by the Federal government and by many States.[281] Stakeholders have informed the Department that the repetitive nature of these requirements dilutes the messages contained in significant communications to the point that some recipients may be disregarding the information entirely.[282] In addition, many beneficiaries do not want to receive extra pages of information they have seen many times before, due to environmental concerns or annoyance.[283] Most significantly, the Department has found scant evidence to demonstrate that repeatedly mailing all beneficiaries of Federal and other health programs taglines with 15 or more languages is an efficient use of covered entities' language access resources when the overwhelming majority of beneficiaries speak English.[284] Savings from the notice and taglines requirements changes are described in more detail in the Regulatory Impact Analysis.

Comment: Some commenters stated that the notices and taglines requirements of the 2016 Rule are burdensome, but that the Department should consult with stakeholders to determine how to most effectively and efficiently communicate with LEP individuals, rather than repeal the requirements.

Response: The Department consulted with the public before and since issuing policy guidance to recipients on compliance with the Title VI obligation to take reasonable steps to ensure meaningful access to their programs by individuals with LEP. The Department also provided stakeholders with an opportunity to comment on the proposed rule during the public comment period.

Comment: The Department received comments opposing the proposed rule's revised § 92.101, which requires covered entities to take reasonable steps to ensure meaningful access to its programs or activities by individuals with LEP. Commenters asserted that the proposed change is contrary to congressional intent because the language in Section 1557 is clear that ''an individual shall not'' be subject to discrimination on the prohibited grounds. Others stated that the proposed § 92.101 inappropriately changes the Section 1557 regulation language and shifts the focus of the regulation from an individual's rights to the covered entity's programs or activities, thus weakening meaningful access and running contrary to the text of Section 1557.

Still others recommended that—through sub-regulatory guidance—the Department should communicate to providers the flexibility of the LEP access requirement.

Response: This final rule fully retains all protections offered by Section 1557, and it does not shift any focus from an individual's rights to the covered entity's programs or activities. It ensures that covered entities do not use their programs or activities to discriminate on the basis of any individual's national origin, which includes (under *Lau's* disparate impact analysis) requiring those entities to provide reasonable access to LEP individuals.

Comment: The Department received comments asserting that language assistance is necessary for individuals with LEP to access Federally funded programs and activities in the healthcare system. Several commenters argued that adequate translation services are a civil right and an important tool for informing individuals with LEP of their healthcare rights. One commenter also expressed concern that informed consent is compromised when a language barrier prevents a patient from understanding what he or she is consenting to. Many commenters also said that individuals with LEP face unique challenges in healthcare that are mitigated by language access services, and that the proposed rule might weaken access by patients with LEP to quality healthcare, resulting in patients' avoiding or postponing the medical care they require out of fear of discrimination or mistreatment due to their national origin or the language they speak.

Response: The Department strongly agrees that language assistance is often vital for ensuring access to Federally funded programs and activities in the healthcare system by individuals with LEP. The Department believes this final rule highlights its commitment to ensuring that individuals with LEP receive language access services that are appropriate under the circumstances and consistent with longstanding enforcement mechanisms and guidance. Accordingly, this final rule clarifies throughout § 92.101 that where language assistance services are required to be offered by a covered entity, they must be no-cost, timely, and accurate; that translators or interpreters provided in order to comply with the law must meet specific minimum qualifications, including ethical principles, confidentiality, proficiency, effective interpretation, and the ability to use specialized terminology as necessary in the healthcare setting; and that a covered entity may not require an individual with LEP to bring his or her own interpreter or rely on a minor child or accompanying adult to facilitate communication, except under limited exceptions. In addition, the Department expects that the cost savings estimated below resulting from repeal of notice and taglines requirements will, where applicable, free up resources that entities can use to provide more access to LEP individuals.

Comment: A commenter said that the proposed rule weakens system-wide standards governing access to language assistance services and will

[281] *E.g.,* 42 U.S.C. 300gg–15(b)(2) and 300gg–19(a)(1)(B) (requiring standards for ensuring that the Summaries of Benefits and Coverage and certain notices are provided in a culturally and linguistically appropriate manner); 42 U.S.C. 1396d(p)(5)(A) (requiring HHS to distribute to States an application form for Medicare cost-sharing in English and 10 non-English languages); 26 CFR 1.501(r)–4(a)(1), (b)(5)(ii) (requiring a hospital organization to translate certain documents, among other requirements, to qualify for a tax-exempt status with respect to a hospital facility); 42 CFR 422.2262(a)(1)–(2) and 422.2264(e) (setting forth Medicare Advantage marketing requirements, which include requiring Medicare Advantage organizations to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area), § 423.2262(a)(1)–(2) and § 423.2264(e) (setting forth Medicare Part D marketing requirements, which include requiring Part D plan sponsors to translate marketing materials into non-English languages spoken by 5% or more of individuals in a plan service area); 45 CFR 155.205(c)(2)(iii)(A) (Marketplaces must post taglines on their websites and include taglines in documents ''critical for obtaining health insurance coverage or access to health care services through a QHP''); 68 FR 47318 (Aug. 8, 2003)—Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (setting forth guidance on translating ''vital'' documents).

[282] *See* Aetna, ''Member Reactions to 1557 Taglines'' (Apr. 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0002;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003;* Pharmaceutical Care Management Association (May 2, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006.*

[283] *See* Aetna (May 1, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005;* Pharmaceutical Care Management Association (Mar. 27, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003.*

[284] *See* Pharmaceutical Care Management Association (Mar. 27, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0007;* American Health Insurance Plans and Blue Cross Blue Shield Association (May 5, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0003.*

disincentivize the broader system from embedding and institutionalizing LEP services.

Response: The Department knows of no evidence to support this assertion and considers it an improbable one, as this final rule simply applies the longstanding and well-known enforcement mechanisms of Title VI that have proven effective over time in ensuring access by individuals with LEP to covered programs.

Comment: Commenters said that it would be beneficial if the Department contacted providers with educational documents outlining the requirements under the proposed rule.

Response: It is not Department practice to reach out to all covered entities individually upon every regulatory change. At the same time, OCR does engage in various kinds of outreach to the regulated community. The proposed rule was published in the **Federal Register** and publicized on OCR's website, and this final rule will be publicized similarly. The Department expects its changes to reduce confusion among covered entities. If OCR sees evidence that this final rule's changes are causing any new confusion, OCR will consider issuing relevant guidance and education.

Comment: The Department received comments opposing the elimination of the provision requiring the Director to consider, if relevant, whether an entity has developed and implemented an effective written language access plan appropriate to its particular circumstances. Commenters stated that language access plans are important for evaluating compliance with Section 1557 and for planning efforts to address the needs of LEP individuals.

Response: The HHS LEP Guidance continues to encourage recipients to produce language access plans, but does not require them, and offers assistance to help ensure that implementation provides meaningful access by individuals with LEP. DOJ's LEP Guidance also does not require entities to produce such a plan. This final rule brings the Department's LEP regulations into closer conformity with the DOJ guidance, while Departmental guidance continues to encourage covered entities to go beyond minimum regulatory requirements.

Comment: One commenter argued that the justifications related to costs and resource availability do not supersede the right to meaningful access for individuals with LEP. Another commenter objected to cost's being the primary determinant for compliance with the proposed rule.

Response: Cost is not the primary factor in the four-factor analysis; no single factor is determinative. The four-factor analysis does not supersede the right to meaningful access but rather helps determine when an entity has taken reasonable steps to secure that right.

Comment: Some commenters believe the four-factor analysis under § 92.101(b) is too broad, lacks clarity, does not ensure that translation and other language services are available under important medical circumstances, may require recipients to provide unnecessarily expensive services, and/or weakens recipient language access obligations to serve persons who speak infrequently encountered languages. Others said that the proposed rule does not require a medical provider to make any effort to secure translation services when a patient faces a dire medical condition. Others supported the proposed rule's changes, indicating they would provide more flexibility for covered entities while ensuring that LEP persons have meaningful access to services. Some indicated that covered entities should not be required to provide expensive forms of language assistance, such as video remote interpreting services.

Response: The Department agrees with commenters who state that the four-factor analysis is an appropriate way to allow flexibility for covered entities while ensuring meaningful access for LEP individuals. As to the specific hypothetical situations described by commenters, OCR will evaluate such situations as they are presented to OCR on a case-by-case basis. The fact-dependent nature of Title VI analysis makes it impossible to make pronouncements on such situations without all the relevant facts.

Comment: Some commenters requested that this final rule stipulate that health insurance plans are in compliance with the four-factor test if they incorporate either State LEP requirements or items 4–7 of the National Standards for Culturally and Linguistically Appropriate Services (CLAS).

Response: The ACA instructs the Department to apply to Section 1557 the enforcement mechanisms available under Title VI, which include mechanisms for enforcing language access cases. This final rule relies on longstanding Federal practice in enforcing Title VI; it is far from clear that the Department would have statutory authority to enforce the CLAS standards or State LEP requirements instead. Moreover, recipients that provide language assistance in accordance with CLAS standards and State LEP requirements may still be utilizing other methods of administration that violate the final rule.

Comment: Some commenters suggested that administrative burden would be relieved by adopting uniform language access policies with other components in the Department like CMS, arguing that it would improve patient experiences and reduce errors.

Response: Because CMS program regulations are often implemented under different statutes than are civil rights regulations, and because LEP standards under Title VI have been subject to longstanding standards under DOJ and HHS guidance, the Department does not believe it is necessary at this time to adopt uniform language access standards across these different regulations. This final rule addresses regulations under Section 1557 and the civil rights statutes it incorporates.

Comment: Some commenters argued the proposed rule weakens the qualifications for language service providers by eliminating the words ''qualified'' and ''above average familiarity with'' from the proposed description of language interpreters and translators.

Response: This final rule does not weaken any qualifications for language service providers. It continues to use the term ''qualified'' six times in its regulatory text to describe ''interpreters,'' ''translators,'' or ''staff'' as relevant. As stated in the 2019 NPRM, this final rule eliminates the term ''qualified'' from the 2016 Rule only where it was redundant and clearly implied by the context—namely, a list of the translator's/interpreter's mandatory qualifications, a list that remains unchanged from the 2016 Rule.[285] And the 2016 Rule expressly declined to include any reference to ''above average familiarity.''[286]

Comment: A commenter asserted that the proposed rule will adversely affect the patient-provider dialogue in addiction treatment programs, and underscored the importance of transparency in discussions about substance use history.

Response: The Department is not aware of any evidence to demonstrate this assertion, and believes that relying on the Department's underlying regulations and guidance will not result in such adverse effects.

Comment: Commenters expressed concern over the Department's proposal to remove requirements on video

[285] 84 FR 27860, 27866.

[286] 81 FR 31390–91.

interpreting quality standards as it relates to using video remote interpreting (VRI) services for LEP individuals or spoken language interpreting. Many commenters noted that most VRI services are done on the same equipment and through the same network and bandwidth for both spoken language and sign language, and that if these standards are removed for spoken language interpreters, there will be an unintended consequence of lower-quality VRI services for deaf and hard of hearing individuals. Other commenters noted that while they appreciated the incorporation of the ADA's definition of VRI, they opposed the removal of the technical and training requirements for the use of VRI for spoken language interpretation.

Some commenters recommended that all covered healthcare entities prioritize the use of on-site sign language interpreters, limit usage of VRI to specific situations, and maintain either a directory of local interpreters available for on-site work or a contract with an interpreter service provider to secure on-site interpreters when needed. Commenters offered detailed suggestions for regulations to limit VRI usage.

Response: In place of blanket requirements for VRI standards, this final rule adopts the four-factor analysis regarding access for LEP individuals, which will help covered entities balance competing considerations related to VRI quality standards. Where high-quality VRI is necessary to provide meaningful access to LEP persons, high-quality VRI will be required just as it was under the 2016 Rule. Furthermore, as is made clear in the next subsection (on proposed § 92.102), this final rule continues to hold covered entities to the ADA Title II standards for video interpretive services where these are needed for effective communication for deaf or hard of hearing individuals.

The Department requested comment on whether HHS's Title VI regulations at 45 CFR part 80 should be amended to address the *Lau* v. *Nichols* [287] precedent.

Comment: A commenter stated that the Department's regulations implementing Title VI do not need to be amended to address *Lau* v. *Nichols* as HHS and DOJ have followed this Supreme Court precedent for decades.

Response: The Department agrees and will continue to enforce Title VI consistent with Federal law.

In reviewing § 92.101 and public comments, the Department observed that the proposed rule inadvertently omitted the word ''or'' from the end of paragraph (b)(4)(ii)(A), concerning exceptions to the prohibition on using an adult accompanying an individual with LEP to interpret or facilitate communication. The ''or'' had been included in the parallel provision of the 2016 Rule at § 92.201(e)(2)(i); in the preamble to the proposed rule, the Department explained that it would apply those exceptions ''[l]ike the current rule'' (meaning as in § 92.201(e) of the 2016 Rule). 84 FR at 27866. To correct this, the Department finalizes § 92.101 with a technical change to insert ''or'' at the end of paragraph (b)(4)(ii)(A).

(2) Effective Communication for Individuals With Disabilities (45 CFR 92.102)

The Department proposed to retain the 2016 Rule's provisions on effective communication for individuals with disabilities. 84 FR at 27866–67.

Comment: A commenter suggested that each Section 1557 covered entity should simply comply with the standards that apply to each entity under the ADA, in order to reduce burden, confusion, and complexity.

Response: As a general matter, the Department does not view a covered entity's compliance with other Federal regulations, adopted with different requirements and for different purposes, as determinative of a covered entity's compliance with Section 1557.

Comment: The Department received comments expressing concern that the proposed rule would cause major harm to people with disabilities, affecting their access to effective healthcare, especially for those individuals in underserved and rural communities. Commenters suggested that because the current rule is working as it was intended, there is not sufficient reason to reopen it. Commenters argued that the ability to effectively communicate includes the individual patient as well as the patient's family/caregivers, and that the inability to effectively communicate can have significant adverse effects on an individual's access to healthcare. Other commenters expressed support for retaining the provisions of 45 CFR 92.202 (redesignated § 92.102), regarding effective communication for individuals with disabilities. Commenters noted that effective communication is a critical component to accessing and receiving healthcare and that often covered entities rely on communication methods that are the preference of the covered entity rather than the choice of the individual with a disability. Commenters stated that giving primary consideration to the choice of aid or service requested by an individual with a disability helps to ensure effective communication and equal opportunity in the healthcare setting. Commenters commended HHS for holding all recipients of Federal financial assistance from HHS to the higher ADA Title II standards.

Response: Access to care continues to be a critical concern for the Department, and access to care clearly requires effective communication. The Department does not believe this final rule will impede individuals' access to care, but that instead it will assist individuals in understanding a covered entity's legal obligations and their own rights under Section 1557. In addition, the rule will assist the Department in complying with the mandates of Congress and further substantive compliance. Finally, because this final rule will lift unnecessary regulatory burdens on providers, the Department hopes that it will increase access to care, including in underserved and rural communities.

Comment: Commenters noted that the current regulation's language tracks the statutory text of Title I and Title III of the ADA and the regulatory language of Title II of the ADA, all of which protect against discrimination based on association or relationship with a person with a disability. They said that the proposed rule's elimination of the 2016 Rule's prohibition on associational discrimination will therefore create bewilderment concerning providers' responsibilities and individuals' rights. Commenters argued that deleting the language will create uncertainty and confusion regarding the responsibilities of providers and the rights of persons who experience discrimination, and inconsistencies with other regulatory requirements that entities are subject to, including the ADA and Section 504.

Response: As stated above, protections against discrimination on the basis of association will be available under this final rule to the extent that they are available under the incorporated civil rights statutes and their implementing regulations. The Department notes that courts have often relied on ADA statutory provisions in their handling of Section 504 claims.[288]

[287] *Lau* v. *Nichols,* 414 U.S. 563 (1974).

[288] *See* Memorandum on Coordination of Federal Agencies' Implementation of Title II of the Americans with Disabilities Act and Section 504 of the Rehabilitation Act, Acting Assistant Attorney General (April 24, 2018); *see, e.g., Theriault* v. *Flynn,* 162 F.3d 46, 48 n.3 (1st Cir. 1998); *Henrietta D.* v. *Bloomberg,* 331 F.3d 261,272 (2d Cir. 2003); *Helen L.* v. *DiDario,* 46 F.3d 325, 330 n.7 (3rd Cir. 1995); *Baird ex rel. Baird* v. *Rose,* 192 F.3d 462, 468 (4th Cir. 1999); *Delano-Pyle* v. *Victoria Cty., Tex.,*

Continued

Comment: Several commenters objected that the definition of auxiliary aids and services at proposed § 92.102(b)(1) excludes the term ''Qualified'' before ''Interpreters'' in subsection (i) and before ''Readers'' in subsection (ii), despite being part of the ADA definition at 28 CFR 35.104. Some Commenters strongly encouraged the Department to incorporate the ADA definition of ''Qualified Reader'' as follows: ''Qualified reader means a person who is able to read effectively, accurately, and impartially using any necessary specialized vocabulary.'' [289]

Response: As stated above regarding § 92.101(a), this final rule eliminates the term ''qualified'' from the 2016 Rule only where it was redundant and clearly implied by the context. In this case, subsection (b)(2) clearly lists the mandatory qualifications for interpreters required under subsection (b)(1), and it adopts that list from the ADA definition at 28 CFR 35.104 and § 36.303(f). It would therefore be redundant to describe those interpreters in subsection (b)(1) as ''qualified.'' No definition of ''Qualified Reader'' appears in the 2016 Rule, so the Department is making no change in that regard. But the Department interprets this subsection naturally as requiring qualifications for readers that are similar to the expressly stated qualifications for interpreters.

Comment: Commenters argued that although the proposed rule claims to incorporate the definition of auxiliary aids and services from the regulations implementing Title II of the ADA, the rule as proposed changes the definition of auxiliary aids and services, omitting ''acquisition or modification of equipment and devices; and other similar services and actions'' from the list of examples of aids and services. Commenters noted that this proposed change will confuse providers and people with disabilities and will lead both groups to assume the list in the proposed rule is exhaustive. Commenters opposed these deletions and requested that the Department retain the definition of auxiliary aids and services from the 2016 Rule.

Response: The Department's definition of auxiliary aids and services is consistent with, even if not identical to, that of the ADA. The Department does not deem it necessary to incorporate all of the ADA's examples, as neither the ADA's list nor this final rule's list claims to be exhaustive.

Comment: Some commenters expressed concern regarding the narrowing of the ''free of charge'' and ''timely manner'' provision at proposed § 92.102(b)(2). Commenters noted that the 2016 Rule's language is consistent with existing ADA Title II regulations, which provide that covered entities may not place a surcharge on a particular individual or group of individuals with a disability to cover the costs of the provision of auxiliary aids or program accessibility. Commenters asserted that the proposed § 92.102(b)(2) significantly narrows this provision by stating that ''interpreting service'' shall be provided to individuals free of charge and in a timely manner. These commenters strongly opposed this change and encourage the Department to replace the words ''interpreting service'' with ''auxiliary aids and services'' to be consistent with the ADA and to prevent unnecessary confusion over the requirement.

Response: Like § 92.202 of the 2016 Rule, which it replaces, § 92.102 of this final rule continues to incorporate the ADA Title II regulations at 28 CFR 35.160–164. The new section also includes new language on the qualifications for interpreters, which is where the term ''free of charge'' now appears; the term did not appear in § 92.202 of the 2016 Rule. To the extent that auxiliary aids must be provided free of charge under the 2016 Rule, they must still be provided free of charge under this final rule.

Comment: One commenter asked that the phrase ''in a timely manner'' as used in Section 92.102(b)(2) of the proposed rule be clarified with clear guidance as to what can and cannot be considered ''in a timely manner.''

Response: Application of the term ''in a timely manner'' requires a nuanced analysis that is fact-dependent. Its meaning can be understood from the long history of enforcement of Section 504 and the ADA in the courts and administratively.

Comment: Some commenters supported an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees, stating that it would help alleviate financial and administrative burden for smaller physician group practices that may already have limited resources. Others said that in some areas of the country, especially in small and rural communities, such an exemption could effectively bar access to many providers. Commenters said that any such exemption would be inconsistent with the standard present in Title II [290] and Title III [291] of the ADA, which require the same businesses to provide auxiliary aids and services to individuals with disabilities where necessary to ensure effective communication, regardless of the number of employees. They said that the existence of two competing regulatory standards will confuse small covered entities as to which standard they should follow. Several commenters noted that although a small economic burden may be placed on small businesses that have to comply with this requirement, there are programs that provide tax benefits and funding for the provision of reasonable accommodations, significantly reducing the burden placed on these entities.[292] Some commenters noted that because Titles II and III of the ADA already provide for sufficient mechanisms for providers to request exemptions based on a fundamental alteration in the nature of goods and services provided and undue burden, no additional exemption is needed through Section 1557.

Response: The Department believes that in the interest of uniformity and consistent administration of the law, all employers that receive Federal financial assistance from HHS, regardless of their size, should be held to the auxiliary aids and services requirement. The Department recognizes the importance of individuals being able to effectively communicate with their healthcare providers and is aware that the inability to effectively communicate can have significant adverse effects on individuals' access to effective healthcare. The Department's decision to require all entities, regardless of size, to provide auxiliary aids and services is consistent with OCR's policy for almost two decades,[293] so covered entities will

302 F.3d 567, 574 (5th Cir. 2002); *McPherson* v. *Michigan High School Athletic Ass 'n, Inc.,* 119 F.3d 453, 459–60 (6th Cir. 1997); *Gorman* v. *Bartch,* 152 F.3d 907, 912 (8th Cir. 1998); *Zukle* v. *Regents of Univ. of Cal.,* 166 F.3d 1041, 1045 n.11 (9th Cir. 1999); *Cohan ex rel. Bass* v. *N.M. Dept. of Health,* 646 F.3d 717, 725–26 (10th Cir. 2011); *Bircoll* v. *Miami-Dade Cty.,* 480 F.3d 1072, 1088 n.21 (11th Cir. 2007).

[289] 28 CFR 35.104.

[290] 28 CFR 35.104.

[291] *See* 42 U.S.C. 12182(b)(A)(iii) (under Title III, privately operated public accommodations regardless of their size are obligated to provide appropriate auxiliary aids and services, when necessary to ensure effective communication with individuals with disabilities, unless the entity can demonstrate that taking such steps would fundamentally alter the nature of their programs, services or activities, or would result in undue financial and administrative burdens).

[292] Commenters cited U.S. Department of Justice American with Disabilities Act Update: A Primer for Small Business. (2010). Retrieved from *https://www.ada.gov/regs2010/smallbusiness/smallbusprimer2010.htm;* Internal Revenue Service. (n.d.); Form 8826, Disabled Access Credit. Retrieved from *https://www.irs.gov/forms-pubs/about-form-8826.*

[293] *See* Notice of Exercise of Authority Under 45 CFR 84.52(d)(2) Regarding Recipients With Fewer Than Fifteen Employees, 65 FR 79368 (Dec. 19, 2000).

be familiar with the obligations being imposed. Title II and Title III of the ADA already require public and private healthcare entities to provide auxiliary aids and services regardless of the number of employees. Both Titles state that an entity is not required to take any action that it can demonstrate would result in a fundamental alteration in the nature of a service, program, or activity or in undue financial and administrative burdens, and § 92.102 incorporates both of those limitations through its incorporation of the ADA Title II regulations at 28 CFR 35.160–164. Therefore, the Department finds it appropriate not to adopt an exemption from the auxiliary aids and services requirement for covered entities with fewer than 15 employees.

Comment: Commenters said that the ''primary consideration'' standard has evolved such that patients will demand that a particular translator or interpreter be used, regardless of the expense. These commenters argued that when patients demand use of a certain company or specific commercial service, this creates additional unnecessary costs for the covered entity. One commenter stated that Title III of the ADA should be the standard that applies to private businesses covered by Section 1557 regarding effective communication for individuals with disabilities. The commenter asserted that the Title II primary consideration standard is not appropriate for use in a clinical setting and that treating clinicians or the entities themselves are in the best position to determine the types of services necessary to address the communication needs of their patients. The commenter argued that applying Title II standards to private entities has created significant confusion for medical group practices accustomed to following longstanding Title III rules.

Response: Since the 2015 NPRM, the Department has held that it is appropriate, as a condition of receipt of Federal financial assistance from HHS, to hold all recipients to the higher 2010 ADA Title II standards regarding effective communication with individuals with disabilities.[294] The Department does not consider the commenters' concerns to be a sufficient reason to change this policy. Section 92.102 of this final rule seeks to avoid confusion by providing covered entities with clear, specific guidance to help them understand their rights and responsibilities regarding effective communication with individuals with disabilities. As mentioned above, it also incorporates the ''undue burden'' and ''fundamental alteration'' limitations of ADA Title II, in order to avoid excessively burdening covered entities.

(3) Accessibility Standards for Buildings and Facilities (45 CFR 92.103)

The Department proposed at § 92.103(a) to retain the 2016 Rule's requirement that new construction or alteration of buildings or facilities subject to Section 1557 must comply with the 2010 ADA Standards for Accessible Design by January 18, 2018, and to retain the 2016 Rule's allowance of departures from the 2010 ADA standards where other methods are permitted that provide substantially equivalent or greater access to and usability of the building. 84 FR at 27867. The Department proposed at § 92.103(b) to create a safe harbor for new construction or alteration of buildings or facilities subject to Section 1557, allowing existing facilities which were only required to be compliant with the Uniform Federal Accessibility Standards (''UFAS''), the 1991 ADA Standards, or the 2010 ADA Standards as of July 18, 2016, to be deemed compliant, unless there is new construction or alteration after January 18, 2018. Finally, the Department proposed at 92.103(c) to identify the three applicable building and facility detailed technical accessibility standards by cross-reference to their underlying regulations, instead of listing them in a separate definitions section.

Upon further consideration of this language and the public comments, the Department observed a potential ambiguity in § 92.203 of the 2016 Rule. The rule distinguished between construction or alteration commenced ''on or after July 18, 2016'' in the first sentence of § 92.203(a), those commenced ''on or before July 18, 2016'' in the first sentence of § 92.203(b), and those commenced ''before July 18, 2016'' in the last sentence of § 92.203(b). This potentially left it unclear how the rule would apply to construction or alteration commenced on July 18, 2016. To avoid confusion, the Department is finalizing § 92.103 with a technical change, by deleting the phrase ''on or'' from the first sentence of § 92.103(a), and adding ''on or'' before the word ''before'' in the last sentence of § 92.103(b). This resolves the ambiguity while providing leeway to activities commenced on July 18, 2016 where it was not clear how the 2016 Rule applied.

Comment: Commenters supported the proposal to continue to apply the 2010 ADA Standards' definition of ''public building or facility'' to all entities covered under Section 1557, by retaining the provisions of 45 CFR 92.203 (redesignated § 92.103) regarding accessibility standards for buildings and facilities. Commenters opposed any type of additional exemption from the requirements concerning multistory building elevators[295] and Text Telephone (TTY) requirements.[296] Some commenters strongly opposed the proposed rule's incorporation of the private entity TTY standard from the 2010 ADA Standards, and requested the retention of the existing TTY ratios, and the adoption of stringent Real-Time Text (RTT) ratios. Others noted that lack of accessible medical equipment presents barriers to effective healthcare for people with impaired mobility or strength and other disabilities, and they requested that the Department require healthcare facilities to follow the 2017 Architectural and Transportation Barriers Compliance Board (U.S. Access Board) Standards for Accessible Medical Diagnostic Equipment.[297]

Response: The Department believes that, because the great majority of entities covered by the 2016 Rule have already been subject to the 2010 ADA Standards, an approach that emphasizes uniform application of the 2010 Standards will promote conformity with pre-existing civil rights statutes while enabling greater consistency among implementing agencies. Any significant reevaluation of those standards or adoption of new standards is beyond the scope of this regulation. In the case of adopting new standards, the Department also declines to make such a significant regulatory change without the benefit of notice and public comment.

(4) Accessibility of Information and Communication Technology (45 CFR 92.104)

The Department proposed to retain the 2016 Rule's provisions on accessibility of information and communication technology for individuals with disabilities. 84 FR at 27867. The Department also proposed at 92.104(c) to update the 2016 Rule's

[294] 80 FR 54186.

[295] *See* 42 U.S.C. 12101 *et seq.* Exception 1 of section 206.2.3 of the 2010 ADA standards exempts multistory buildings besides the professional office of a healthcare provider owned by private entities from the requirement to provide an elevator to facilitate an accessible route throughout the building. This exemption does not apply to public entities.

[296] The 2010 ADA Standards also specifies TTY requirements for public buildings different from private buildings. Compare ADA 2010 Standard 217.4.3.1 (public buildings) with ADA 2010 Standard 217.4.3.2 (private buildings).

[297] *See* Information and Communication Technology (ICT) Standards and Guidelines, 82 FR 5790 (Jan. 18, 2017) (final rule); 83 FR 2912 (Jan. 22, 2018) (technical edits).

outdated term ''electronic and information technology'' with the term ''information and communication technology,'' as defined in the U.S. Access Board regulations. 84 FR at 27871.

Comment: Commenters expressed concern with the Department's proposed change to the definition of ''information and communication technology'' (ICT), in proposed § 92.104(c). Commenters noted that the critical phrase ''but are not limited to'' has been removed from the definition the Department claims to have incorporated from the U.S. Access Board's definition for ICT.[298] The commenters argue that due to the difficulty in predicting what technologies will be in place moving forward, it is important to maintain flexibility and ensure that the regulation keep pace with emerging technologies.

Response: The list of auxiliary aids was not intended as an all-inclusive or exhaustive catalogue of possible or available auxiliary aids or services—nor could it possibly be, given the new devices that will become available with emerging technology. The Department omitted the phrase ''but are not limited to'' merely in order to avoid unnecessary legal jargon. The plain meaning of ''include'' already encompasses ''but are not limited to,'' as it signifies that the listed items are only parts of a larger whole.

Comment: One commenter requested that the Department require recipients of Federal financial assistance to ensure that health programs or activities provided through their websites comply with the requirements of Title III, rather than Title II, of the ADA, if the recipient is otherwise covered by Title III. The commenter argued that the burden placed on small practices by having to comply with both Title II and Title III would likely outweigh any benefit to individuals who require accessible technology.

Response: The Department believes that this comment understates the benefit of the Title II standards to individuals who require accessible technology. Effective communication is a critical component for individuals to be able to access and receive healthcare, and this includes being able to access covered entities' websites. The Department believes that in the interest of uniformity of access for individuals with disabilities, all entities that receive Federal financial assistance from HHS should be held to the higher information and communication technology standards of Title II. The ADA does not exempt small providers from this requirement, although § 92.104 does incorporate the ADA's ''undue financial and administrative burden'' and ''fundamental alteration'' exemptions in order to protect covered entities from excessive burdens.

Comment: Some commenters stated that the Department should cross-reference Section 508 in its proposed § 92.104. The commenters noted that although the proposed rule tracks the concepts of the Section 508 regulations, it does not include the appropriate cross-reference, which will cause confusion if and when the Section 508 regulations are updated.

Response: If and when Section 508 regulations are updated, the Department will evaluate whether or not to update § 92.104 accordingly. Because this final rule does not incorporate Section 508 regulations but merely tracks them, the Department believes that a cross reference could cause unnecessary confusion if and when Section 508 regulations are updated or changed.

(5) Requirement To Make Reasonable Modifications (45 CFR 92.105)

The Department proposed at § 92.105 to retain the 2016 Rule's requirement that covered entities make reasonable modifications to policies, practices, or procedures when necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that the modification would fundamentally alter the health program or activity. 84 FR at 27868. The Department sought comment on whether to include an exemption for ''undue hardship.'' *Id.*

Comment: Commenters strongly opposed an exemption for undue hardship in regard to the requirement that covered entities make reasonable modifications to policies, practices, or procedures when necessary, to avoid discrimination on the basis of disability, except if the modification would fundamentally alter the nature of the health program or activity. Commenters pointed out that the current regulations track Title II of the ADA. Commenters stated that Title III does not absolve a covered entity from providing all forms of auxiliary aids if providing a particular auxiliary aid would result in undue burden, and that a provider has an obligation to find an alternative auxiliary aid in such cases. Commenters noted that because Title II and III of the ADA already provide mechanisms for providers to request exemptions based on an undue burden, no additional exemption is needed. Commenters stated that the substitute language proposed is from regulations related to employment and ill-fitting and inappropriate in a healthcare context. Commenters requested that if an exemption for undue hardship is provided, it should mirror the undue burden provision of the ADA, to ensure the two Federal laws are in sync and do not conflict with one another and lead to confusion.

Response: The Department agrees with commenters who ask that the regulations continue tracking Title II of the ADA, whose requirement for reasonable modifications includes a fundamental alteration exemption but no undue hardship exemption. The Department believes that this position helps promote continued consistency with pre-existing civil rights statutes. The reasonable modification analysis already applies to many entities subject to Section 1557 and is well-defined by regulation and decades of case law. Continuing to apply the ''reasonable modification'' analysis to Section 1557 promotes consistency with pre-existing civil rights law and is consistent with the U.S. Supreme Court's decision interpreting Section 504 in *Alexander* v. *Choate,* 469 U.S. 287 (1985), Title II of the ADA, and OCR's longstanding interpretation of Section 504.

Comment: Commenters objected to substituting the Title II reasonable modification language with language stating that covered entities ''shall make reasonable accommodation to the known physical or mental limitations of an otherwise qualified'' individual with a disability. Further, a commenter argued that use of the term ''known,'' outside the employment context, would suggest an overly narrow interpretation of the scope of Section 1557 and introduce an unnecessarily burdensome and intrusive process into the healthcare context. Commenters expressed concern that importing the ''known physical or mental limitation'' language would suggest to covered entities that their obligations are limited, and would create an undue focus on the measures that entities must take in response to requests for modifications.

Response: The Department shares the concern that introduction of the phrase ''known physical or mental limitations'' may cause covered entities to introduce

[298] *See* 36 CFR app. A § 1194 (2011) (defining ICT as ''Information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include but are not limited to: Computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; customer premises equipment; multifunction office machines; software; applications; websites; videos; and electronic documents.'').

exceedingly burdensome and intrusive processes into the healthcare context. In contrast, the concept of reasonable modification taken from Title II has long applied to a wide range of entities covered by Section 1557, making such entities familiar with the requirements imposed, and is well-defined by regulation and decades of case law. The Department believes that continuing to apply the reasonable modification analysis to Section 1557 will help promote consistency with pre-existing civil rights statutes.

Comment: Several commenters noted that the citation for the proposed reasonable modification language the Department claims conforms to the Department of Justice's Section 504 coordinating regulations is to a non-existent portion of the Code of Federal Regulations. These commenters argue that these incorrect citations make it impossible for the public to analyze the context or case law of the proposed imported language and that such uncertainty makes it impossible for the public to reliably know what the Department is proposing.

Response: The Department thanks these commenters for bringing this citing error to its attention. For clarity, the Department notes that it intended to cite to 28 CFR 42.511, not § 92.205.[299] But for the reasons stated above, the Department has determined that it should retain the current Title II reasonable modification language.

Comment: Some commenters recommended that the rule include the addition of examples of programmatic modifications that are often needed by those with disabilities, such as the modification of wait times, office hours, and other business practices that can make accessibility to healthcare for people with disabilities difficult.

Response: The Department declines to enshrine a list of examples of ''programmatic modifications'' needed by those with disabilities. Because this final rule applies to a diverse range of covered entities, codifying examples would not provide meaningful guidance to the full spectrum of regulated covered entities. The Department believes that each covered entity ought to determine for itself which programmatic modifications with respect to its health programs and activities should be undertaken to avoid discrimination on the basis of disability, subject to enforcement by OCR in case of a complaint.

Comment: Commenters found inappropriate the Department's requesting comment on whether it has struck the appropriate balance in proposed §§ 92.102 through 92.105 with respect to Section 504 rights and obligations imposed on the regulated community, as such a balancing exercise is not called for by the statute and inserts inappropriate regulatory subtlety.

Response: In any rulemaking, addressing obstacles that impede individuals from exercising their rights should be balanced against potentially unnecessary obligations that may be imposed on the regulated community. Agencies engage in this type of balancing in order to ensure that the interests and issues of both individuals and the regulated community are fairly considered during the rulemaking process, helping to minimize the burden associated with Federal regulations.

Comment: A commenter said that in order to promote clarity and affirm that VRI quality standards apply in any remote interpreting situation that may arise for a person with a disability, § 92.101 of the proposed rule ought to cross-reference the VRI quality standards in § 92.102.

Response: Section 92.102 covers individuals with disabilities. § 92.101 covers individuals with LEP status, which is not a disability. Individuals with disabilities have different needs than LEP individuals, and the current regulatory text reflects that difference. If an LEP individual happens also to have a disability, then the VRI quality standards of § 92.102 will apply to him/her.

(6) Summary of Regulatory Changes

The Department finalizes the proposed sections § 92.101 through 92.105 without change, except that technical changes are made to add the word ''or'' at the end of § 92.101(b)(4)(ii)(A), to delete the phrase ''on or'' from the first sentence of § 92.103(a), and to add the phrase ''on or'' before the word ''before'' in the last sentence of § 92.103(b).

D. Title IX Regulations

The Department proposed to conform its Title IX regulations to current statutory provisions.

(1) Nomenclature, Rules of Appearance, Effective Date Modifications to Rules at 45 CFR 86.31 and 86.71

The Department proposed to make a nomenclature change to the Title IX regulation by replacing ''United States Commissioner of Education'' with the official's current title, ''Secretary of Education.'' [300] The Department also proposed to update the Title IX regulation's statutory citations to include the full current text of Title IX as amended by the CRRA.

The Department also proposed to repeal a prohibition on discrimination on the basis of ''rules of appearance'' in 45 CFR 86.31. The Department further proposed to update the enforcement section in the Department's Title IX regulation at 45 CFR 86.71, which currently discusses only enforcement procedures for the interim period before the issuance of the consolidated Title IX regulation. This final rule applies language from the Title IX regulation, which incorporates Title VI procedures.

Comment: The Department received comments indicating that the rules of appearance prohibition is well supported by Title IX and that HHS provides no basis for removing the prohibition.

Response: This final rule's NPRM explained that currently, the Department is the only Federal agency with Title IX regulatory language prohibiting discrimination ''against any person in the application of any rules of appearance.'' [301] The phrase ''rules of appearance'' does not appear in Title IX and was never defined in any agency's Title IX regulations. Consequently, the Department believes the phrase may cause confusion in the public about Title IX's coverage and compliance responsibilities, and has already led to at least one lawsuit. Because this language is not in the current regulations of any other agencies, this final rule limits the potential for conflicting and inequitable Federal agency enforcement of Title IX with respect to ''rules of appearance.''

(2) Abortion Neutrality of 20 U.S.C. 1688 in 45 CFR 86.2 and 86.18

The Department also proposed to modify its Title IX regulations, at 45 CFR 86.18, to reflect the statutory text Congress enacted in Title IX. This text includes what some commenters referred to as the Danforth Amendment, 20 U.S.C. 1688, which states that Title IX is not to be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion; to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use

[299] *See* 84 FR 27868 (citing to 28 CFR 92.205).

[300] *See* 45 CFR 86.2(n).

[301] *See, e.g.,* 47 FR 32527 (July 28, 1982) (Department of Education Title IX regulation); 65 FR 52858 (Aug. 30, 2000) (common rule adopted by twenty agencies), 66 FR 4627 (Feb. 20, 2001) (common rule adopted by Department of Energy); 82 FR 46656 (Oct. 6, 2017) (U.S. Department of Agriculture adopting common rule).

of facilities, related to an abortion; or to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.[302] The Department also proposed to add a provision, similar to the provision of the Section 1557 regulation discussed above under ''relation to other laws,'' ensuring that its Title IX regulation would be construed consistently with various religious freedom and conscience statutes, including the explicit religious exemptions in the text of Title IX itself.

Comment: One commenter stated that adding Title IX's abortion neutrality language in the Department's Title IX regulations would be a violation of the plain language of the definition of sex discrimination in the regulations, which includes termination of pregnancy. Others noted that discrimination based on termination of pregnancy has been recognized by courts as sex discrimination and therefore argued that the proposed rule is contrary to civil rights laws and constitutional principles. Some noted that Title IX itself expressly does not permit penalties based on a woman's prior termination of pregnancy.

Others, however, supported the incorporation of Title IX's religious exemptions and other Federal conscience statutory protections, arguing that they are consistent with abortion neutrality. Still others stated that discrimination on the basis of sex should not include termination of pregnancy at all, under existing law and the statutory text of Section 1557 and Title IX. Some submitted legislative history from Title IX (Senate Committee Report 100–64) to show that Congress intended to allow for abortion exemptions and exclusion of health insurance coverage for abortion services, and that Congress did not intend to require all hospitals to provide abortion services to the general public.[303] But other commenters were critical of using legislative history to interpret a statute.

Response: This final rule does not remove the language from the Department's Title IX regulations that prohibits certain forms of discrimination on the basis of ''termination of pregnancy.''[304] However, as stated above in the section on discrimination on the basis of sex (subsection on ''termination of pregnancy''), the Title IX regulations are governed by the text of the Title IX statute and cannot be ''construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion'' (20 U.S.C. 1688). This final rule adds language to the Title IX regulations in order to make this clear. Although some commenters cite legislative history, the Department interprets the statutory text as written. Regardless, the Department does not believe there is tension between the legislative history and the text.

By adding the abortion neutrality language to the Title IX regulations, and stating in the Section 1557 regulation that it will be applied consistent with Title IX (including that language), this final rule ensures compliance with the rationale in *Franciscan Alliance,* where the Court rightly held that the Department's regulations forbidding discrimination on the basis of sex must be construed in light of the underlying text of Title IX, including abortion neutrality.

Comment: Commenters stated that religious exemptions would make it harder to find healthcare in low provider areas, and that religious refusals also harm people who live in rural areas and must travel for an abortion. However, other commenters stated that this inclusion of various Federal conscience statutes and appropriations riders would ensure that healthcare providers who have conscience objections to abortion will feel welcome within the healthcare profession and will ease retention of healthcare providers already in the field.

Some specifically stated their support for the Department's inclusion of the First Amendment, and for Department guidance that the proposed rule be construed consistent with religious liberty and free speech protections, to clarify that the interpretation, application, and enforcement of the proposed rule will be consistent with religious liberty. Other commenters stated that referring to the First Amendment rightly addresses the recent Supreme Court ruling in *NIFLA* v. *Becerra.*[305] Commenters were concerned that the 2016 Rule would require a faith-based hospital to inform a patient about terminating her pregnancy in direct contravention of sincerely-held religious beliefs. This would be in conflict with *NIFLA,* where the Supreme Court held that such a mandate ''imposes an unduly burdensome disclosure requirement that will chill [] protected speech.''[306]

Response: The Department agrees that this final rule should be construed consistent with the First Amendment, conscience statutes, and all relevant statutes and appropriations riders relating to abortion, to the extent they remain in effect or applicable. Agency regulations are subject to the requirements of the First Amendment in any case, and the Department considers it appropriate to say so explicitly here. All the other laws referenced establish Congressionally required parameters that may apply to the Department's interpretation, implementation, and enforcement of Title IX and of this final rule.[307] Commenters' policy objections to these statutory constraints are not a sufficient reason for the Department not to finalize this provision of the rule, which will ensure compliance with statutory requirements.

(3) Summary of Regulatory Changes

For the reasons described herein and having considered the comments received, the Department finalizes changes to 45 CFR 86.2, 86.18, 86.31, and 86.71 without change.

E. Conforming Amendments to CMS Regulations

The Department proposed to make conforming amendments to ten regulations of CMS that prohibited discrimination on the basis of gender identity and/or sexual orientation in the establishment and operation of ACA exchanges; in the marketing and design practices of health insurance issuers under the ACA; in the administration, marketing, and enrollment practices of QHPs under the ACA; in beneficiary enrollment and the promotion and delivery of services under Medicaid; and in the delivery of services under the PACE program. These conforming changes were proposed, among other

[302] *See* Public Law 100–259, 102 Stat. 28, sec. 8 (Mar. 22, 1988) (codified at 20 U.S.C. 1688).

[303] *See* Senate Committee Report 100–64 (''This bill does not expand abortion rights. Religiously-controlled organizations will continue to be able to apply for, and receive, an exemption from Title IX requirements where compliance with those requirements would violate their religious tenets. For example, a religiously controlled university that wished to exclude insurance coverage of abortions from an otherwise comprehensive student health insurance policy, could seek a religious exemption. . . . Title IX covers only students and employees, and does not reach the public at large. Therefore, claims that the bill would require hospitals to provide abortion services to the general public are false.'').

[304] *See* 45 CFR § 86.21(c)(3), 86.40(b)(1), 86.40(b)(4), 86.40(b)(5), 86.51(b)(2), 86.51(b)(6), 86.57(b), 86.57(c), 86.57(d).

[305] *Natl. Inst. of Fam. and Life Advocates* v. *Becerra,* 138 S. Ct. 2361 (2018).

[306] *Id.* at 2378.

[307] To the extent the relevant provisions are found in an appropriations rider, they apply to the Department's interpretation, implementation, and enforcement of Title IX every year that they are enacted.

reasons, to ensure uniformity across the Department with respect to regulations that cover many of the same entities.

(1) Generally

Comment: Several commenters contended that the proposed rule exceeds the authority of the Director of OCR by attempting to remove references to gender identity and sexual orientation from all HHS healthcare regulations, including those issued by other HHS agencies unrelated to Section 1557, although the rule purported to be promulgated by authority from Section 1557 and other sections within the ACA. Commenters stated that the nondiscrimination protections proposed to be eliminated from CMS regulations are unrelated to Section 1557 and its regulation, and that this elimination was proposed without sufficient legal, policy, or cost-benefit analyses as well as without knowledge of their potential impacts on various CMS programs and on LGBT patients, who (commenters said) may be discriminated against if these amendments are finalized. Also, commenters contend the conforming amendments, if implemented, would affect a wide range of healthcare programs, including private insurance and education programs. Some said they were unaware of any instances in which inclusion of sexual orientation as a basis for nondiscrimination in these CMS rules had been challenged or opposed. Others said that it was arbitrary to single out sexual orientation and gender identity for elimination, since some of the CMS regulations being amended also protect other characteristics not expressly enumerated by statute.

Response: Both the proposed rule and this final rule are promulgated by the Secretary of Health and Human Services, who has jurisdiction over all Department regulations, including those falling under the jurisdiction of CMS. Moreover, each of the programs, activities, or entities in the proposed conforming amendments falls within the scope of Section 1557 as entities established under Title I of the ACA (for example, Exchanges [308]), entities administered under Title I of the ACA (for example, QHPs [309]) or health programs or activities receiving Federal financial assistance from the Department, including contracts of insurance.[310] The ACA and certain Federal statutes identifying other protected categories provide the bases for the nondiscrimination clauses in health programs and activities funded or administered by HHS.[311]

The Department has reviewed the legal authorities underlying and cited in the nondiscrimination provisions of these CMS regulations and the explanations set forth in those rules. Some of them relied on or referenced Section 1557, some relied on different statutory provisions, and some are cross-referenced in the 2016 Rule. None of the statutory authorities underlying the CMS rules amended here explicitly references sexual orientation or gender identity. To the extent some of those regulations were promulgated based on broad authority to issue regulations,[312] inclusion of nondiscrimination criteria that are not explicitly set forth in other applicable civil rights statutes may not necessarily exceed the Department's statutory authority. Nevertheless, the Department deems it appropriate to pursue a more uniform practice concerning nondiscrimination categories across programs and activities to which Section 1557 applies, and to do so consistent with the government's position concerning discrimination on the basis of sex.

In addition, for several of the CMS final rules, their corresponding proposed rules had not mentioned adding sexual orientation and gender identity as nondiscrimination categories.[313] Although some of those proposed rules also did not mention adding other common nondiscrimination categories, the Department now views the addition of sexual orientation and gender identity as nondiscrimination categories as having presented different legal and policy concerns from other categories. Notably, these nondiscrimination categories are not required by applicable law, appear in only a handful of federal antidiscrimination statutes, and have been the subject of extensive litigation, controversy, and confusion generally. Thus, the Department believes the addition of sexual orientation and gender identity as nondiscrimination categories in its regulations should have been submitted for public comment and, notwithstanding the lack of legal challenge to these CMS regulations on this basis, proposes conforming amendments for purposes of clarity, consistency, and uniformity.

Therefore, the Department deems it appropriate to finalize the proposed conforming amendments to these CMS regulations without change (with the exception of a technical correction described below), in order to create a more uniform practice concerning nondiscrimination on the basis of sex among HHS programs to which Section 1557 applies, and to avoid the possibility that there was insufficient statutory authority to impose gender identity or sexual orientation nondiscrimination prohibitions through those regulations.

The Department is unaware of any data that would make cost-benefit analyses for these specific changes possible, and notes that the insertion of sexual orientation and gender identity language (repealed by these amendments) had already been implemented without any cost-benefit analyses. These provisions are eliminated for reasons parallel to those put forth here and in the proposed rule with respect to proper statutory construction, legal authority, and the Department's policy goals.

Comment: Some commenters supported proposals to remove the provisions prohibiting discrimination on the basis of sexual orientation specifically from regulations encompassed by the conforming amendments, in order to reflect current law and current regulatory policy. They reiterated the 2016 Rule's statement that there is no settled statutory law or court-settled law that discrimination on the basis of sexual orientation is legally included within the reach of Title IX.

Response: For the reasons explained above, the Department agrees with the 2016 Rule's decision not to include an explicit prohibition on sexual orientation discrimination. Similarly, the Department concludes it is appropriate to remove such language through these conforming amendments.

(2) Delivery of Medicaid Services (42 CFR 438.3(d)(4), 438.206(c)(2), 440.262)

The Department proposed conforming amendments to multiple provisions in Title 42 of the Code of Federal Regulations that apply to delivery of

[308] *See* Public Law 111–148, tit. I, subtit. D, Part II (Consumer Choices and Insurance Competition Through Health Benefit Exchanges).

[309] *See* Public Law 111–148, tit. I, subtit. D, Part I (Establishment of Qualified Health Plans).

[310] These include Medicare Advantage (Medicare Part C) plans, Medicare Part D plans, Medicaid Managed Care Organizations (MCOs), Medicaid Prepaid Inpatient Health Plans, (PIHPs), Medicaid Prepaid Ambulatory Health Plans (PAHPs), Medicaid Primary Care Case Managers (PCCMs), Primary Care Case Management Entities (PCCM-Es) and Programs for All-inclusive Care for the Elderly serving Medicare and Medicaid beneficiaries (PACE).

[311] *See* 42 CFR 438.3(d)(4), 438.206(c)(2), 440.262, 460.98(a)(3), 460.112(a).

[312] *See, e.g.,* ACA Section 1321 (42 U.S.C. 18041(a)) (authorizing the Secretary to ''issue regulations setting standards . . . with respect to . . . the establishment and operation of Exchanges . . . the offering of qualified health plans through such Exchanges . . . and . . . such other requirements as the Secretary determines appropriate'').

[313] *See, e.g.,* 78 FR 13406 (Feb. 27, 2013) (final rule) and 77 FR 70584, 70585 (Nov. 26, 2012) (NPRM).

Medicaid services found in § 438.3(d)(4) as applied to MCOs, PIHPs, PAHPs, PCCMs or PCCM entities, § 438.206(c)(2) by MCOs, PIHPs, and PAHPs participating in State efforts, and § 440.262 by the States themselves.

Three of the provisions applied to Medicaid managed care. The Department proposed on June 1, 2015, and then finalized on May 6, 2016, a regulation with several nondiscrimination provisions applicable to fee-for-service medical assistance under Medicaid. 80 FR 31098 (June 1, 2015) (Medicaid NPRM); 81 FR 27895 (May 6, 2016) (Medicaid final rule). The Department prohibited discrimination on the basis of ''sexual orientation and ''gender identity'' by MCOs, PIHPs, PAHPs, PCCMs, and PCCM-Es. 42 CFR 438.3(d)(4). And it required that certain of these entities promote access and/or delivery of services ''in a culturally competent manner to all enrollees . . . regardless of gender, sexual orientation or gender identity.'' 42 CFR§ 438.206(c)(2).

In promulgating these regulations, the Department relied on a statute granting general rulemaking authority to the Secretary of HHS to make and publish rules and regulations as may be necessary to efficiently administer Medicare and Medicaid. Section 1102 of the Social Security Act, 42 U.S.C. 1302(a). It also cited provisions of the Social Security Act that require Medicaid State plans for medical assistance to ''provide . . . such methods of administration . . . as are found by the Secretary to be necessary for the proper and efficient operation of the plan.'' Section 1902(a)(4) of the Social Security Act (42 U.S.C. 1396a(a)). And it cited Section 1902(a)(19) of the Social Security Act to justify additional methods of administration and new protected categories necessary for the proper operation of a State plan, for best interest of the beneficiaries, and for cultural competency. 81 FR 27895 (Medicaid final rule). None of these authorities prohibits discrimination on the basis of gender identity or sexual orientation.

In reviewing § 440.262, the Department became aware that in proposing a conforming amendment to the first sentence, the proposed rule is worded to delete the second sentence of that section, which reads ''These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.'' The Department's intent was to make a conforming amendment to the first sentence of that section, but not to delete the second sentence. Therefore, the Department finalizes the conforming amendment to the first sentence of § 440.262 without change, but makes a technical correction by finalizing the section to retain the second sentence of that section. In other words, the Department is finalizing the change to the first sentence of § 440.262, but is not finalizing the deletion of the second sentence. In addition, the Department corrects the grammar of the second sentence, by changing the word ''meet'' to ''meets.'' Medicare's PACE Program Employees and Organizations (42 CFR 460.98(b)(3), 460.112(a)).

The Department proposed conforming amendments to two provisions that apply to PACE, a health program receiving HHS Federal financial assistance that is therefore subject to Section 1557.

In 2006, the Department promulgated a regulation administering PACE that prohibited discrimination on the basis of sexual orientation. 71 FR 71244 (Dec. 8, 2006) (PACE final rule). Sexual orientation had not been identified as a protected category in the statute authorizing PACE. *See* Public Law 98–21, as amended (codified at 42 U.S.C. 1396u–4 *et seq.*).

In the PACE final rule, in response to a request from two commenters to ''broaden the list of categories under which the PACE Organization cannot discriminate to include sexual orientation,'' the Department agreed to amend 42 CFR 460.98(b)(3) to prohibit discrimination on the basis of sexual orientation for Medicare and Medicaid participants. The PACE proposed rule also prohibited discrimination on the basis of sexual orientation by employees and contractors of Medicare-participating PACE programs. 42 CFR 460.112(a) (providing that ''[e]ach participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment'').

Medicare Part A programs, including PACE, are subject to Title VI, Title IX, Section 504, and the Age Act. OCR has the authority to review recipient policies and procedures and certify that recipients of Federal financial assistance under Medicaid Part A comply with Title VI, Title IX, Section 504, and the Age Act, and their implementing regulations. CMS now directs applicants to an online attestation portal on the OCR website to assure compliance with those four civil rights statutes as well as with Section 1557.

In reviewing § 460.112(a), the Department became aware that in proposing a conforming amendment to the first two sentences, the proposed rule is worded to delete the remainder of the subsection. The Department's intent was to make a conforming amendment to the first two sentences of subsection (a), but not to delete its remainder. Therefore, the Department finalizes the conforming amendment to the first two sentences of § 460.112(a) without change, but as a matter of technical correction does not finalize the deletion of the remaining sentences, and instead finalizes subsection (a) to retain the remainder of that subsection.

Comment: Commenters expressed concern that PACE organizations would be allowed to discriminate against LGBTQ people under the proposed rule.

Response: The Department believes that everyone should be treated with dignity and respect and given every protection afforded by the Constitution and the laws passed by Congress. None of the statutes authorizing the PACE regulations prohibits discrimination on the basis of gender identity or sexual orientation.

(3) General Standards for Exchanges, QHPs for Exchanges, and Health Plan Issuers (45 CFR 155.120(c)(ii)), 156.200(e))

In 2012, the Department added ''sexual orientation'' and ''gender identity'' into certain regulations for the administration of the ACA by States, the Exchanges, and QHP issuers. 77 FR 18469 (Mar. 27, 2012) (''Administration of Exchanges final rule''). The Department cited Section 1321 of the ACA as its authority to add new nondiscrimination requirements. 76 FR at 41873, 41897 (July 15, 2011) (''Administration of Exchanges proposed rule'').

Section 1321 is a general regulatory provision allowing HHS to regulate establishment, operation, and standards in Exchanges and for QHPs. It does not contain the words ''sexual orientation'' or ''gender identity,'' or specify that the authority to set standards includes the authority to specify classes protected from discriminatory conduct that are not otherwise specified in nondiscrimination statutes.[314] Sections 155.120(c)(ii) and 156.200(e) were both later referenced in the preamble to the 2016 Rule as nondiscrimination provisions that the 2016 Rule

[314] Section 1321(a) of the ACA provides that the Secretary of the Department of Health and Human Services ''shall, as soon as practicable after the date of enactment of this Act, issue regulations setting standards for meeting the requirements under this title, and the amendments made by this title, with respect to—(A) the establishment and operation of Exchanges (including SHOP Exchanges); (B) the offering of qualified health plans through such Exchanges . . .'' 42 U.S.C. 18041(a)(1)(A)–(B).

''complements.'' *See* 81 FR 31376, 31428 (May 18, 2016). The 2016 Rule also provided that the States, Exchanges, and issuers are ''obligated to comply with both sets of requirements.'' *Id.*

(4) Guaranteed Coverage (45 CFR 147.104(e))

In the February 27, 2013 edition of the **Federal Register**, the Department finalized a new regulation expanding the nondiscrimination provisions applicable to QHP issuers, including prohibitions on discrimination on the basis of gender identity and sexual orientation, citing Section 1321(a) of the ACA as the applicable statutory authority. 78 FR 13406 (Guaranteed Coverage final rule, codified at 45 CFR 147.104(e)). Nevertheless, the language in the final rule prohibiting discrimination on the basis of gender identity and sexual orientation was not in the proposed rule. *See* 77 FR 70584, 70613 (Nov. 26, 2012). It appears that the Department added this language in response to a commenter asking that HHS ''broaden[ ] [§ 147.104(e)] to apply to all forms of discrimination prohibited by the March 27, 2012 Exchange final rule and section 1557 of the Affordable Care Act, such as discrimination based on age, disability, race, ethnicity, gender, and sexual orientation, not just discrimination against individuals with significant or high cost healthcare needs.'' 78 FR at 13417.

As legal authority, the Department also relied on Section 2702 of the Public Health Service Act, as amended by the Affordable Care Act, Public Law 111–148 (Mar. 23, 2010), which only required that any ''individual or group market in a State must accept every employer and individual in the State that applies for such coverage.'' There was no explicit reference to categories of individuals protected by nondiscrimination laws.

The rule administered the ACA's guarantee of coverage in the group and individual health insurance markets. *See* 42 U.S.C. 300gg–1. The Department attached the sexual orientation and gender identity nondiscrimination provision as part of the requirement for issuers to accept every employer and individual in the State who applies for coverage, subject to a few exceptions. Section 300gg–1 does not specify nondiscrimination criteria, including sexual orientation or gender identity.

The rule applied not only to the health plan issuer but also to its ''officials, employees, agents and representatives.'' 45 CFR 147.104(e). It prohibited these covered entities from discriminating based on a variety of bases, including an individual's sex, sexual orientation, or gender identity. *Id.* In the Guaranteed Coverage final rule, the Department justified the 45 CFR 147.104(e) nondiscrimination provision on the ground that it ''ensures consistency with . . . the non-discrimination standards applicable to QHPs under § 156.200(e),'' to which sexual orientation and gender identity provisions had previously been added (as described above). 78 FR at 13426. The Guaranteed Coverage final rule was also referenced in the preamble to the 2016 Rule, which described it as both ''independent of''' and ''complement[ary]'' to Section 1557. 81 FR at 31428.[315]

The Department notes that this amendment to the Guaranteed Coverage final rule does not negate the rule's requirement that health insurance issuers offering group or individual coverage ''must offer to any individual or employer in the State all products that are approved for sale in the applicable market, and must accept any individual or employer that applies for any of those products.'' 45 CFR 147.104(a). That requirement applies independent of the explicit nondiscrimination categories set forth in § 147.104(a).

(5) Enrollment in QHPs Through Exchanges by Agents or Brokers (45 CFR 155.220(j)(2)(i))

In the December 2, 2015 edition of the **Federal Register**, the Department proposed a rule that would prohibit agents or brokers from discriminating on the basis of sexual orientation and gender identity when assisting individuals and employers in applying for or enrolling in QHPs sold through a Federally-facilitated Exchange. 80 FR 75488. This proposed rule was adopted without change in March of the following year. 81 FR 12204 (Mar. 8, 2016) (codified at 45 CFR 155.220(j)(2)(i)). The final rule also stated that covered entities must comply with ''certain other Federal civil rights laws [that] impose non-discrimination requirements,'' such as Section 1557 of the ACA.[316] The final rule further directed issuers who seek certification of one or more QHPs to the OCR website for information about the Section 1557 NPRM.[317]

(6) Enrollment in QHPs and Exchanges by QHP Issuers (45 CFR 156.1230(b)(2))

In the September 6, 2016 edition of the **Federal Register**, the Department proposed a gender identity and sexual orientation nondiscrimination provision to rules governing marketing or conduct by issuers of individual market QHPs sold through the Federally-facilitated Exchanges in the direct enrollment of individuals in a manner that is considered to be through the Exchange. 81 FR 61456. The rule proposed that QHP issuers would be required to ''refrain from marketing or conduct that is misleading . . . coercive, or discriminates based on race, color, national origin, disability, age, sex, gender identity, or sexual orientation.'' *Id.* The proposed language was finalized that December. 81 FR 94058 (Dec. 22, 2016) (codified at 45 CFR 156.1230(b)(3), since redesignated as 45 CFR 156.1230(b)(2) (see 84 FR 17454, 17568 (Apr. 25, 2019, effective June 24, 2019))). The Department cited Section 1321 of the ACA as its authority to promulgate the nondiscrimination provision. The authority section of the regulation also encompasses Section 1311 of the ACA, which prohibits QHPs from ''employ[ing] marketing practices or benefit designs that have the effect of discouraging the enrollment in such plan by individuals with significant health needs.'' [318]

(7) Summary of Regulatory Changes

The Department finalizes without change the proposed conforming amendments at 42 CFR 438.3(d), 438.206(c)(2), and 460.98(b)(3), and 45 CFR§ 147.104(e), 155.120(c)(ii), 155.220(j)(2)(i), and 156.200(e). It finalizes the proposed conforming amendment of the first sentence of § 440.262 without change, but retains the second sentence of that section without deleting it, and makes one grammatical correction to the second sentence. It finalizes the proposed conforming amendment of the first two sentences of § 460.112(a) without change, but retains the remainder of that subsection without deleting it.

With respect to 45 CFR 156.1230(b)(2), the proposed rule indicated it would amend § 156.1230(b)(3), but effective June 24, 2019, § 156.1230(b)(3) was redesignated as § 156.1230(b)(2). *See* 84 FR at 17568.

[315] *See* 81 FR 31376, 31428 (May 18, 2016) (''We noted that this section [92.207] is independent of, but complements, the nondiscrimination provisions that apply to . . . issuers of qualified health plans under other Departmental regulations, and that entities covered under those provisions and Section 1557 are obligated to comply with both sets of requirements.'').

[316] 81 FR 12312 (''Issuers that receive Federal financial assistance, including in connection with offering a QHP on an Exchange, are subject to Title VI of the Civil Rights Act of 1964, the Age Discrimination Act of 1975, section 504 of the Rehabilitation Act of 1973, and section 1557 of the Affordable Care Act'').

[317] *Id.*

[318] 42 U.S.C. 18031.

Therefore, this rule finalizes the change at the redesignated location of the text at § 156.1230(b)(2).

IV. Regulatory Impact Analysis

The Department has examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review, 58 FR 51735 (Oct. 4, 1993); Executive Order 13563 on Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011); Executive Order 13132 on Federalism, 64 FR 43255 (Aug. 4, 1999); Executive Order 13175 on Tribal Consultation, 65 FR 67249 (Nov. 6, 2000); Executive Order 13771 on Reducing Regulation and Controlling Costs, 82 FR 9339 (Jan. 30, 2017); the Congressional Review Act (Pub. L. 104–121, sec. 251, 110 Stat. 847 (Mar. 29, 1996)); the Unfunded Mandates Reform Act of 1995, Public Law 104–4, 109 Stat. 48 (Mar. 22, 1995); the Regulatory Flexibility Act (Pub. L. 96–354, 94 Stat. 1164 (Sept. 19, 1980); Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking, 67 FR 53461 (Aug. 16, 2002); Executive Order 12250, Leadership and Coordination of Nondiscrimination Laws, 45 FR 72995 (Nov. 2, 1980), and the Paperwork Reduction Act of 1995, 44 U.S.C. 3501, *et seq.*

A. Executive Orders 12866 and Related Executive Orders on Regulatory Review

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 13563 is supplemental to Executive Order 12866 and reaffirms the principles, structures, and definitions governing regulatory review established there.

As discussed below, the Department has estimated that this final rule will have a beneficial effect on the economy greater than $100 million in at least one year. Thus, it has been concluded that this final rule is economically significant. It has, therefore, been determined that this final rule is a ''significant regulatory action'' under Executive Order 12866 and, accordingly, the Office of Management and Budget (OMB) has reviewed this final rule.

The executive summary at the beginning of this preamble contains a summary of this final rule in its summary of major provisions, and describes the reasons it is needed in describing the purpose of this final rule.

(1) Consideration of Regulatory Alternatives

The Department carefully considered several alternatives, including the option of not pursuing any regulatory changes, but rejected that approach for several reasons.

First, not pursuing any regulatory changes would be inconsistent with the Administration's policies of appropriately reducing regulatory burden, in general, with respect to individuals, businesses and others, and from the ACA specifically.

Second, not pursuing any regulatory change would be inconsistent with various court rulings that have rejected or undermined the legal positions taken by the Department in the 2016 Rule. It would not, for example, ensure that the text of the Code of Federal Regulations accurately reflects the *vacatur* of the provisions including gender identity and termination of pregnancy as prohibited grounds of discrimination on the basis of sex. It also would not account for the decision of the Northern District of Illinois that the ''plain and unambiguous'' statutory text of Section 1557 indicated that a plaintiff could only use the enforcement mechanism of the underlying civil rights statute that corresponds to its claim. *Briscoe* v. *Health Care Serv. Corp.,* 281 F. Supp. 3d 725, 737–38 (N.D. Ill. 2017) (dismissing a Section 1557 claim for sex discrimination using a disparate impact standard, because plaintiffs cannot bring disparate impact claims under Title IX); *accord Galuten on Behalf of Estate of Galuten* v. *Williamson Med. Ctr.,* 2019 WL 1546940, at * (M.D. Tenn. Apr. 9, 2019); *E.S. by and through R.S.* v. *Regence BlueShield,* 2019 WL 4566053, at *4 (W.D. Wash. Sept. 24, 2018); *but see Rumble* v. *Fairview Health Servs.,* No. 14–cv–2037 (SRN/FLN) (D. Minn. Mar. 16, 2017) (declining to determine the specific standard on a motion to dismiss and rejecting the implication that Congress meant to create a ''new anti-discrimination framework completely 'unbound by the jurisdiction of the four referenced statutes,' '' but concluding Congress ''likely'' intended a single standard to avoid ''patently absurd consequences''). In addition, it would fail to account for the decisions of Federal courts in California, New York, and Iowa that did not recognize disparate impact claims for sex discrimination under Section 1557, because such claims are not cognizable under Title IX. *See Condry* v. *UnitedHealth Group,* No. 3:17–cf–00183–VC (N.D. Calif. June 27, 2018) (Slip. Op. at 7); *Weinreb* v. *Xerox Business Services,* 323 F. Supp. 3d 501, 521 (S.D.N.Y. 2018); *York* v. *Wellmark, Inc.,* No. 4:16–cv–00627–RGE–CFB, Slip. Op. at *30 (S.D. Iowa Sep. 6, 2017). A court in Pennsylvania similarly indicated that there is no disparate impact claim for discrimination on the basis of race under Section 1557, because such claims are unavailable under Title VI. *See Southeastern Pennsylvania* v. *Gilead,* 102 F. Supp. 3d 688 (E.D. Pa. 2015); *but see Callum* v. *CVS Corp.,* 137 F. Supp. 3d 817 (D.S.C. 2015).

Third, the Department believes that the status quo would not address, much less remedy, public confusion regarding complainants' rights and covered entities' legal obligations. The Department believes that revisiting the rule will address inconsistences between the Department's underlying regulations and the regulations and actions taken by other components of the Government. As applied to sex discrimination claims, the 2016 Rule set forth a definition of discrimination on the basis of sex under Section 1557 implementing Title IX that varied from the practice of other Departments. If the Department uses interpretations of Title IX that differ from other Departments and from the legal interpretation of the U.S. Government as set forth by the Department of Justice, it could lead to inconsistent outcomes across complainants and covered entities, with the problem especially acute in cases involving a single covered entity being investigated with respect to the same allegations by multiple Departments that come to different conclusions on effectively the same question.

The Department also considered adding ''gender identity'' and ''sexual orientation'' to a definition of ''sex'' or ''on the basis of sex'' under Title IX. The Department concluded it is inappropriate to do so in light of the ordinary public meaning of discrimination on the basis of sex under Title IX. This final rule will also significantly restore the ability of States to establish policies in this area, based on their weighing of the competing interests at stake. As a policy matter, the Department believes State and local entities are better equipped to address with sensitivity issues of gender dysphoria, sexual orientation, and any competing privacy interests, especially when young children or intimate settings are involved. The Department's position will not bar covered entities from choosing to grant protections on the basis of sexual orientation and gender identity that do not conflict with any other Federal law. The Department has also determined that economic incentives, performance objectives, or

other related forms of regulation are neither appropriate nor feasible solutions to the problems to be solved.

The Department also considered simply repealing the 2016 Rule *in toto* and not issuing a replacement regulation. Such an approach would be consistent with the Administration's goals of reducing the regulatory burden on covered entities, and is allowed under Section 1557, as that provision does not require the Department to issue implementing regulations. However, the Department is committed to vigorous enforcement of civil rights and nondiscrimination laws as directed by Congress, and considers it worthwhile to set forth that commitment in a Section 1557 regulation which takes the position that the Department will use the enforcement mechanisms available under the statutes cited in Section 1557 and their underlying regulations. Additionally, the Department believes that certain provisions—such as those addressing the assurance of compliance with Section 1557, effective communication and accessibility for individuals with disabilities, and certain language access services—address applications of civil rights laws without the statutory or legal conflicts, or excessive regulatory burdens, entailed by other provisions of the current Rule.

The Department also considered retaining the provision on visual standards for video remote interpreting services for LEP individuals. However, the burden of requiring covered entities to provide video technology training and utilize expensive software does not appear to be justified based on minimal benefit to language speakers who can effectively communicate when there is clear audio transmission through the remote interpreting service.

Accordingly, the Department believes it is appropriate to clarify how OCR will enforce the ACA's nondiscrimination protections by replacing the 2016 Rule with regulatory provisions (1) applying the enforcement mechanisms provided under the civil rights statutes and related implementing regulations cited in Section 1557 to the contexts identified in Section 1557, (2) vesting enforcement authority under Section 1557 with the Director of the Office for Civil Rights, and (3) specifying how Section 1557 enforcement shall interact with existing laws—while retaining certain language and disability access provisions and the assurances provision.

With respect to the requirement that covered entities provide nondiscrimination notices and taglines, the Department considered keeping the requirement but limiting the frequency of required mailings to one per year to each person served by the covered entity. To estimate the cost of this option, the Department adopted the base assumptions described in this Regulatory Impact Analysis regarding the number of covered entities and the average unit cost associated with the low-end and high-end costs of a notice and taglines mailing (materials, postage, and labor).[319] The Department adjusted the volume of mailings based on the average number of individuals served by each covered entity.[320] The Department assumed the same covered entity compliance rate for the insurance industry as under this Regulatory Impact Analysis but assumed an increased compliance rate for non-insurers (assuming 30% instead of 10%) to reflect that more entities would likely comply with the requirements if the burden were to be significantly reduced to one mailing per customer/patient per year. Based on this method, the estimated total cost of this alternative is approximately $63 million per year. Although this option poses a significantly reduced burden, the Department believes the costs under this alternative still outweigh the benefits because such mass multi-language taglines mailings would still be received overwhelmingly by English speakers and because the requirement to issue nondiscrimination notices would be largely duplicative of nondiscrimination notice requirements that already exist under Section 1557's underlying civil rights regulations.[321]

(2) Considerations for Cost-Effective Design

In this final rule, the Department replaces much of the 2016 Rule, to significantly reduce regulatory burdens and to return to the longstanding understanding of the underlying nondiscrimination obligations imposed by the civil rights laws referenced in Section 1557.

In the preamble to the 2016 Rule, the Department observed that there were pre-existing requirements under Federal civil rights laws that, ''except in the area of sex discrimination,'' applied to a large percentage of entities covered by the 2016 Rule. 81 FR at 31446. Thus, in the 2016 Rule the Department concluded it did not expect covered entities to undertake additional costs with respect to that rule's prohibitions on discrimination on the basis of race, color, national origin, age, or disability, ''except with respect to the voluntary development of a language access plan.'' *Id.*

By finalizing this rule without the 2016 Rule's definition of sex discrimination and eliminating the requirements regarding notices, taglines, and visual standards in video remote interpreting services for LEP individuals, language access plans, and duplicative grievance procedures, the final rule also allows covered entities the freedom to order their operations more efficiently, more flexibly, and in a more cost-effective manner.

Accordingly, returning to the familiar longstanding requirements is a cost-effective way of (1) removing the unjustified burdens imposed by the 2016 Rule; (2) reducing confusion among the public and covered entities; (3) promoting consistent, predictable, and cost-effective enforcement; and (4) creating space for innovation in the provision of compliant services by covered entities (including flexible and innovative language access practices and technology), while faithfully and vigorously enforcing Section 1557's civil rights protections.

(3) Methodology for Cost-Benefit Analysis

For purposes of this Regulatory Impact Analysis (RIA), the final rule adopts the list of covered entities and other cost assumptions identified in the 2016 Rule's RIA and that of the 2019 proposed rule. The use of assumptions from the 2016 Rule in the present RIA, however, does not mean that the Department adopts those assumptions in any respect beyond the purpose of estimating (1) the number of covered entities that would be relieved of burden, and (2) cost relief. For example, the 2016 Rule based several cost estimates on an expansive definition of Federal financial assistance, which significantly impacted the number of covered entities currently burdened by the 2016 Rule; thus, it is appropriate to use that definition for estimating cost relief. Such use, however, should not be interpreted as an endorsement or

[319] The average of the low ($0.035) and high ($0.32) unit costs is $0.18 per notice and tagline mailing.

[320] The estimated volume is expected to vary based on covered entity type. For instance, each of the 180 health insurance issuers serve 685,138 individuals on average, based on the number of insured individuals (123 million), which equates to 685,138 mailings per issuer. Each of the 185,649 physicians' offices serve 1,703 individuals, based on the average number of individuals (316 million) associated with 990 million physicians visits. On average, each covered entity serves about 3,000 persons per entity, which equates to 3,000 mailings per entity, based on 820 million persons served by 275,002 covered entities.

[321] *See* 45 CFR 80.6(d) (Title VI), 84.8 (Section 504), 86.9 (Title IX), 91.32 (Age Act).

acceptance of the definition for any other purpose.

The Department also does not ''carry over'' every assumption from the 2016 Rule for this final rule's RIA calculation. Most notably, the Department no longer considers its prior estimates of costs imposed due to the 2016 Rule's taglines requirement to be accurate or valid, and provides a more thorough and accurate estimate for purposes of this final rule.

Cost savings result from the repeal of (1) the provision on the incentive for covered entities to develop language access plans and (2) the provisions on notice and taglines. In addition, the Department quantitatively analyzes and monetizes the impact that this final rule may have on covered entities' voluntary actions to re-train their employees on, and adopt policies and procedures to implement, the legal requirements of this final rule. The Department analyzes the remaining benefits and burdens qualitatively because of the uncertainty inherent in predicting other concrete actions that such a diverse scope of covered entities might take in response to this final rule.

The Department also considered the public comments submitted in response to the proposed rule. The Department appreciates the information and various perspectives provided in those comments, which are summarized below and for which responses are provided.[322]

(4) Cost-Benefit Analysis

a. Overview

In the 2016 Rule, the Department estimated $942 million [323] in costs (over five years) due to impacts on personnel training and familiarization, enforcement, posting of nondiscrimination notices and taglines, and revisions in covered entity policies and procedures. 81 FR 31446, and 31458–59 (at Table 5). As stated earlier, the Department estimated in the 2016 Rule that these costs would arise *primarily* from requirements imposed by the 2016 Rule with which covered entities were not already complying.[324] The Department specifically identified the 2016 Rule's interpretation of sex discrimination to cover gender identity and sex stereotyping,[325] and the 2016 Rule's consideration of language access plans for compliance purposes, as provisions triggering the imposition of new costs.[326] *See* 81 FR 31459—Table 5.

In 2016, the Department estimated that the 2016 Rule's nondiscrimination notice requirement would impose approximately $3.6 million in one-time additional costs on covered entities. 81 FR 31469. Regarding these requirements, the Department stated: ''We are uncertain of the exact volume of taglines that will be printed or posted, but we estimate that covered entities will print and post the same number of taglines as notices and therefore the costs would be comparable to the costs for printing and disseminating the notice, or $3.6 million.'' 81 FR 31469. Thus, the total notice and taglines cost was estimated at $7.2 million in the first year and was predicted to go down to zero after year one, despite the regulatory requirement for covered entities to provide notices and taglines to beneficiaries, enrollees, and applicants by appending notices and taglines to all ''significant publications and significant communications'' larger than postcards or small brochures. *Compare* 81 FR 31458 (Table 5), *with* 45 CFR 92.8.

For reasons explained more fully below, the 2016 estimate of $7.2 million in one-time costs stemming from the notice and taglines requirement was a gross underestimation, and thus this final rule's elimination of those requirements would generate a large economic benefit of approximately $2.9 billion over five years on the repeal of the notice and taglines provision.

Table 1 shows the expected cost savings from the repeal of the notice and taglines provision and the quantified costs to firms for training and revising procedures and policies.

TABLE 1—ACCOUNTING TABLE OF ECONOMIC BENEFITS AND COSTS OF ALL FINALIZED CHANGES

[In millions]

	Year 1	Year 2	Year 3	Year 4	Year 5	Total
Savings:						
Total (undiscounted)	$643	$614	$585	$556	$528	$2,926
Total (3%)	624	579	536	494	455	2,688
Total (7%)	601	536	478	425	376	2,416
Costs—Quantified Costs:						
Total (undiscounted)	276	0	0	0	0	276
Total (3%)	269	0	0	0	0	269
Total (7%)	259	0	0	0	0	259
Net Total (undiscounted | 3% | 7%)						2,650 $2,319 (3%) $2,157 (7%)

Non-quantified benefits and costs are described below.

[322] The population, labor, and similar statistical data used in this RIA are also not changed from those used in the RIA in the proposed rule, because updating that data from the time of the proposed rule in June 2019 to the time of the publication of this final rule would not lead to substantive changes in the analysis.

[323] Throughout the regulatory impact analysis in the 2016 Rule, the 2016 estimates used 2014 dollars unless otherwise noted.

[324] 81 FR 31446 (''to the extent that certain actions are required under the final rule where the same actions are already required by prior existing civil rights regulations, we assume that the actions are already taking place and thus that they are not a burden imposed by the rule'').

[325] 81 FR 31455 (''Although a large number of providers may already be subject to state laws or institutional policies that prohibit discrimination on the basis of sex in the provision of health services, the clarification of the prohibition of sex discrimination in this regulation, particularly as it relates to discrimination on the basis of sex stereotyping and gender identity, may be new.'').

[326] Although the 2016 Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director ''shall'' take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would be induced to develop and implement a language access plan following issuance of the 2016 Rule. 81 FR 31454.

b. Generally Applicable Benefits and Burdens

i. Simplification and Flexibility

This final rule would result in other tangible benefits for covered entities. First, because this final rule is simpler and more easily administrable, it would be less likely that covered entities will need to pay for legal advice or otherwise expend organizational resources to understand their obligations under Section 1557, either in general or with respect to any particular situation that arises. Second, this final rule reduces the need for covered entities to expend labor and money on an ongoing basis to maintain internal procedures for mitigating the legal risk that persists due to unresolved controversy over the meaning of Section 1557. The Department solicited comment regarding the nature and magnitude of such ongoing costs incurred by covered entities, and below the Department summarizes and responds to significant comments regarding the regulatory impact of changes to the notice and taglines requirements.

This final rule will also carry intangible benefits, including that covered entities would enjoy increased freedom to adapt their Section 1557 compliance programs to most efficiently address their particular needs, benefiting both covered entities and individuals. The value of knowledge of civil rights is difficult to quantify. Covered entities will be free under the final rule to implement policies and procedures that comply with Federal civil rights laws in creative, effective, and efficient ways that are tailored to the covered entities and the communities that they serve.

ii. Policies and Procedures Concerning Gender Identity

In the proposed rule, the Department anticipated that the 2016 Rule likely induced many covered entities to conform their policies and operations to reflect gender identity as a protected category under Title IX. The Department requested and received public comments on the possible benefits and burdens related to changes in the proposed rule.

Comment: Many commenters contended that the proposed rule would lead covered entities to remove protections from transgender individuals in their policies and procedures. Commenters contended that these changes would lead to a wide range of burdensome results, including discrimination on the basis of gender identity and resulting negative health consequences, increased costs for treatment of such conditions, cost-shifting to transgender individuals, and increased burdens on the public health system due to the changes. Commenters also contended that similar results would occur from the Department's decision not to include sexual orientation nondiscrimination provisions in the proposed rule.

Response: The Department does not believe that this final rule will lead to significant burdens on entities due to changes to the gender identity language from the 2016 Rule, nor that the commenters have identified sufficient data to show that these negative consequences will occur or the extent to which they will occur. In December 2016, the *Franciscan Alliance* court preliminarily enjoined the gender identity provisions of the 2016 Rule on a nationwide basis, and more recently the court vacated those provisions. Consequently, this final rule's revisions to the provisions addressing gender identity do not change covered entities' obligations. Therefore, even though some entities may have changed their policies and procedures at the outset of the 2016 Rule, the Department concludes that because the gender identity provisions of the 2016 Rule have been vacated prior to this rule being finalized, it is even less likely than at the time of the proposed rule that this final rule will lead to changes in policies and procedures concerning gender identity. In addition, as explained above, the 2016 Rule did not include language prohibiting discrimination on the basis of sexual orientation status standing alone as a form of sex discrimination. The Department therefore does not anticipate any material change to covered entities' policies concerning sexual orientation as a result of this final rule.

In addition, it is worth noting that many covered entities are located in jurisdictions that prohibit sexual orientation and gender identity discrimination under State or local laws. Therefore, such entities are unlikely to change their policies, training, or grievance procedures concerning gender identity as a result of this final rule. Moreover, nothing in this final rule, or in the court decisions, prohibits entities from maintaining gender identity nondiscrimination policies and procedures voluntarily, and the Department believes some covered entities will continue to do so.

If some entities change their policies and procedures based on this final rule, such a reversion may entail amending organizational nondiscrimination policies and training materials, and communicating those changes to employees. The process of voluntarily reverting to previous practices would likely result in net cost savings to covered entities. Otherwise these entities likely would not take such action. In addition, the Department believes that, if this final rule led to covered entities changing policies and procedures, some covered entities may no longer incur costs associated with processing grievances related to gender identity discrimination under Title IX, because such claims will not be cognizable under this final rule.

The Department, however, is uncertain as to the total number of covered entities that will change their policies and grievance processes to reflect the changes in this final rule. The reasons for this uncertainty include, as stated above, the fact that such changes would only be indirectly attributable to this rule, not caused by this rule, because previous court rulings have negated the gender identity provisions from the 2016 Rule for over three years, and this rule has no effect on State and local gender identity protections. The Department is not aware of data about how many entities might change their policies for these indirect reasons.

Similarly, the Department also lacks the data necessary to estimate the number of individuals who currently benefit from covered entities' policies governing discrimination on the basis of gender identity who would no longer receive those benefits after publication of this rule—nor data to estimate how many of those individuals may experience the workplace and health-related negative consequences that many commenters contend will result from this final rule. The Department similarly lacks data to estimate what greater public health costs, cost-shifting, and expenses may result from entities changing their nondiscrimination policies and procedures after promulgation of this rule. The Department reiterates that it believes these effects will be minimal, again due to the fact that gender identity provisions were vacated from the 2016 Rule by the *Franciscan Alliance* court before this rulemaking was finalized.

c. Baseline Assumptions

The following discussion identifies the economic baselines from which the Department measures the expected costs and benefits of this final rule. Its baselines includes the cost estimates in the 2016 Rule, in addition to data it has gathered since the 2016 Rule was implemented, as described in more detail below. The Department also considered public comments, and

responds to significant comments in this discussion.

Key assumptions track those set forth in the proposed rule and include the following: (1) The 2016 Rule triggered significant activity on the part of covered entities, generating both costs and benefits; (2) under the December 2016 nationwide preliminary injunction in *Franciscan Alliance,* and the October 2019 final judgment in that case, the gender identity and termination of pregnancy provisions of the 2016 Rule have been unenforceable and are now absent from the 2016 Rule, without regard to whether this rule is finalized; (3) covered entities were already generally complying with civil rights laws and related regulations that were in effect before the 2016 Rule, and so this final rule generally does not impose any new burden beyond those imposed prior to the issuance of the 2016 Rule;[327] (4) the projected costs from the 2016 Rule for years 1 and 2 have been incurred, and the projected costs from years 3, 4, and 5 have not been incurred; (5) repeal of the 2016 Rule's notice and taglines requirements does not affect notice or taglines requirements required by CMS guidance or regulations that do not reference, rely on, or depend upon the taglines requirements of the 2016 Rule; (6) a relatively small percentage of physicians and hospitals currently append notices and taglines to billing statements sent to patients, while all insurance companies append notices and taglines to their explanations of benefits statements; and (7) covered employers are more likely to train employees who interact with the public than those who do not.

d. Covered Entities

i. Entities Covered by Section 1557

The 2016 Rule and this final rule apply to any entity that has a health program or activity, any part of which receives Federal financial assistance from the Department, any program or activity administered by the Department under Title I of the ACA, or any program or activity administered by an entity established under such Title. Covered entities under the 2016 Rule's definition[328] include the following:

(A) Entities With a Health Program or Activity, Any Part of Which Receives Federal Financial Assistance From the Department

The RIA for the 2016 Rule stated that the Department, through agencies such as the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Centers for Disease Control and Prevention (CDC), and the Centers for Medicare & Medicaid Services (CMS), provides Federal financial assistance through various mechanisms to health programs or activities of local governments, State governments, and the private sector. An entity may receive Federal financial assistance from more than one component in the Department. For instance, Federally qualified health centers receive Federal financial assistance from CMS by participating in Medicaid programs and may also receive Federal financial assistance from HRSA through grant awards. Because more than one funding stream may provide Federal financial assistance to an entity, the examples we provide may not uniquely capture entities that receive Federal financial assistance from only one component of the Department. Under the 2016 Rule, the covered entities consisted of the following:

(i) Entities receiving Federal financial assistance through their participation in Medicare (excluding Medicare Part B) or Medicaid (about 133,343 facilities).[329] Examples of these entities cited in the 2016 Rule's RIA include:

- Hospitals (includes short-term, rehabilitation, psychiatric, and long-term)
- Skilled nursing facilities/nursing facilities (facility-based and freestanding)
- Home health agencies
- Physical therapy/speech pathology programs
- End-stage renal disease dialysis centers
- Intermediate care facilities for individuals with intellectual disabilities
- Rural health clinics
- Physical therapy—independent practice
- Comprehensive outpatient rehabilitation facilities
- Ambulatory surgical centers
- Hospices
- Organ procurement organizations
- Community mental health centers
- Federally qualified health centers.

(ii) Laboratories that are hospital-based, office-based, or freestanding that receive Federal financial assistance through Medicaid payments for covered laboratory tests (about 445,657 laboratories with Clinical Laboratory Improvement Act certification).

(iii) Community health centers receiving Federal financial assistance through grant awards from HRSA (1,300 community health centers).[330]

(iv) Health-related schools in the United States and other health education entities receiving Federal financial assistance through grant awards to support 40 health professional training programs that include oral health, behavioral health, medicine, geriatric, and physician's assistant programs.[331]

(v) State Medicaid agencies receiving Federal financial assistance from CMS to operate CHIP (includes every State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vi) State public health agencies receiving Federal financial assistance from CDC, SAMHSA, and other HHS components (includes each State, the District of Columbia, Puerto Rico, Guam, the Northern Marianas, U.S. Virgin Islands, and American Samoa).

(vii) QHP issuers receiving Federal financial assistance through advance payments of premium tax credits and cost-sharing reductions (which include at least the 169 health insurance issuers in the Federally-facilitated Exchanges receiving Federal financial assistance

[327] OMB Circular A–4 discusses the practice whereby an RIA for a rule codifying a policy may include the impacts of that policy, even if the effects follow directly from an action by another branch of the federal government. The Circular notes that: ''In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases, you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.'' Although a baseline established prior to the *Franciscan Alliance* court's December 2016 and October 2019 orders would be considered analogous to the pre-statute baseline discussed in Circular A–4, given the existence of the RIA for the 2016 Rule, an assessment relative to a pre-*Franciscan Alliance* baseline would add little to the body of relevant analysis, and the longstanding duration of the court orders contributes to a lack of new data pertaining to certain alleged effects of language falling under those orders. For these reasons, the baseline established after December 2016, which isolates the effects most directly attributable to certain elements of this rule's finalization, is emphasized throughout the relevant parts of this RIA.

[328] As noted above, we use the list and number of covered entities and other figures from the 2016 Rule's RIA in this RIA for the sake of consistency and convenience, but such use does not mean that we adopt or accept any of the underlying analysis, definitions, or assumptions from the 2016 Rule's RIA for any other purpose related to this final rule.

[329] CMS, Provider of Service file (June 2014), *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Provider-of-Services/POS2014.html.*

[330] HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

[331] HRSA, Justification of Estimates for Appropriation Committee For Fiscal Year 2016, 53, *http://www.hrsa.gov/about/budget/budgetjustification2016.pdf.*

through advance payments of premium tax credits and cost-sharing reductions, and at least 11 health insurance issuers operating in the State Exchanges).[332]

(viii) Physicians receiving Federal financial assistance through Medicaid payments, ''meaningful use'' payments, and other sources, but not Medicare Part B payments (Medicare Part B payments to physicians are not Federal financial assistance). The Medicare Access and CHIP Reauthorization Act amended Section 1848 of the Act to sunset ''meaningful use'' payment adjustments for Medicare physicians after the 2018 payment adjustment.

In the 2016 Rule, the Department estimated that that rule likely covered almost all licensed physicians because they accept Federal financial assistance from sources other than Medicare Part B. Many physicians participate in more than one Federal, State, or local health program that receives Federal financial assistance, and many practice in several different settings, which increases the possibility that they may receive payments constituting Federal financial assistance.

For the sake of consistency and convenience, the Department uses the 2016 Rule's RIA estimate of the number of physicians receiving Federal financial assistance. As the 2016 Rule RIA noted, based on 2010 Medicaid Statistical Information System data (the latest available), about 614,000 physicians accept Medicaid payments and are covered under Section 1557 as a result.[333] This figure represents about 69% of licensed physicians in the United States, based on the 890,000 licensed physicians reported in the Area Health Resource File.[334] In addition, physicians receiving Federal payments from non-Part B Medicare sources will also come under Section 1557. The 2016 RIA noted that, as of January 2014, 296,500 Medicare-eligible professionals had applied for funds to support their ''meaningful use'' technology efforts.[335] Adding the approximately 614,000 physicians who receive Medicaid payments to the 296,500 physicians who receive meaningful use payments would yield over 900,000 physicians potentially reached by Section 1557 because they participate in Federal programs other than Part B of Medicare. Because physicians can receive both Medicaid and meaningful use payments, and these figures are not adjusted for duplication, the 900,000 result is best interpreted as an upper bound.

When the Department compared the upper-bound estimated number of physicians participating in Federal programs other than Medicare Part B (over 900,000) to the number of licensed physicians counted in HRSA's Area Health Resource File (approximately 890,000), and allowing for duplication in both the Medicare/Medicaid and HRSA numbers,[336] the Department concluded in the 2016 Rule RIA that almost all practicing physicians in the United States are reached by Section 1557 because they accept some form of Federal remuneration or reimbursement apart from Medicare Part B.

(B) Programs or Activities Administered by the Department Under Title I of the ACA

This final rule applies to programs or activities administered by the Department under Title I of the ACA. Such programs or activities include temporary high-risk pools (section 1101), temporary reinsurance for early retirees (section 1102), Department mechanisms for identifying affordable health insurance coverage options (section 1103), the wellness program demonstration project (section 1201, adding Public Health Service (PHS) Act 2705(*l*)), the provision of community health insurance options (section 1323), and the establishment of risk corridors for certain plans (section 1342).

(C) Entities Established Under Title I of ACA

This final rule applies to the health insurance exchanges established under Title I of the ACA. Such exchanges currently include the 12 State Exchanges (and D.C. Exchange), six State Exchanges on the Federal platform and 32 Federally-facilitated Exchanges.[337] Title I additionally establishes State advisory councils concerning community health insurance (section 1323) and certain reinsurance entities under the transitional reinsurance program (section 1341).

ii. Entities Covered by Title IX

Title IX applies to recipients of Federal financial assistance for education programs or activities. 20 U.S.C. 1681. The population of applicable covered entities is defined by the term ''recipient'' in the Department's Title IX regulations. The population includes any State or political subdivision thereof, or any instrumentality of a State or political subdivision thereof, any public or private agency, institution, or organization, or other entity, or any person, to whom Federal financial assistance is extended directly or through another recipient and that operates an education program or activity that receives such assistance, including any subunit, successor, assignee, or transferee thereof. *See, e.g.,* 45 CFR 86.2. Under the definition of program or activity, recipients of Federal financial assistance within the scope of Title IX may include colleges, universities, local educational agencies, vocational education systems, or other entities or organizations principally engaged in the business of providing education. *See, e.g.,* 45 CFR part 86, App. A (cross-referencing Appendix B to 45 CFR part 80).

e. Cost Savings From Eliminating Notice and Taglines Requirement

The Department's baseline for calculating the savings from repealing the notice and taglines requirement includes approximately $585 million in additional average annual costs (over the next five years) that were not considered in the 2016 Rule. It is important to note that, while industry estimates prompted the Department to reassess the burdens imposed by the 2016 Rule, the Department conducted and relied upon its own cost analysis in developing the RIA for this final rule.

The 2016 Rule estimated $7.1 million for covered entities and $70,400 for the Federal government in combined annual costs for printing and distributing nondiscrimination notices and taglines, with the costs being apportioned roughly equally between notices and taglines. 81 FR at 31453. As explained in detail below, the Department estimates the combined notice and taglines requirement has actually cost

[332] Qualified Health Plans Landscape Individual Market Medical (2015), *https://data.healthcare.gov/dataset/2015-QHP-Landscape-Individual-Market-Medical/mp8z-jtg7.*

[333] John Holahan and Irene Headen, Kaiser Commission on Medicaid and the Uninsured, Medicaid Coverage and Spending in Health Reform: National and State-by-State Results for Adults at or Below 133% FPL (2010), *https://kaiserfamilyfoundation.files.wordpress.com/2013/01/medicaid-coverage-and-spending-in-health-reform-national-and-state-by-state-results-for-adults-at-or-below-133-fpl.pdf.* Estimates are based on data from FY 2010 MSIS.

[334] HRSA, Area Health Resource Files (2015), *http://ahrf.hrsa.gov.*

[335] Mynti Hossain and Marsha Gold, Mathematical Policy Research Inc.: Prepared for The Office of the National Coordinator for Health Information Technology, HHS, Monitoring National Implementation of HITECH: Status and Key Activity Quarterly Summary (Jan. to Mar. 2014), *http://www.healthit.gov/sites/default/files/globalevaluationquarterlyreport_januarymarch2014.pdf.*

[336] The Area Health Resource File itself double counts physicians who are licensed in more than one State.

[337] CMS, State-Based Exchanges for Plan Year 2018 (Nov. 1, 2019), *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/state-marketplaces.html.*

covered entities hundreds of millions of dollars per year.

The 2016 Rule requires covered entities to include a notice and taglines for any ''significant'' document or publication, but did not define the term ''significant.'' 45 CFR 92.8(f)(1)(i).[338] Thus, covered entities have interpreted this provision to require a notice and taglines to accompany many communications from covered entities, including annual benefits notices, medical bills from hospitals and doctors, explanations of benefits from health insurance companies or health plans, and communications from pharmacy benefit managers.

This led to an extraordinary amount of mailed or electronically delivered communications by entities such as plan administrators and pharmacy benefit managers, including with every auto-ship refill reminder, formulary notice, and specialty benefit letter. Further, some other entities that operate in multiple States have interpreted the 2016 Rule as requiring them to include taglines for as many as 60 languages, or have included that many taglines in mailed or electronically-delivered communications due to the cost or technical barriers to customizing mailing inserts on a State-by-State basis, and thus have incurred costs to send up to an additional two double-sided pages of notices with each communication.[339]

To estimate the volume of notices and taglines that accompany an annual benefits notice, we began with the approximately 300 million persons in the United States who have health insurance,[340] or approximately 91% of the U.S. population. The Department then assumed that the annual notice of benefits (that includes a notice and taglines) is sent to each policyholder, not to each individual member of a covered household, such as covered children. Of the total U.S. population, 306 million individuals belong to 117.7 million households. For the data set relied on, a ''household'' includes ''all the people who occupy a housing unit . . . . The occupants may be a single family, one person living alone, two or more families living together, or any other group of related or unrelated people[341] who share living arrangements.''[342] By implication, 17.3 million individuals do not belong to a household,[343] and live in group quarters.[344] The Department assumed that the percentage of the U.S. population that is uninsured, 9%, is the same percentage of U.S. individuals belonging to U.S. households that are uninsured. To calculate the number of annual benefits notices, the Department added the total number of individuals that do not belong to a household (17.3 million) to the total number of households (117.7 million), and discounted the sum (135 million) by 9% to exclude those individuals who are not insured. The total number of annual notices of benefits that include a nondiscrimination notice and taglines is therefore approximately 123 million (approximately 91% of 135 million).

To estimate the volume of notices and taglines that accompany communications from the health insurance Exchanges, the Department assumes the Exchanges send communications to the 11.8 million individuals enrolled in the individual market.[345] It assumes that the Exchanges send out approximately 1.5 notices per person per year. This accounts for the annual re-enrollment communication plus additional communications Exchanges will send for special enrollment periods. Thus, the total estimated volume of notices and taglines attributable to the Exchanges is 17.7 million.

To estimate the volume of notices and taglines that accompany hospital bills and explanations of benefits sent by insurance companies (or health plans) for hospital admissions, the Department first estimated the total number of hospital bills and explanation of benefits that would be sent to patients annually. There are 35 million hospital admissions per year.[346] For the purpose of this estimate, the Department assumes that each admission generates three bills from one hospital visit—each of which would include a notice and taglines document, for a total of 105 million bills, assuming three bills per admission.[347] The Department assumes that 10% of the 105 million bills will have a notice and taglines document attached, for a total of 10.5 million notice and taglines documents.

For patients who were insured upon admission to the hospital, in addition to the three hospital bills they would receive (on average), they would receive three associated explanations of benefits from their insurer or health plan, each of which would also include notice and taglines documents. If more than three service providers bill a patient for a hospital visit, then the savings associated with this patient encounter will be greater than estimated due to the additional notice and taglines documents that the insurer would send with each additional explanation of benefits beyond the initial three assumed. If fewer than three service providers bill for a hospital visit, then the savings will be less due to the decreased volume of notice and taglines documents that the insurer would send because the insurer would send fewer than three explanation of benefits. Given that approximately 91% of the U.S. population is insured, the

[338] After publishing the 2016 Rule, OCR issued guidance explaining that any significant publication printed on an 8.5 x 11 sheet of paper is not considered small sized and, thus, must include a minimum of 15 taglines. *See* OCR, Question 23, General Questions about Section 1557 (May 18, 2017), *https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/index.html.*

[339] Although OCR has issued guidance stating that a covered entity may identify the top 15 languages spoken across all the States that the entity serves, *See https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/aggregation_tagline/index.html,* evidence of notices that some covered entities shared with OCR suggests covered entities with beneficiaries in multiple States may issue more comprehensive tagline notices with more than 15 languages, likely because of reasonable interpretations of the relevant provisions of the 2016 Rule, and the higher cost of attempting to tailor notices and taglines to individuals based on their specific State.

[340] Calculated by subtracting total uninsured population (28.1 million as of 2016), *See https://www.census.gov/library/publications/2017/demo/p60-260.html,* from the total U.S. Population (327 million as of March 14, 2018), *See https://www.census.gov/popclock.*

[341] The calculations do not take into account households where two or more unrelated persons have individual coverage, and thus receive separate annual notices at the same household. The Department believes, however, that this exclusion has only a minor impact on the overall figures.

[342] U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, *https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf* (defining ''household'' under ''Household Type and Relationship'').

[343] The Department subtracted 306 million individuals belonging to a household from the total U.S. population of 323.4 million individuals. *See* U.S. Census Bureau, *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk* (relied on 2016 population nationally).

[344] U.S. Census Bureau, American Community Survey and Puerto Rico Community Survey 2016 Subject Definitions 76, *https://www2.census.gov/programs-surveys/acs/tech_docs/subject_definitions/2016_ACSSubjectDefinitions.pdf* (''People not living in households are classified as living in group quarters.''). ''Group quarters include . . . college residence halls, . . . skilled nursing facilities, . . . correctional facilities, and workers' dormitories.'' U.S. Census Bureau, 2016 American Community Survey/Puerto Rico Community Survey Group Quarters Definitions, 1 *https://www2.census.gov/programs-surveys/acs/tech_docs/group_definitions/2016GQ_Definitions.pdf.*

[345] *See* CMS, *Health Insurance Exchanges 2018 Open Enrollment Period Final Report* (Apr. 3, 2018), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-03.html.*

[346] CDC, Chartbook on Long-Term Trends in Health (2016), *http://www.cdc.gov/nchs/data/hus/hus16.pdf#317.*

[347] The Department presumes one hospital visit likely will generate a bill from the physician and two bills from any combination of services, such as anesthesia, ambulance service, imaging/radiology, or laboratory or blood work.

Department estimates that approximately 32 million of the 35 million hospital admissions are associated with insured patients (91% of 35 million hospital admissions).[348] This assumption does not account for variation in healthcare consumption between the insured and uninsured populations. It is possible that more hospital admissions are attributable to the uninsured than the insured population. If such is the case, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be lower. Further, this estimate does not account for outpatient hospital visits, which would increase the volume of notices and taglines. Moreover, if the elderly, nearly all of whom are insured by Medicare, make up a disproportionate share of hospital admissions, the Department's estimate for the number of notices and taglines attributable to explanations of benefits would be higher.

As discussed further below, the Department assumes 100% of insurance companies are compliant with the notice and taglines requirement. Thus, approximately 96 million notice and taglines documents are attributable to the explanations of benefits sent by insurers (32 million admissions times three explanation of benefits). Using rounded values, approximately 107 million additional notices and taglines (96 million plus 11 million) are related to hospital admissions.

To estimate the volume of notices and taglines that accompany doctor's bills and explanations of benefits from a physician's visit, the Department relied on data showing that individuals visit physicians' offices approximately 990 million times each year.[349] Given that approximately 9% [350] of Americans are uninsured, the Department assumes (and subtracting an estimated 5% for uninsured patients who do not visit the doctor, except in an emergency) that 95% of individuals who see doctors every year are insured in some form. The Department assumes that each visit to a compliant doctor's office will generate at least one bill from the doctor and at least one explanation of benefits from the health insurance company. As explained below, it also assumes that 10% of doctors and 100% of insurance companies comply with the notice and taglines requirement. Thus, approximately 99 million notices and taglines are attributable to doctors billing the patients directly, and approximately 941 million are attributable to explanations of benefits sent by insurers, which results in a total of 1.04 billion additional notices and taglines related to physician visits.

Because experience and substantial feedback from healthcare insurers suggests a very high degree of compliance with the notice and taglines requirements when it comes to documents such as explanations of benefits, the Department presumes 100% compliance for purposes of this RIA. Anecdotal evidence, however, suggests that hospital and physician compliance with the notice and taglines requirements in the documents discussed above is not standard industry practice. The Department estimates that, at most, 10% of such covered entities include notices and taglines in their significant mailed communications with patients. Although, according to the 2016 Rule's RIA, most hospitals and physicians are covered entities under Section 1557, the Department believes their failure to adopt notices and taglines as a standard billing and communication practice may be due to the fact the notice and taglines requirement in the 2016 Rule mentions a duty to notify ''beneficiaries, enrollees, applicants, and members of the public'' and does not explicitly mention ''patients.'' 45 CFR 92.8(a). Additionally, the preamble to the 2016 Rule explained that the notice and taglines requirement covered communications ''pertaining to rights or benefits,'' which insurance companies have universally interpreted as applying to significant numbers of communications they send to beneficiaries. 81 FR at 31402. For these reasons, the Department's calculations presume a 10% compliance rate for hospitals and physicians and a 100% compliance rate by health insurance companies concerning the notice and taglines requirement as it relates to bills and explanations of benefits, respectively.

To estimate the volume of notices and taglines that accompany pharmacy-related communications, the Department relied on estimates from the Pharmaceutical Care Management Association, which, due to the nature of its organization, obtained an estimated number of impacted beneficiaries from its member organizations. Approximately 173 million beneficiaries are being impacted annually by the notice and taglines requirement, and these beneficiaries receive between 6 and 28 communications per year with an accompanying notice and taglines. The Department relied on the average of this estimate (17 communications per year per beneficiary) to determine that 2.9 billion prescription-related communications (*e.g.,* communications from pharmacy benefit managers) are sent each year.[351]

To calculate the costs of the notice and taglines requirement, the Department assumes that the underlying communication to which a nondiscrimination notice and taglines document is attached is a communication that is on average three sheets of paper or less. Combined with the nondiscrimination notice and taglines (which constitute another 1–4 sides of a page, that is, 1 sheet single-sided [352] to 2 sheets of paper double-sided), the total number of sheets of paper that would be transmitted is equivalent to 4–5 sheets of paper or less. The associated costs of the notice and taglines requirement are (1) materials, (2) postage, and (3) labor. Because of the uncertainty around some of the estimates, we report ranges for some values in this analysis.

For materials, the Department assumes that materials (paper and ink) per notice and taglines mailing insert will cost between $0.025 and $0.10. The Department assumes that low materials cost would be $0.025 to print a 1-page notice and taglines on a single sheet of paper single-sided, and the high materials cost of $0.10 to print a 4-page notice and taglines on 2 sheets of paper double sided.

For postage, the Department estimates that the additional weight of the notice

[348] Calculated by subtracting total uninsured population (28.1 million as of 2016), *See https://www.census.gov/library/publications/2017/demo/p60-260.html,* from the total U.S. Population in 2016 (323,405,935), *See https://www.census.gov/popclock. http://news.gallup.com/poll/225383/uninsured-rate-steady-fourth-quarter-2017.aspx?g_source=Well-Being&g_medium=newsfeed&g_campaign=tiles.*

[349] CDC, Ambulatory Care Use and Physician Office Visits (2016), *https://www.cdc.gov/nchs/fastats/physician-visits.htm.* As noted above, the Department relies on the 2016 RIA assumption that virtually all doctors receive Federal financial assistance and, thus, are subject to the 2016 Rule.

[350] Calculated by subtracting total uninsured population (28.1 million as of 2016), *See https://www.census.gov/library/publications/2017/demo/p60-260.html,* from the total U.S. Population in 2016 (323,405,935), *See https://www.census.gov/popclock.*

[351] Source: Pharmaceutical Care Management Association (May 2, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0006.*

[352] Although this cost-benefit analysis assumes a lower-bound estimate that a notice of nondiscrimination and 15 taglines may be printed on one side of one sheet of paper, the Department believes that a notice of that length is likely noncompliant with the 2016 Rule requirement to be posted ''in conspicuously-visible font size.'' *See also* OCR, Sample Notice Informing Individuals About Nondiscrimination and Accessibility Requirements and Sample Nondiscrimination Statement: Discrimination is Against the Law (printed on two sides of one sheet of paper), *https://www.hhs.gov/sites/default/files/sample-ce-notice-english.pdf.*

and taglines inserts result in a range of no incremental postage costs (low-end) to $0.21 per mailing (high-end). For instance, if an underlying communication is three sheets of paper or less, a covered entity's inclusion of one double-sided page (or shorter) of notice and taglines insert would likely weigh one ounce or less (approximately four letter-sized pages weigh one ounce).[353] Consequently, in this scenario, the notice and taglines insert would not increase the total weight of the mailing beyond the one ounce of postage that a covered entity would already expect to incur. If, however, a covered entity included 2 sheets of paper double-sided containing the nondiscrimination notice and taglines, added to a communication of three sheets of paper or more, the total weight of the mailing would likely be at least five sheets of paper, and therefore over one ounce. The marginal cost of postage for each ounce is $0.20.[354]

For labor, the Department estimates the burden to download, print, and include these notices and taglines with all significant communications for an office clerk (Occupation Code No. 43–9061) with a mean hourly wage of $16.92/hour[355] plus an additional $16.92/hour in fringe benefits, or $33.84/hour for labor costs.[356] Based on experience, entities can manually fold and insert notices and taglines into envelopes at a rate of approximately 360 per hour. Entities that use commercial machines can fold and insert notices and taglines as fast as 5,400 envelopes per hour.[357] The Department uses the average of 2,880 notices and taglines that can be folded and placed into an envelope in an hour. Under these assumptions, the unit labor cost per notice and taglines mailing is $0.01.

Considering materials, postage, and labor, the per-unit cost for the notice and taglines insert ranges from $0.035 at the low end (for one single-sided sheet of paper of notice and taglines) to $0.32 at the high end (for two double-sided sheets of paper of notice and taglines), if the Department assumes that the average underlying mailer is 3 sheets of paper.

In addition, the Department estimates that some of these costs would be mitigated absent this final rule, due to transitions to electronic delivery for some communications affected by the 2016 Rule. The Department estimated, in the RIA for the Proposed Rule, that electronic delivery would reduce costs of affected communications by approximately 10–20% absent this final rule, shifting linearly from 10% in the first year to 20% in the fifth year following implementation (in other words, increasing by 2.5 percentage points each year). Survey results from Cognizant[358] indicate that 70 percent of respondents consider it important to be able to view medical care-related statements (*e.g.,* explanation of benefits documents) electronically, and that 42 percent are able to do so currently. But the same survey found that ''[a]doption rates are low for the digital services currently offered by health insurers, even for those that respondents rated as very important,'' with ''just about half of the members who were aware of'' a given digital service having actually ''used it.'' According to another survey by InstaMed,[359] 23% of providers offer some electronic billing, but even out of those providers who do, 58% still provide fewer than half of their bills electronically.[360] Moreover, it is likely that younger generations are the ones currently enrolling in e-statements; given that a disproportionate amount of health care services and products, especially pharmaceuticals, are consumed by the elderly, the communications containing the notices and taglines affected by this rule may be relatively unlikely to use e-statements. Therefore, as one end of a range of electronic delivery estimates, the Department maintains the earlier assumption of 10 percent in the first year, growing linearly to 20 percent in the fifth year after finalization, and departs from the preliminary RIA's assumption only in that the linear growth is extended past the fifth year. At the opposite end of the range of estimates, the electronic delivery rate is assumed to be 21 percent upfront (reflecting the higher of the two survey results cited above, with adjustment to account for the fact that in those surveys, 50% or less of patients offered electronic delivery have been accepting it) and 42 percent in Year 5 (reflecting the same survey, without such adjustment), with subsequent increases continuing at 5.25 percentage points per year.

In combining the two input ranges for Table 2 below—the cost per printed and mailed communication and the electronic delivery rates—the low ends are used together and the high ends are used together, to reflect that entities facing relatively high costs for printed communications would have greater incentive to shift to electronic delivery where feasible. The primary estimates relied on for Table 1, however, use simply the midpoint of each of the two input ranges.

Electronic delivery would eliminate postage costs, but may to a certain extent merely shift the costs of paper and printing from the entity providing the communication to the consumer/beneficiary/patient, given that some consumer/beneficiary/patient recipients of electronic communications will print them out and incur costs for the paper and ink associated with doing so. The Department has not included such consumer/beneficiary/patient costs in its estimates.

The Department averages the low and high-end estimates to determine a primary estimate of annual cost savings, which results in average savings of approximately $0.58 billion per year, over the first five years, after adjusting for electronic delivery.

As discussed above, the proposed rule noted that, with repeal of the 2016 Rule requirements, the Department assumed that two other regulatory requirements for taglines would also be fully repealed because they depend on, or refer to, the 2016 Rule for authority for the taglines requirement. The first is the requirement placed on Health Insurance Exchanges (*see* 45 CFR 155.205(c)(2)(iii)(A)), which the Department estimates issue 17.7 million communications per year, primarily through eligibility and enrollment communications. The second is the requirement placed on QHP issuers (*see* HHS Notice of Benefit and Payment Parameters for 2016; 2016 Rule, 80 FR 10750, 10788 (Feb. 27, 2015)), whose costs are incorporated into the volume calculations for annual notices of benefits, and explanations of benefits discussed in more detail above. Those

[353] *See* ''How Many Sheets of Paper Fit in a 1 Ounce Envelope for Mailing Purposes,'' *https://www.reference.com/business-finance/many-sheets-paper-fit-1-ounce-envelope-mailing-purposes-84ba93a60789c2e1.*

[354] *See* U.S. Postal Service Postage Rates, *https://www.stamps.com/usps/current-postage-rates/.*

[355] BLS, Occupational Employment and Wages (May 2018), *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

[356] CMS estimates that the labor costs would be a one-time cost of $16,244 for Medicaid managed care and a one-time cost of $9,669 for CHIP managed care. The Department assumes for its calculations that the labor costs for the notice and tagline provisions are not one-time but are ongoing costs associated with the value of office clerks' time printing and including the notices and taglines with significant publications and significant communications.

[357] *See, e.g.,* Pitney Bowes, ''Folders and Inserters,'' *https://www.pitneybowes.com/nz/folders-inserters.html.*

[358] *See https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf.*

[359] *See https://www.instamed.com/white-papers/trends-in-healthcare-payments-annual-report/.*

[360] *See https://www.cognizant.com/InsightsWhitepapers/The-Digital-Mandate-for-Health-Plans-codex1760.pdf* and *https://www.instamed.com/white-papers/trends-healthcare-payments-report-2018/.*

two other regulations have not yet been amended in this respect, but the Department clarified above that because those requirements inform entities they will be deemed in compliance if they are in compliance with the Section 1557 rule's notice and taglines requirement, and because the latter has now been repealed by this final rule, covered entities do not need to independently comply with those two other regulatory requirements cross referencing the Section 1557 rule. As a result, these estimates continue to assume this final rule will result in cost savings with respect to those requirements.

The Department also assumes that health insurance entities would not voluntarily append notices and taglines to routine monthly premium statements absent the 2016 Rule, but are doing so because of it (or because of a requirement in another regulation that bases its requirement on the 2016 Rule's requirement).

TABLE 2—ANNUAL SAVINGS FROM REPEAL OF REQUIREMENT TO PUBLISH AND MAIL NOTICES AND TAGLINES, BY VOLUME OF TRANSACTIONS PER TYPE PER YEAR AFTER ACCOUNTING FOR ELECTRONIC DELIVERY

[in millions]

	Count	Estimated low Savings ($0.035/unit)	Estimated high savings ($0.32/unit)
Exchange eligibility and enrollment communications	17.7	Year 1: $1 Year 5: $0	Year 1: $4. Year 5: $3.
Annual notice of benefits	123	Year 1: $4 Year 5: $3	Year 1: $31. Year 5: $23.
Explanations of Benefits—hospital admissions	96	Year 1: $3 Year 5: $3	Year 1: $24. Year 5: $18.
Explanations of Benefits—physician's visits	941	Year 1: $30 Year 5: $26	Year 1: $238. Year 5: $175.
Medical bills—hospital admissions	11	Year 1: $0 Year 5: $0	Year 1: $3. Year 5: $2.
Medical bills—physician visits	99	Year 1: $3 Year 5: $3	Year 1: $25. Year 5: $18.
Pharmacy-related notices	2,900	Year 1: $91 Year 5: $81	Year 1: $733. Year 5: $538.
Total, accounting for electronic communications	4,188	Year 1: $132 Year 5: $117	Year 1: $1,059. Year 5: $777.

The primary estimate of annual savings is approximately $0.63 billion in Year 1 and $0.51 billion in Year 5 after accounting for electronic delivery. The Department assumes that the nine other CMS regulations or guidelines requiring taglines will continue to be in effect, and the cost of complying with these CMS requirements would need to be subtracted from the total savings that the 2016 Rule's rescission generates for the healthcare sector as set forth in Table 2. These requirements include (1) Group Health Plans and Health Insurance Issuers requirements; [361] (2) Navigator requirements; [362] (3) Non-Navigator Assistance Personnel requirements; [363] Medicaid requirements; [364] Medicaid Managed Care requirements; [365] CHIP requirements; [366] CHIP Managed Care requirements; [367] Hospitals Qualifying for Tax-Exempt Status requirements; [368] and Medicare Advantage (Part C) and Prescription Drug Plans (Part D) requirements.[369]

Comment: Some commenters indicated that the notice and taglines requirements that the Department proposed for removal led to substantial costs that the Department understated. For example, they contended costs may be higher than the Department estimated in the proposed rule because plans had to revise internal documents, incur significant IT costs, and work with outside vendors to implement the 2016 Rule. Commenters also contended the 2016 Rule resulted in significant annual printing costs.

One commenter calculated that the costs of the mailings related to pharmacy services yielded additional costs of $1 billion a year. The commenter supported the Proposed Rule's RIA aggregate estimate that the requirement would save plans $101 to $928 million a year and provided a specific example in which an affected entity reported incurring $3.9 million in printing costs and $4 million in operations costs to send 55.5 million communications.

Another company reported almost $1 million in annual increased expenses on toner, developer, paper, and postage related to notice and taglines requirements. Another commenter stated the costs associated with complying with the 2016 Rule's requirement accounts for 4.5% of one company's budgeted operating income. Some commenters also stated the proposed rule would significantly reduce the administrative burden placed on providers, saying that what constitutes a ''significant'' communication has been insufficiently clear and has resulted in broad interpretations and providers using the taglines in almost every document.

Some commenters estimated that the dental profession has spent over $240 million to date on compliance with the 2016 Rule. The commenter noted that the time and cost for dental offices to interpret the regulations, print documents, alter existing publications, and modify websites has been significant. Several dental offices believe repealing the notice and taglines requirements will lead to cost savings and will allow staff to spend time on appropriate patient care and communication instead.

One commenter explained that in its Pennsylvania line of business, it serves

[361] 45 CFR 147.136(e)(2)(iii) and (e)(3), and § 147.200(a)(5).

[362] 45 CFR 155.215(c)(4).

[363] 45 CFR 155.215(c)(4).

[364] 42 CFR 435.905(b)(3).

[365] 42 CFR 438.10(d)(2) through (3), (d)(5)(i) and (iii), and (j).

[366] 42 CFR 457.340(a).

[367] 42 CFR 457.1207.

[368] 26 CFR 1.501(r) through 1(b)(24)(vi).

[369] Medicare Marketing Guidelines § 30.5.1, *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.html.*

800,000 persons and sends them 2-page double-sided notices and taglines 6,205,000 times a year under the 2016 Rule, resulting in $245,175 in annual mailing costs. The commenter noted it has similar experiences in all of its Medicaid lines of business.

Other commenters suggested the Department overestimated the costs of the 2016 Rule's notice and taglines requirements. One association stated that the Department's estimate in the proposed rule overestimated by failing to account for notices generated by a machine, included in bulk mailings, or facilitated through the use of computers. The commenter also believed that, while electronic delivery would eliminate postage costs, it would not shift the cost of paper and printing to the consumer/beneficiary/patient, stating it is unlikely that a significant percentage of individuals would download and print documents sent to them electronically. Similarly, the commenter contended the Department failed to account for the significant degree to which communications can be provided electronically and the degree to which some entities, such as insurance plans, have already been doing so for years.

Another commenter, however, agreed with OCR's calculation that the notice and taglines requirement has resulted in the inclusion of one to two sheets of paper. Similarly, one commenter stated it implemented multiple versions of the two-page notice and taglines on thousands of documents in its businesses, which consumed significant resources. The commenter noted that the requirements also impacted covered entity partners as well, particularly print vendors.

Some commenters asked the Department to separate out costs for providing notices as distinct from providing taglines, and for posting notices as distinct from mailing them.

Response: The Department appreciates the comments regarding the costs of the 2016 Rule's notice and taglines requirements. The Department agrees with commenters who contend that the requirements imposed significant and costly burdens far beyond the estimates set forth in the 2016 Rule. The Department finalizes this rule in significant part to relieve those burdens.

Some commenters contended the Department's estimates in the proposed rule were understated, and others contended the Department's estimates were overstated. The comments generally provided data from specific entities or circumstances.

The Department's estimate of the average cost of mailings is based on data received from covered entities across the affected industry, and generally takes into account processes and methods used in mailings such as machines, computers, and bulk handling. Although the Department suggested that some patients and beneficiaries might print notices electronically mailed to them, the Department did not factor those potential costs in its estimate. To the extent that commenters contended the Department failed to consider the extent to which notices and taglines are delivered electronically, this is incorrect, as the Department's preliminary estimates included downward adjustments to its estimates based on electronic delivery, and its revised estimates reflect a broader range of potential electronic delivery rates. Moreover, other commenters contend that they continue to experience significant costs based on non-electronic delivery—contending in some cases that the Department's estimates of those costs were understated.

Commenters were correct to identify that some costs, such as revising internal documents, IT costs, and setting up relationships with outside vendors, resulted from the 2016 Rule. The Department does not estimate that this final rule will lead to cost savings with regard to those types of expenses, however, because they are generally sunk costs that covered entities incurred at the time of the 2016 Rule and will not be able to recover as a result of this final rule. This final rule does not prohibit entities from continuing to provide the type and number of notices and taglines required by the 2016 Rule, but gives covered entities the flexibility to not provide them.

The Department declines to accept the suggestion of some commenters that the Department separate out the costs of notices from the costs of taglines. Information from covered entities indicates that notices and taglines are usually provided together, often on overlapping pages. Because this final rule removes both requirements, the Department's estimates are intended to cover the costs of both notices and taglines.

Comment: One commenter stated that the Department improperly relied on healthcare corporations for its fact-finding and analysis in the proposed rule. In particular, conclusions that the repetitive nature of notices and taglines dilute messages, that beneficiaries do not want to receive them, and that there is no evidence that more beneficiaries have sought language assistance because of the notices, were largely gathered from the covered entities themselves.

Response: The Department relies on its own data, publicly available data, and data submitted by members of the public—including covered entities—to attempt to estimate the impact of its regulations. The Department takes into consideration the sources of the data it considers, and attempts to weigh all such data appropriately based on the information the Department has available to it.

f. Costs Arising From Removal of Notice and Taglines Requirement

Repealing the notice and taglines requirement may impose costs, such as decreasing access to, and utilization of, healthcare for non-English speakers by reducing their awareness of available translation services.

Comment: Some commenters generally supported the Department's assessment that the benefits from the notice and taglines requirements were hard to quantify and likely not significant. A health insurance plan commenter stated that since the implementation of the 2016 Rule, it has not experienced significant changes in its member demographics or languages spoken, and has not seen any notable increases in requests for translation services. One commenter also stated that its pharmacy benefit manager found that since 2017, the volume of valid complaints about discrimination are less than 1% overall and could be better handled by personnel already in place. The commenter stated further that since 2017, it has filled approximately 3.5 billion prescriptions and mailed nearly half a billion beneficiary communications. In this time period, approximately 0.002% (26 of 14,000) of calls made to the discrimination hotline were closely related to a complaint. Several commenters stated they did not see a significant increase in requests after the 2016 Rule required notices and taglines, but instead experienced relatively flat demand.

Some commenters also expressed concerns regarding wastefulness of the notice and taglines. A commenter calculated that it has spent nearly $16 million since 2017 to accommodate the current requirements and will save at least $3.5 million annually under the proposed rule. One commenter suggested that an analysis of the impact of the notice and taglines should take into account the content and frequency of the notices, overall consumer health literacy, costs and administrative burdens, and whether notices are truly meaningful to consumers.

Other commenters suggested that the 2016 Rule's notice and taglines requirements likely yielded benefits to intended individuals. A hospital commented that it observed a 10% increase in the volume of interpreter service encounters each year over the last three years. Another commenter stated that it saw a 28% reduction on its per-member per-month claims cost with its Spanish-speaking population. Several commenters from a variety of organizations request an analysis of the impact on those who most use the services affected by the proposed provision (LEP individuals) and on those who provide services to the impacted population. Several organizations, including a State government, also contended that LEP individuals are a significant portion of the population and tend towards poorer health outcomes. They also suggested that removing the notice and taglines requirements may cause such individuals to delay care or not receive care until their medical issues are more severe and costlier to treat, and they urged the Department to estimate such costs.

Another commenter stated that even though HHS justified the proposed rule in part by citing data that over three-quarters of the U.S population over the age of 18 speak only English at home and are not well served by taglines or notices, the commenter believes that if a quarter of the population does not speak English at home that is an argument against repealing the notice and taglines.

Several commenters suggested repeal of the taglines provisions may negatively impact LEP individuals. One commenter cited a study claiming that health inequities cost the U.S. economy $309.3 billion a year.

Response: The Department appreciates the comments concerning the effectiveness and benefits of the notice and taglines requirements from the 2016 Rule. As noted in the proposed rule, previously received reports from covered entities are consistent with some public comments suggesting that the 2016 Rule's requirements did not appreciably increase the use of translation services. One such report indicated that utilization of translation services did not appreciably rise after the 2016 Rule's imposition of notice and taglines requirements.[370] Although some commenters contended that they experienced an increase in translation services after the 2016 Rule, others reported a different experience. The Department generally agrees with the latter, and the difference in reports from different commenters and other sources reinforces the Department's view of the difficulty of attempting to calculate the 2016 Rule's benefits to individuals needing translation services. The Department does not believe it has data enabling it to fulfill the request of commenters who urged the Department to calculate the value of such benefits lost as the result of this final rule, as distinct from data that more generally estimate costs resulting from inequality or delay in care.

As noted in the proposed rule, there are other reasons to believe the 2016 Rule's notice and taglines requirements imposed burdens disproportionate to potential benefits for intended beneficiaries. The vast majority of recipients of taglines do not require translation services. For example, according to Census statistics, as of 2015, over three-quarters (79%) of the U.S. population over age five speak only English at home, followed by Spanish (13%).[371] Although a commenter contends this statistic provides an argument in favor of maintaining multi-language taglines, the Department disagrees regarding a requirement to send such taglines where almost 80% of the recipients likely speak only English at home, and a majority of the remainder spoke English ''very well.''[372] Additionally, of persons selecting a written language preference when registering for coverage on the HealthCare.gov platform for 2017, 90.29% selected English, followed by 8.23% who selected Spanish.[373] These data indicate that, for the large majority of people who receive them, the required language taglines mailings provide little to no benefit because they are already proficient English speakers with little need for translation services.

Furthermore, the 2016 Rule's requirements added 47 languages to existing language access requirements, but that only increased access to 0.4% of the entire U.S. population. This was after broadly defining ''limited English proficiency'' to include those who speak English ''well'' but not ''very well.''[374] The Department's Office for Civil Rights also produced a list of the top 15 languages in each State; however, 26 of the languages on OCR's list are spoken by less than 0.004 percent of the population. As a result, in some States, especially those with sparser populations, the 2016 Rule required health insurance issuers to provide taglines services in languages spoken by very few people in the State. For instance, in Wyoming, issuers needed to provide translation notices in Gujarati and Navajo in every significant communication sent to beneficiaries to account for approximately 40 Gujarati speakers and 39 Navajo speakers; in Montana issuers were required to provide notices to account for approximately 80 speakers of Pennsylvania Dutch; and in Puerto Rico, issuers had to provide taglines notices to account for approximately 22 Korean speakers and 22 French Creole speakers.[375]

The Department also continues to believe that the notice and taglines required by the 2016 Rule imposed burdens on many recipients and may interfere in their receipt and understanding of important healthcare information. Prior to the proposed rule, the Department received many communications from beneficiaries and advocacy groups complaining about the excessive amount of paperwork they receive. These individuals and groups

[370] *See* Aetna (May 1, 2017), available at *https://www.regulations.gov/document?D=HHS-OCR-2019-0007-0005.*

[371] U.S. Census Bureau, *B16007: Age by Language Spoken at Home for the Population 5 Years and Over,* 2011–2015 American Community Survey (American FactFinder) (2017), *https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US. See also* Kimberly Proctor, Shondelle M. Wilson-Frederick, et *al., The Limited English Proficient Population: Describing Medicare, Medicaid, and Dual Beneficiaries,* 2.1 Health Equity 87 (May 1, 2018), *http://online.liebertpub.com/doi/10.1089/heq.2017.0036* (identifying Spanish as the language of the largest majority of limited English proficient speakers in Medicaid and Medicare, according to the 2014 American Community Survey).

[372] U.S. Census Bureau, *B16007: Age by Language Spoken at Home for the Population 5 Years and Over,* 2011–2015 American Community Survey (American FactFinder) (2017), *https://factfinder.census.gov/bkmk/table/1.0/en/ACS/16_5YR/S1601/0100000US.*

[373] CMS, *Race, Ethnicity, and Language Preference in the Health Insurance Marketplaces 2017 Open Enrollment Period* (April 2017), *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Data-Highlight-Race-Ethnicity-and-Language-Preference-Marketplace.pdf.* States that that do not use the *HealthCare.gov* platform, such as California and New York, were not included in this report.

[374] *See* HHS OCR, Frequently Asked Questions to Accompany the Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency under Section 1557 of the Affordable Care Act, Question 2 (Sept. 1, 2016), *https://www.hhs.gov/civil-rights/for-individuals/section-1557/1557faqs/top15-languages/index.html* (using 2013 year estimates). *See* U.S. Census Bureau, Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over, *https://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ACS_14_5YR_B16001&prodType=table* (2016 year estimates).

[375] OCR, Resource for Entities Covered by Section 1557 of the Affordable Care Act, Estimates of at Least the Top 15 Languages Spoken by Individuals with Limited English Proficiency for the 50 States, the District of Columbia, and the U.S. Territories (Aug. 2016), *https://www.hhs.gov/sites/default/files/resources-for-covered-entities-top-15-languages-list.pdf.*

explained that few people read the notice and taglines and most ignore the last pages of lengthy health documents. Additionally, documents that contain a significant number of pages that recipients do not value can often induce annoyance or frustration due to perceived wasting of time, ignorance of the customers' actual needs or language abilities, waste of economic resources, or insensitivity to environmental concerns.

These communications coincide with the views of some commenters and generally support the Department's conclusion that the 2016 Rule has resulted in ''cognitive overload,'' where individuals experience a diminished ability to process information when inundated with duplicative information and paperwork. These frustrations, though difficult to quantify, are reasonable to expect given the large volume of healthcare communications with notice and taglines that most Americans receive. It is also reasonable to expect that repeated mailings of taglines to people who do not want them may negatively impact their likelihood to read truly significant documents from their insurers or doctors, and may negatively impact health outcomes in some cases.

It is also noteworthy that other rules exist to benefit the persons whom the 2016 Rule's notice and taglines requirements intended to assist. Regulations under Section 504 of the Rehabilitation Act generally require the provision of auxiliary aids and services in health programs or activities that receive Federal financial assistance. 45 CFR 84.52(d). Because the notice requirement under the 2016 Rule required frequent mailed notification of the availability of auxiliary aids and services, the Department suggested in the proposed rule that repealing the notice of nondiscrimination requirement may result in additional societal costs, such as decreased utilization of auxiliary aids and services by individuals with disabilities due to their reduced awareness of such services. Some commenters agreed, but they did not suggest any way to reliably calculate such effects, and the Department is not aware of any. This impact may also be limited because the Section 504 regulations already require recipients of Federal financial assistance employing fifteen or more persons to provide notice to participants, beneficiaries, applicants, employees, and other interested persons of the availability of such aids and services. 45 CFR 85.12 and § 84.22(f).

Additionally, some commenters contended that repealing the notices and taglines may lead to persons not being made aware of their right to file complaints with OCR, and that some of those persons may suffer remediable grievances but will not complain to OCR absent notices informing them of the process. The Department continues, however, to not be aware of a way to quantify those potential effects. In addition, as noted above, the regulations implementing Section 1557's four underlying statutes already contain notice provisions, *see* 45 CFR 80.6 and Appendix to Part 80 (Title VI), § 84.8 (Section 504), § 86.9 (Title IX) and § 91.32 (Age Act), and therefore this potential cost may be minimal.

g. Cost Savings From Changes to Language Access Plan Provisions

Although the 2016 Rule did not require covered entities to develop a language access plan, the Rule stated that the development and implementation of a language access plan is a factor the Director ''shall'' take into account when evaluating whether an entity is in compliance with Section 1557. 45 CFR 92.201(b)(2). Therefore, the Department anticipated that 50% of covered entities would develop and implement a language access plan following issuance of the 2016 Rule. 81 FR at 31454.

Comment: One commenter noted that physician group practices report financial losses and significant costs when treating patients that require interpretation or translation services. The commenter stated that providing reimbursement at the Federal level would help offset extra costs incurred to provide these services free of charge and reimburse group practices for increased upfront costs and time required to care for LEP individuals. The commenter contended that face-to-face interpretation services cost between $50 and $150 per hour and may include a minimum hour requirement and transportation fee. The commenter points to one practice that reported being billed nearly $300 for a single in-person interpreter service this year due to a minimum rate and transportation fee. The practice reported paying $1,200 in interpretation fees for one month for nine individuals.

Response: The Department appreciates these comments. With respect to serving LEP patients, this final rule gives more flexibility to covered entities, while specific obligations to patients will be governed by criteria that has been set forth in longstanding guidelines. It is not within the scope of this rule to provide for Federal reimbursements.

Comment: Several commenters claim the proposed rule failed to consider the benefits to LEP individuals that will be lost by repealing certain provisions. Such commenters state there are tens of millions of LEP people who rely on protections from Section 1557. Another commenter notes that four million Medicare beneficiaries are LEP. A commenter notes that only 15 States use the Medicaid option to reimburse for interpretation. Commenters state that the language access protections in the 2016 Rule benefit Latino/a patients, Asian American and AAPI patients, LEP gender-based violence victims, low-income LEP patients, older adults, people with disabilities, and lower-income older adults.

Some commenters contend that the rule will lead to reduced awareness of language services by LEP persons and by the general public about their rights and protections. One commenter stated that if the rule is finalized, organizations like community health centers that are not funded or do not receive reimbursement for language services will face increased burdens when fewer clients will be aware of their language access rights and likely turn to them instead of to covered entities.

Commenters opposing the proposed rule claimed it would lead to inequality and a reduction in the quality of language access available; the avoidance of care, leading to worsened conditions and avoidable higher-cost hospital services; increased costs due to missed appointments, delayed care, and ''non-compliant'' self-care; increased Emergency Room use; lower preventive care access and use; malpractice costs; avoidable hospital readmissions; higher rates of uninsurance; unnecessary tests and procedures; higher rates of mortality; misunderstood diagnoses and prognoses leading to poor quality of care; and costs due to lower rates of outpatient follow-up, poor medication adherence, and lack of understanding of discharge diagnosis and instructions.

One commenter claimed that HHS's estimate that covered entities would save around $17.7 million per year by eliminating references to language access plans overlooks larger healthcare savings generated by access to interpretation services. Two commenters point to a 2017 study finding that easily accessible language interpretation services avoided an estimated 119 readmissions that were associated with savings of $161,404 per month in an academic hospital. Two commenters pointed to a 2010 report finding that at least 35 of 1,373 malpractice claims were linked to inadequate language access.

Another commenter cited a report that found that 2.5% of one malpractice carrier's closed claims involved language issues that cost the carrier over $5 million in damages, settlements, and legal fees. Costs included damages paid to patients, legal fees, time lost when defending the lawsuit, loss of reputation and patients, fear of possible monetary loss, and stress.

Response: The Department acknowledges the potential of reduced awareness of the availability of language services by LEP individuals by the changes made in this rule, or downstream effects on malpractice claims due to less awareness. As noted above, however, this final rule continues to provide protections for LEP individuals and commits the Department to enforcement of Section 1557. The Department believes, therefore, that the negative effects predicted by some commenters may be mitigated by the continued commitment to enforcement of Section 1557. The data cited by commenters either do not assess the overall impact of the 2016 Rule as compared to a regime with continued enforcement of Section 1557, or address information about broader matters without providing a method for the Department to specifically analyze how this final rule will cause the effects commenters fear may occur. In this respect, the Department believes that malpractice carriers themselves, not Federal civil rights regulators, are best equipped to determine what practices malpractice carriers should require for the sake of reducing their own financial risk.

Therefore, in consideration of the public comments and the Department's analyses, the Department adopts the estimates from the proposed rule concerning changes to language access plan provisions.

In the proposed rule, OCR estimated that the burden for developing a language access plan is approximately three hours of medical and health service manager staff time in the first year, and an average of one hour of medical and health service manager staff time per year to update the plan in subsequent years. Throughout, we assume that the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate. The value of an hour of time for people in this occupation category, after adjusting for overhead and benefits, is therefore estimated to be $109.36 based on Bureau of Labor Statistics (BLS) data for 2018.[376] These are within the general range provided by some commenters' description of costs they have experienced.

The Department estimated that approximately 269,141 entities could potentially make changes and develop language access plans in response to the 2016 Rule, as part of the requirement to take reasonable steps to provide meaningful communication with LEP individuals (calculated by reducing the 275,002 affected entities by the 5,861 hospitals and nursing care facilities that were already subject to language access plan requirements under Medicare Part A). The Department further assumed that only 50% of the identified entities would actually make changes to implement a language access plan. If the actual compliance rate were higher, the costs would be higher. These assumptions imply that the total cost of developing language access plans will be approximately $44.1 million (269,141 entities multiplied by 50% of entities multiplied by 3 hours per entity multiplied by $109.36 per hour) in the first year and approximately $14.7 million (269,141 entities multiplied by 50% of entities multiplied by 1 hour per entity multiplied by $109.36 per hour) per year in subsequent years. The Department assumes sunk costs cannot be recovered by this rule, and therefore that initial language access plan development costs attributable to the 2016 Rule cannot be recovered.

By repealing the provision of the 2016 Rule regarding the Language Access Plans, the Department estimates annual savings are $14.7 million.

h. Cost Savings Attributed to Covered Entities' Handling of Certain Grievances

This final rule repeals the requirement for each covered entity with 15 or more employees to have a compliance coordinator and a written grievance procedure to handle complaints alleging violations of Section 1557. The Department estimates that, under the final rule, covered entities no longer have to incur certain labor costs associated with processing grievances related to sex discrimination complaints as they relate to gender identity as defined under the 2016 Rule because such definitions would be repealed and no longer binding. This repeal would not, however, affect the independent obligations that entities covered by Section 1557 have to comply with Federal regulations under Section 504 and Title IX to have written processes in place to handle grievances alleging certain disability and sex discrimination claims, respectively.[377]

For the sake of consistency and convenience, the Department used the methodology from the 2016 Rule as a foundation for estimating the projected savings from this proposed rule provision.

The 2016 Rule estimated that, in years three through five of the 2016 Rule's implementation, covered entities with 15 or more employees would incur $85.5 million in costs annually to handle Section 1557 grievances. 81 FR at 31458. This estimate assumed that covered entities would experience an average increase in grievances equal to OCR's projected long-term increase in caseload of about 1%. *Id.* The 2016 Rule monetized this 1% increase in caseload as a labor cost equivalent to 1% of the annual median wage for a medical and health service manager (occupation code 11–9111). *Id.* The Department continues to assume that OCR's increase in caseload attributed to the 2016 Rule reasonably informs the increase in grievance processing that covered entities will experience.

Based on OCR's tracking of Section 1557 complaints received from promulgation of the 2016 Rule (May 18, 2016) until present, OCR predicts that its long-term caseload would have increased 5% rather than 1% as originally predicted. Further, OCR believes roughly 60% of this increase (which equals 3% of the overall increase) would have been attributable to discrimination claims based on the 2016 Rule's definition of sex discrimination with respect to gender identity and sex stereotyping. The Department uses the phrase ''would have'' with regard to OCR's caseload because, as described above, the Department has been preliminarily enjoined on a nationwide basis by a Federal court from enforcing claims based on the 2016 Rule's definition of sex discrimination, and those provisions have now been vacated by the same court.

The 2016 Rule asserted that private parties have the right to challenge a violation of Section 1557 or the 2016 Rule in Federal court, independent of OCR enforcement or involvement. 45 CFR 92.302(d). In the preamble to the 2016 Rule, the Department suggested that the ability for private parties to sue

[376] BLS, Occupational Employment and Wages (May 2018), *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

[377] *See, e.g.,* 45 CFR 84.7(a) (HHS regulations implementing Section 504) (requiring a written process to be in place for handling grievances alleging disability discrimination), § 86.8(a) (HHS regulations implementing Title IX) (requiring a written process to be in place for handling grievances alleging sex discrimination).

under the 2016 Rule would result in covered entities bearing increased compliance costs. 81 FR at 31395 (''the presence of a coordinator and grievance procedure enhances the covered entity's accountability and helps bring concerns to prompt resolution, oftentimes prior to an individual bringing a private right of action.''). The preliminary injunction did not apply to suits filed by private parties. Although the Supreme Court has recognized a private right of action for some civil rights statutes enforced by the Department, under this final rule the Department would no longer assert in the regulatory text or the preamble to the rule that a private right of action exists for parties to sue covered entities for any and all alleged violations. Because the issue of whether a person has a right to sue in Federal court under Section 1557 is one determined by the courts themselves and not by the Department's regulations, the Department does not estimate that this change will lead to any economic impact.

Although this final rule removes from the 2016 Rule the expansive inclusion of gender identity and sex stereotyping in the definition of sex discrimination, a court has recently vacated the gender identity provisions of the 2016 Rule. Regarding sex stereotyping, to the extent the 2016 Rule used that term to encompass gender identity, the sex stereotyping provision had no real-world effect after the court decision. To the extent sex stereotyping in the 2016 Rule did not encompass gender identity, the Supreme Court already recognized a degree of relevance of sex stereotyping in sex discrimination claims. This is discussed in more detail in the section above on sex-based discrimination. Therefore, the Department does not believe there would be a direct material economic impact regarding grievance procedures from this final rule's change in the definitions concerning sex stereotyping.

In addition, due to voluntary policies or more stringent State requirements, the Department expects that 50% of covered entities would likely continue to accept and handle grievances alleging discrimination based on gender identity and sex stereotyping as set forth under the 2016 Rule.

In the proposed rule, the Department estimated that covered entities would have experienced a 3% increase in gender identity and sex stereotyping grievance claims over the long term due to the 2016 Rule, and half of that caseload (1.5%) could have been due to the 2016 Rule's language encompassing gender identity and sex stereotyping claims in States where covered entities are not otherwise required to handle those claims. The proposed rule estimated an annual savings in labor attributed to a 1.5% decrease in grievance caseload as $123.4 million, representing 1.5% of the annual median wage of a medical and health service manager ($199,472 fully loaded) multiplied by the 41,250 covered entities with 15 or more employees.

Nevertheless, in this final rule the Department does not estimate a cost savings concerning grievance procedures. This is because, as stated repeatedly elsewhere, the court order vacating the gender identity provisions of the 2016 Rule means that this final rule's changes concerning gender identity will have no direct material economic impact. The *Franciscan Alliance* court order forms the new legal baseline in this respect, and therefore the primarily-emphasized economic baseline, for the purposes of this estimate. To the extent sex-stereotyping claims remain viable, they were already authorized by the Supreme Court's longstanding interpretation of sex stereotyping.

i. Additional Costs for Training and Familiarization

To comply with the final rule, the Department anticipates that some covered entities may incur costs to re-train employees in order to realize potential longer-term costs savings from the deregulatory aspects of this final rule's changes. The Department assumes that employers are most likely to train employees who interact with the public, and will therefore likely train between 40% and 60% of their employees, as the percentage of employees that interact with patients and the public varies by covered entity. For purposes of the analysis, the Department assumes that 50% of the covered entity's staff will receive one-time training on the requirements of the regulation. It uses the 50% estimate as a proxy, given the lack of certain information as described below. For the purposes of the analysis, the Department does not distinguish between employees whom covered entities will train and those who obtain training independently of a covered entity.

i. Number of Covered Entities That May Train Workers

The 2016 Rule estimated that 275,002 covered entities would train their employees on the rule's requirements in general (including training regarding language access provisions), and used that 275,002 figure as the basis for calculating costs to covered entities arising specifically out of the rule's prohibition on discrimination on the basis of sex. *See* 81 FR at 31450. The Department assumes, for purposes of this analysis, that the 2016 Rule's estimate was an accurate and reasonable basis for calculating costs arising from the need to provide training regarding the 2016 Rule.

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE

NAIC	Entity type	Number of firms
62142	Outpatient mental health and substance abuse centers	4,987
621491	HMO medical centers	104
621492	Kidney dialysis centers	492
621493	Freestanding ambulatory surgical and emergency centers	4,121
621498	All other outpatient care centers	5,399
6215	Medical and diagnostic laboratories	7,958
6216	Home healthcare services	21,668
6219	All other ambulatory healthcare services	6,956
62321	Residential intellectual and developmental disability facilities	6,225
6221	General medical and surgical hospitals	2,904
6222	Psychiatric and substance abuse hospitals	411
6223	Specialty (except psychiatric and substance abuse) hospitals	373
6231	Nursing care facilities (skilled nursing facilities)	8,623
44611	Pharmacies and drug stores	18,852
6211	Offices of physicians	185,649
524114	Insurance Issuers	180

TABLE 3—NUMBER OF HEALTHCARE ENTITY FIRMS COVERED BY RULE—Continued

NAIC	Entity type	Number of firms
	Navigator grantees	100
Total Entities		275,002

ii. Number of Individuals Who Will Receive Training

The first category of healthcare staff that may receive training comprises health diagnosing and treating practitioners. This category includes physicians, dentists, optometrists, physician assistants, occupational, physical, speech and other therapists, audiologists, pharmacists, registered nurses, and nurse practitioners. The BLS occupational code for this grouping is 29–1000, and the 2018 reported count for this occupational group is approximately 5.4 million, with average loaded wages of $98.04 per hour.

The second category of healthcare staff that the Department assumes will receive training comprises degreed technical staff (Occupation code 29–2000) and accounts for 3.1 million workers with average loaded wages of $46.52 per hour. Technicians work in almost every area of healthcare: x-ray, physical, speech, psychiatric, dietetic, laboratory, nursing, and records technicians, to name but a few areas.

The third category of healthcare staff that the Department assumes will receive training comprises non-degreed medical assistants (Occupation code 31–0000), and includes psychiatric and home health aides, orderlies, dental assistants, and phlebotomists. Healthcare support staffs (technical assistants) operate in the same medical disciplines as technicians, but often lack professional degrees or certificates. The Department refers to this workforce as non-degreed, compared to medical technicians who generally have degrees or certificates. There are approximately 4.1 million individuals employed in these occupations, with average loaded wages of $31.14 per hour.

The fourth category of healthcare staff that the Department assumes will receive training is healthcare managers (approximately 0.4 million based on BLS data for occupation code 11–9111), with average loaded wages of $109.36 per hour. Because the Department assesses costs of familiarization with the regulation for one manager at each entity, it assumes that those managers will have already become familiar with the regulation and will not need additional training.

The fifth category of healthcare staff that the Department assumes will receive training is office and administrative assistants—Office and Administrative Support Occupation (Occupation code 43–0000). These workers are often the first staff patients encounter in a health facility and, because of this, covered entities might find it important that staff, such as receptionists and assistants, receive training on the regulatory requirements. Approximately 2.8 million individuals were employed in these occupations in health facilities in 2018, with average loaded wages of $36.50 per hour. The Department assumes that outreach workers are included in the five categories listed above, especially in the manager category.

iii. Total Costs of Training

The 2016 Rule estimated that covered entities would incur $420.8 million in undiscounted costs to train employees on the requirements of the Rule, distributed roughly evenly over the first two years after the 2016 Rule's effective date. 81 FR at 31458. This conclusion presumed covered entities were already periodically training employees on their obligations under Section 1557, but that the 2016 Rule's new sex discrimination requirements would induce covered entities to engage in additional ''comprehensive training.'' 81 FR at 31447.

For the purposes of this regulatory impact analysis, the Department assumes covered entities would face similar costs to retrain the workforce on this final rule's requirements.[378] However, because some covered entities will avoid incurring training expenses when they are not required to (as they will not be subject to the final rule), and because several States with large populations already prohibit gender identity discrimination in healthcare, the Department further assumes that only 50% of covered entities would modify their policies and procedures to reflect the changes in the final rule. Moreover, to the extent entities were motivated to provide training specifically due to the sex discrimination components of the 2016 Rule, a court has already vacated the gender identity and termination of pregnancy provisions of the 2016 Rule, and this final rule simply amends the Code of Federal Regulations to conform to the *vacatur* in that regard. The Department further assumes that 50% of covered entities, or 137,501, would train their employees to reflect the changes in this final rule. As in the 2016 Rule, the Department assumes that approximately half of the employees at these covered entities will engage in an average of an additional hour of training, and that this will occur in the first year of implementing this rule. These assumptions imply total training costs of $235.9 million. The 2016 Rule's calculations of training costs did not anticipate any ongoing training costs after year one—either in the form of annual refresher training for returning employees or training for new employees. The Department now believes that covered entities likely incur such costs, but assumes that equal costs would also be incurred under this final rule. Therefore, the Department has excluded ongoing training costs from the calculation of the baseline and from the calculation of the projected costs of the proposed rule, because such training has a net zero effect on projected costs.

j. Additional Costs for Revising Policies and Procedures

As discussed above, the Department anticipates that 50% of covered entities, or approximately 137,501 entities, would choose to revise their policies or procedures to reflect this final rule's clarification of the application of Section 1557, while other covered entities may retain their policies to ensure compliance with State or local laws. The Department assumes that it would take, on average, three to five hours for a provider to modify policies and procedures concerning this final rule. The Department selects four hours, the midpoint of this range, for the analysis. The Department further assumes that an average of three of these hours would be spent by a mid-level manager equivalent to a first-line

[378] Training costs in the 2016 Rule relied upon 2014 wages. *See, e.g.,* 81 FR at 31451 (estimating the median hourly wage for occupation code 29–1000 at $36.26, unloaded, at *https://www.bls.gov/oes/special.requests/oesm14nat.zip* .

supervisor (Occupation code 43–1011), at a cost of $57.06 per hour [379] after adjusting for overhead and benefits, while an average of one hour would be spent by executive staff equivalent to a general and operations manager (Occupation code 11–1021), at a cost of $119.12 per hour [380] after adjusting for overhead and benefits. The total cost for the estimated 137,501 covered entities to make their policies and procedures consistent with the final rule's changes is estimated to be approximately $39.9 million following implementation of this rule.

The above estimates of time and number of entities that would choose to revise their policies under the regulation are approximate estimates based on general BLS data. Due to the wide range of types and sizes of covered entities, from complex multi-divisional hospitals to small neighborhood clinics and physician offices, the above estimates of time and number of entities that would choose to revise their policies under the regulation is difficult to calculate precisely.

k. Other Benefits or Costs

The 2016 Rule's regulatory impact analysis did not include an economic cost-benefit analysis of the regulation's impact on health insurance benefit design. The Department lacks sufficient data on how much burden the 2016 Rule has placed on the development and operation of insurance benefits policies, and thus is unable to fully assess the benefit of removing this requirement.

The Department received several comments concerning the impact of the proposed rule on issues concerning discrimination on the basis of LGBTQ status, sex stereotyping, termination of pregnancy, and other provisions.

Comment: Many commenters objected that the Department did not estimate the potential for increases in the denial, delay, or substandard delivery of healthcare services from the rule's changes concerning gender identity.

One commenter suggested exploring quantitative analysis based on a survey by Harvard University and National Public Radio (NPR) in which 18% of LGBTQ people polled in 2017 reported foregoing care that they need, including preventive care, due to fears of or experiences of discrimination (including 22% of transgender people).[381] The comment estimated that this regulation will cost $1.4 billion in excess costs over the next ten years simply to treat cases of four particular cancers that would have been detected and prevented by screening, and that there will be an 18% increase in preventable mortality from these four cancers among LGBT people. The comment cited the 2016 value of a statistical life (VSL) used by the U.S. Department of Transportation to estimate these preventable deaths as being worth $39 billion to the U.S. economy over the next ten years.

Another commenter provided a list of potential sources of economic costs the proposed rule could produce concerning transgender patients, including out-of-pocket costs shifted because of transgender exclusions; increased costs from healthcare issues exacerbated by discriminatory delay or denial of care; increased costs related to sex coding; or increased costs due to substandard delivery of care. Other commenters similarly contended that literature on increased costs due to discrimination could be used to estimate economic costs. But such commenters did not provide quantitative values of such costs, or of ways to attribute the costs or portions thereof to this rulemaking.

One healthcare provider stated that they have not incurred any unreasonable costs in delivering care to its LGBTQ patients from complying with nondiscrimination protections based on sexual orientation and gender identity. The commenter added that adopting transgender-inclusive healthcare practices can reduce the costs associated with complications that arise when care is delayed or denied transgender patients due to discrimination.

One commenter stated that patients without primary care would experience an increase in emergency room visits, which would result in increased costs for the healthcare system—including from hospitals' and the government's absorbing and subsidizing the costs of uninsured patients.

Commenters raised similar comments concerning sexual orientation as did the commenters discussing gender identity or LGBTQ issues more broadly, contending the proposed rule should estimate the impact of not including protections against sexual orientation discrimination.

Response: The Department appreciates the comments concerning the regulatory impact of this final rule's changes concerning gender identity.

This rule commits the Department to vigorous enforcement of the nondiscrimination provisions of Section 1557 and Title IX as incorporated therein, according to the plain meaning of the protections set forth in those statutes. In addition, the gender identity provisions of the 2016 Rule were preliminarily enjoined on a nationwide basis by a court from December 2016 until October 2019, when they were vacated entirely. As a result, this final rule maintains the status quo with respect to gender identity under the enforcement of the Section 1557 rule.

Based on the Department's review of the public comments, the commenters did not provide, and the Department is not otherwise aware of, reliable data or methods to calculate the economic impacts concerning gender identity that they allege would be attributable to this final rule. Commenters cited various sources of data, but many were either too narrow in not providing a basis to estimate the impacts of this rule nationwide, or were too broad in discussing aspects of the healthcare system but not impacts of this specific rule. For example, citations to data about the percent of transgender persons who forgo care due to fears or experiences of discrimination, and a calculation of the costs to the healthcare system resulting from such occurrences, are not sufficient to estimate the effects of this final rule itself, due to court orders preliminarily enjoining and then vacating provisions in the 2016 Rule, State and local laws that already provide gender identity protections, and other factors that prevent the Department from showing that this final rule is causing those effects. For example, one poll cited by commenters was conducted in 2017, when the 2016 Rule was already in place, but when its gender identity provisions were preliminarily enjoined. So it is not clear from that poll that the 2016 Rule yielded the benefits the commenters say it did, and it is even less clear how this final rule will remove those benefits. Generally, the Department's review of comments is that concerns about increased costs to LGBT persons from this final rule do not offer sufficient quantitative evidence for the Department to provide an estimate along these dimensions.

Finally, as discussed above, because the 2016 Rule contained no prohibition on sexual orientation discrimination in the 2016 Rule, the Department does not deem there to be an economic impact resulting from this final rule with respect to sexual orientation discrimination.

[379] BLS, Occupational Employment and Wages, May 2018, *https://www.bls.gov/oes/2018/may/oes_nat.htm.*

[380] *Id.*

[381] NPR, ''Discrimination in America: Experiences and Views of LGBTQ Americans'' (Nov. 2017), available at *https://www.npr.org/documents/2017/nov/npr-discrimination-lgbtq-final.pdf.*

Consequently, commenters' warnings of effects of this rule's changes on these issues do not give rise to impacts that are properly attributable to this rule and that the Department believes can be estimated for the purposes of this analysis.

Comment: One commenter contended that the Department should include analysis of the consequences of removing sex stereotyping language from the rule. The commenter suggested that costs of this rescission could include increased confusion for patients and covered entities, increased discrimination based on sex stereotyping with attendant economic and non-economic costs to patients and the public health system, increased need for legal advice, and increased litigation.

Response: To the extent that sex stereotyping language from the 2016 Rule was interpreted to encompass gender identity, court orders have preliminarily enjoined and now vacated those provisions. Therefore, this final rule does not directly induce changes in this regard. To the extent that sex stereotyping is a recognized category of sex discrimination under longstanding Supreme Court precedent, this final rule commits the Department to continuing to vigorously enforce Title IX through Section 1557, and therefore the Department estimates that this final rule will not have any material effect on the scope of sex stereotyping claims as authorized by Title IX and Section 1557.

Comment: A commenter objected that the proposed rule did not estimate the economic impact of withdrawal of Federal guidance and technical support concerning the 2016 Rule.

Response: All guidance and technical support concerning the 2016 Rule was withdrawn by operation of the preamble to the proposed rule, which itself is a guidance document—not directly by this final rule. The outdated guidance documents are in the process of being removed from the Department's websites. The Department is not aware of any data that would allow it to estimate the effects of changes to its sub-regulatory guidance. To the extent that certain guidance and technical support concerned provisions of the 2016 Rule that were enjoined and vacated, this final rule is not the direct cause of the Department's non-enforcement of those provisions.

Comment: Some commenters contended that the proposed rule would lead to economic burdens concerning termination of pregnancy for women and other patients who are denied access to care. One commenter stated that there is well-documented research that shows the significant healthcare costs women experience when they face healthcare denials. Another commenter stated that women will suffer negative health effects or death if they are denied services relating to complications from an abortion or a miscarriage. Another commenter stated that there are costs to patients facing discrimination as a result of having a previous termination of pregnancy.

Several commenters contended that the proposed rule would place undue costs and burdens on survivors of sexual and domestic violence. The commenters stated that healthcare programs provide critical and costly care for survivors of domestic violence, sexual assault, and human trafficking. The commenters stated that recent data from the CDC shows that the lifetime per-victim cost of intimate partner violence was $103,767 for women victims, with 59% going to medical costs, and that more than 550,000 injuries due to intimate partner violence require medical attention each year.

Response: The Department appreciates comments in this regard. This final rule fully commits the Department to enforcement of Section 1557 and Title IX to protect women from discrimination on the basis of sex, including and especially vulnerable populations such as survivors of domestic violence, sexual assault, and human trafficking. As noted above, court orders have already enjoined and now vacated the termination of pregnancy provisions from the 2016 Rule. Therefore, this final rule does not have a direct material economic impact with regard to discrimination on the basis of termination of pregnancy. This final rule further ensures the Department will enforce Section 1557 and Title IX consistent with the statutory provisions of Title IX. The Department lacks data or methods enabling it to provide quantitative estimates of any alleged economic impacts related to termination of pregnancy provisions.

Comment: A commenter contended that the Department should conduct a cost-benefit analysis specifically on the impact of adopting Title IX's religious exemptions, or compliance with RFRA.

Response: The Department disagrees. The Title IX statute already includes certain exemptions concerning religious groups, and RFRA protects certain exercises of religion from substantial burdens. This final rule affirms that the Department will only enforce Section 1557 consistent with the statutory provisions of Title IX and RFRA, and amends the Title IX regulations to explicitly include the provisions of the Title IX statute concerning religious groups and abortion neutrality. As the Department is already bound by statute to implement Title IX and Section 1557 consistent with those statutes and with RFRA, the Department does not attribute its compliance with those statutes to be attributable to this final rule. Economic impacts due to compliance with Title IX and RFRA would be attributable, not to this final rule, but to those statutes themselves, and are not relevant for this regulatory impact analysis.

Comment: One commenter stated that the Department should estimate the economic impacts of its conforming amendments.

Response: Section 1557 encompasses all the CMS programs addressed by the conforming amendments, so the Department's estimates of impacts of changes to the Section 1557 rule already encompass the impact on entities covered by those rules.

(5) Impact on State, Local, and Tribal Entities Under Executive Orders 12866, 13132, and 13175

a. State and Local Governments

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Executive Order 13132, 64 FR 43255 (Aug. 4, 1999). The Department does not believe that this final rule would (1) impose substantial direct requirements costs on State or local governments; (2) preempt State law; or (3) otherwise have Federalism implications. Section 1557 itself provides that it shall not be construed ''to supersede State laws that provide additional protections against discrimination on any basis described in subsection (a) [of Section 1557].'' 42 U.S.C. 18116(b).

The final rule maintains the full force of Federal civil rights laws' protections against discrimination, but does not attempt to impose a ceiling on how those protections may be observed by States. State and local jurisdictions would continue to have the flexibility to impose additional civil rights protections.

The Department believes that there would be reduced costs to State and local entities, by repealing wasteful Federal mandates and giving States more flexibility to address the needs of LEP individuals or other regional-specific issues.

The Department believes that the change to its Title IX regulations will

not have a substantial direct effect on the States, on the relationship between the national government and the States, on the distribution of power and responsibilities among the various levels of government, or on tribal self-government or sovereignty. This final rule does not subject Title IX funding recipients to new obligations, but rather implements Title IX according to its statutory text, and relieves potential burdens on the States or tribes that could have resulted from any prior interpretation of Title IX by HHS that was inconsistent with the statute. This final rule allows States and tribes to adopt or continue to provide nondiscrimination protections on the basis of sexual orientation, gender identity, or termination of pregnancy, in State, local, and tribal law. Therefore, the Department has determined that this final rule does not have sufficient Federalism implications to warrant the preparation of a Federalism summary impact statement under Executive Order 13132, and that the rule would not implicate the requirements of Executive Orders 12866 and 13175 with respect to tribes.

Comment: One commenter stated it was inconsistent for the Department to say the 2016 Rule imposed burdens on States but that the proposed rule would not impose new burdens.

Response: The 2016 Rule imposed or may have imposed burdens concerning notices and taglines, as well as gender identity and termination of pregnancy provisions beyond the text of Title IX. This final rule can relieve such burdens without imposing new burdens. To the extent that the gender identity and termination of pregnancy provisions were vacated in October 2019, the Department agrees this final rule does not relieve such burdens, but to the same extent, this final rule does not impose any corresponding burdens.

Comment: A commenter stated that HHS points to no evidence of substantial burdens on States and localities as regards the provision or coverage of medically necessary care related to gender transition.

Response: The Department's conclusion that this final rule does not impose new burdens on States and localities is independent of the Department's suggestion that the 2016 Rule, to the extent it prohibited discrimination on grounds exceeding Title IX and State and local law, also imposed burdens on such States and localities.

Comment: One commenter stated that the proposed rule could impose additional costs on States that adopted policies related to private insurance and Medicaid based on the 2016 Rule that see an increase in healthcare discrimination complaints in their State-level human rights commissions, as HHS OCR will no longer receive such complaints, and such States may reinstate or maintain exclusions and face costly litigation.

Response: The court orders preliminarily enjoining and eventually vacating the 2016 Rule's gender identity and termination of pregnancy provisions have been in effect since December 2016. States have, therefore, not been bound by those provisions, and this final rule's changes in that regard will not cause States to need to change their policies in that regard. States will also not likely see an increase in complaints at the State level as a result of this rule, because HHS OCR has not been able to enforce those provisions for almost the entire lifespan of the 2016 Rule. Finally, this rule does not require States to reinstate exclusions from coverage, so litigation that States might face as a result of doing so are not directly attributable to this final rule.

b. Tribal Governments

Executive Order 12866 directs that significant regulatory actions avoid undue interference with State, local, or tribal governments, in the exercise of their governmental functions. Executive Order 12866 at § 6(a)(3)(B).[382] Executive Order 13175 further directs that Agencies respect Indian tribal self-government and sovereignty, honor tribal treaty and other rights, and strive to meet the responsibilities that arise from the unique legal relationship between the Federal Government and Indian tribal governments. Executive Order 13175 at § 2(a). The Department does not believe that the final rule would implicate the requirements of Executive Orders 12866 and 13175 with respect to tribal sovereignty.

(6) Avoidance of Inconsistent, Incompatible, or Duplicative Regulations

Executive Order 12866 requires the Department to avoid issuing regulations that are inconsistent, incompatible, or duplicative with other regulations that it has issued or that have been issued by other Federal agencies. Executive Order 12866 at § 1(b)(10). Section 1557 itself requires avoidance of duplication by providing that the enforcement mechanisms under specifically identified civil rights laws ''shall apply for purposes of violations'' of Section 1557. 42 U.S.C. 18116(a).[383] The preamble to the 2016 Rule repeatedly stated that, with the exception of issues concerning notices, sex discrimination, and language access plans, it was merely applying civil rights protections that were already applicable and familiar to covered entities. *See* 81 FR at 31446. (''It is important to recognize that this final rule, except in the area of sex discrimination, applies pre-existing requirements in Federal civil rights laws to various entities, the great majority of which have been covered by these requirements for years.''); 81 FR at 31464 (''For the most part, because this regulation is consistent with existing standards applicable to the covered entities, the new burdens created by its issuance are minimal.'').

With regard to the current 2016 Rule's notice and taglines requirement, covered entities are already subject to dozens of regulations concerning multi-language taglines or notices concerning an individual's right to have documents translated. For example, CMS imposes taglines requirements on health insurance marketplaces, QHP issuers, group health plans and health insurance issuers, navigators, non-navigator assistance personnel, Medicaid, Medicaid managed care, Children's Health Insurance Program, Medicare Advantage, and Medicare Part D.[384]

[382] As stated in the preceding section, the final rule does not have Federalism implications.

[383] For the applicable enforcement mechanisms, *See* 45 CFR parts 80 and 81 (Title VI), 85 (Section 504), 86 (Title IX), 90 and 91 (Age Act).

[384] 45 CFR 147.136(e)(2)(iii) and (e)(3) and § 147.200(a)(5) (requiring group health plans and QHP issuers to post taglines in languages in which 10% of individuals with LEP county-wide are exclusively literate on internal claims and appeals notices, and requiring QHP issuers to post on its Summary of Benefits and Coverage), § 155.215(c)(4) (requiring Navigators and non-Navigator personnel in States with Marketplaces operated by HHS to ''[p]rovide oral and written notice to consumers with LEP, in their preferred language, informing them of their right to receive language assistance services and how to obtain them''); 42 CFR 435.905(b)(3) (Medicaid regulations requiring individuals to be ''informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non–English languages indicating the availability of language services''); § 438.10(c)(5)(i) through (ii) (Medicaid managed care regulations requiring taglines until July 1, 2017); § 438.10(d)(2) through (3), (d)(5)(i), (d)(5)(iii) and (d)(5)(j) (Medicaid managed care regulations requiring taglines on ''all written materials for potential enrollees'' in the prevalent non-English languages in the State and requiring notification that ''oral interpretation is available for any language and written translation is available in prevalent languages'' during the rating period for contracts with managed care entities beginning on or after July 1, 2017), § 457.340(a) (applying certain Medicaid requirements to the Children's Health Insurance Program, including § 435.905(b)(3), which requires individuals to be ''informed of the availability of language services . . . and how to access . . . [them] through providing taglines in non-English languages indicating the availability of language services''), 457.1207 (applying certain

Furthermore, a Department of Treasury regulation imposed taglines requirements for hospital organizations to qualify for tax-exempt status.[385] Additionally, in 2003, the Department issued guidance under Title VI, setting forth a flexible four-factor framework to assess the necessity and reasonableness for providing written translation for LEP individuals.[386] Finally, the ACA itself provides that each summary of benefits and coverage provided by issuers—perhaps the single most important health insurance-related document a person receives—must be ''presented in a culturally and linguistically appropriate manner.'' 42 U.S.C. 300gg–15(b)(2).

Substantially replacing many provisions of the 2016 Rule, including removing the notice and taglines requirements, would eliminate significant redundancies identified above, while maintaining vigorous enforcement of existing Federal civil rights statutes.

B. Executive Order 13771 on Reducing and Controlling Regulatory Costs

This final rule is deemed an E.O. 13771 deregulatory action. The Department estimates that this final rule would generate $0.24 billion in net annualized savings at a 7% discount rate (discounted relative to year 2016, over a perpetual time horizon, in 2016 dollars).

Furthermore, Executive Order 13765 states that ''the Secretary of Health and Human Services (Secretary) and the heads of all other executive departments and agencies (agencies) with authorities and responsibilities under the [ACA] shall exercise all authority and discretion available to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the [ACA] that would impose a fiscal burden on any State or a cost, fee, tax, penalty, or regulatory burden on individuals, families, healthcare providers, health insurers, patients, recipients of healthcare services, [or] purchasers of health insurance.'' Executive Order 13765, 82 FR 8351, 8351 (Jan. 24, 2017). In implementing Section 1557 of the ACA, the 2016 Rule imposed significant regulatory burdens on covered entities, including States, healthcare providers, and health insurers, without sufficient corresponding benefits for patients or beneficiaries. By proposing to substantially replace the 2016 Rule with a regulation that requires compliance with pre-existing civil rights laws, the Department is acting in accordance with Executive Order 13765 in exercising its authority and discretion to address the fiscal burdens on States, and the regulatory burdens imposed on individuals, families, healthcare providers, health insurers, patients, and recipients of healthcare service. The final rule will particularly reduce the economic burden imposed on healthcare providers and insurers required to provide taglines under the 2016 Rule. Decreasing the burden on these providers and insurers will allow them to pass along some of the cost savings to individuals, families, patients, and beneficiaries of insurance to whom they provide services or coverage. Additionally, eliminating the taglines requirement will alleviate burdens on patients and insurance beneficiaries that neither need nor want to receive repeated taglines mailings.

C. Congressional Review Act

The Congressional Review Act (CRA) defines a ''major rule'' as ''any rule that the Administrator of the Office of Information and Regulatory Affairs (OIRA) of the Office of Management and Budget finds has resulted in or is likely to result in—(A) an annual effect on the economy of $100,000,000 or more; (B) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or (C) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.'' 5 U.S.C. 804(2). Based on the analysis of this final rule under Executive Order 12866, this rule is expected to be a major rule for purposes of the CRA because it generates cost savings of over $100 million. The Department will comply with the CRA's requirements to inform Congress.

D. Unfunded Mandates Reform Act

This final rule is not subject to the Unfunded Mandates Reform Act because it falls under an exception for regulations that establish or enforce any statutory rights that prohibit discrimination on the basis of race, color, religion, sex, national origin, age, handicap, or disability. 2 U.S.C. 1503(2).

E. Regulatory Flexibility Act and Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking

The Regulatory Flexibility Act (RFA) requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Public Law 96–354, 94 Stat. 1164 (Sept. 19, 1980) (codified at 5 U.S.C. 601 through 612). The RFA requires an agency to describe the impact of a rulemaking on small entities by providing an initial regulatory flexibility analysis, unless the agency expects that the rule will not have a significant economic impact on a substantial number of small entities, provides a factual basis for this determination, and proposes to certify the statement. 5 U.S.C. 603(a), 605(b). If an agency must provide an initial regulatory flexibility analysis, this analysis must address the consideration of regulatory options that would minimize the economic impact of the rule on small entities. 5 U.S.C. 603(c).

For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. HHS considers a rule to have a significant impact on a substantial number of small entities if it has at least a three percent impact on revenue for at least five percent of small entities.

Based on its examination, the Department has concluded that this final rule does not have a significant economic impact on a substantial number of small entities. The preamble to the 2016 Rule discussed the character of small entities impacted by the 2016 Rule in detail. 81 FR at 31463–64. Although this final rule will affect numerous small entities, it does not create new or expanded requirements,

Medicaid managed care requirements to Children's Health Insurance Program managed care, including § 438.10(c)(5)(i)–(ii) until the State fiscal year beginning on or after July, 1, 2018), § 438.10(d)(2)–(3), (d)(5)(i), (iii), (j) (applying certain Medicaid managed care requirements to Children's Health Insurance Program managed care, in the State fiscal year beginning on or after July, 1, 2018); CMS, 2017 Medicare Marketing Guidelines, § 30.5.1, § 100.2.2, § 8, § 80–8 (Jun. 10, 2016), *https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/Downloads/2017MedicareMarketingGuidelines2.pdf* (providing a CMS Multi-Language Insert'' for certain Medicare Advantage Plan's and Medicare Part D Plan Sponsors' marketing materials meeting the percentage translation threshold in § 422.2264(e) and § 423.2264(e) of Title 42 of the CFR). As discussed in the RIA section, we presume 45 CFR 155.205(c)(2)(iii)(A) (requiring Marketplaces and QHP issuers to post taglines on their websites and documents ''critical for obtaining health insurance coverage or access to health care services through a QHP'') and other provisions that depend or refer to 45 CFR part 92 for their tagline requirements will no longer apply under this final rule.

[385] *See* 79 FR 78954 (Dec. 31, 2014) (finalizing rule requiring the plain language summary of the financial assistance policy for hospital organizations to qualify as tax exempt, to indicate, if applicable, whether the summary, the financial assistance policy, and the application for such assistance are available in other languages).

[386] Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons, 68 FR 47315 (Aug. 8, 2003) (HHS LEP Guidance).

and, for all the reasons stated in the RIA, it will be reducing economic burdens on such entities overall. The changes concerning gender identity and termination of pregnancy, having already been vacated by court order, are not expected to result in any impact. The changes to the Department's Title IX rule would not impose any new substantive obligations on Federal funding recipients and, in fact, would provide regulatory clarity and relief for any small entities previously subject to several of the policies and requirements imposed by the Department. The changes made in conforming amendments overlap those made in the Section 1557 rule and described in the RIA.

To the extent that this final rule imposes economic costs, these are generally limited to entities' voluntary choices to revise their policies and procedures and conduct training, and the Department believes these costs are well below those required to have a significant impact on a substantial number of small entities. In addition, the majority of the costs associated with this final rule are proportional to the size of entities, meaning that even the smallest of the affected entities are unlikely to face a substantial impact.

For these reasons, the Secretary certifies that the final rule will not have a significant impact on a substantial number of small entities.

Executive Order 13272 on Proper Consideration of Small Entities in Agency Rulemaking reinforces the requirements of the RFA and requires the Department to notify the Chief Counsel for Advocacy of the Small Business Administration if the final rule may have a significant economic impact on a substantial number of small entities under the RFA. Executive Order 13272, 67 FR 53461 (Aug. 16, 2002). Because the economic impact of the proposed rule is not significant under the RFA, the Department is not subject to Executive Order 13272's notification requirement.

F. Executive Order 12250 on Leadership and Coordination of Nondiscrimination Laws

Pursuant to Executive Order 12250, the Attorney General has the responsibility to ''coordinate the implementation and enforcement by Executive agencies of . . . Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*)'' Executive Order 12250 at § 1–2(b), 45 FR 72995 (Nov. 2, 1980). The proposed rule was reviewed and approved by the Attorney General, and this final rule was also reviewed and approved by the Attorney General in finalizing the proposed rule without change.

G. Paperwork Reduction Act

The Department has determined that this final rule does not impose additional reporting or recordkeeping requirements under the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.* Under the rule, OCR will update and revise its burden analysis by removing the burden associated with the posting of a nondiscrimination notice and taglines, development and implementation of a language access plan, and designation of a compliance coordinator and adoption of grievance procedures for covered entities with 15 or more employees. OCR has obtained Paperwork Reduction Act approval for this reporting requirement via an update to HHS Form 690 (Consolidated Civil Rights Assurance Form) [387] separate from this rulemaking.

(D) Delegation of Authority

Notice is hereby given that I have delegated to the Director, Office for Civil Rights (OCR), with authority to re-delegate, enforcement and administration of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116]. This delegation includes the authority to develop and direct implementation of the requirements of Section 1557 of the Patient Protection and Affordable Care Act [42 U.S.C. 18116] as applied to the Department and recipients of the Department's funds. This delegation supersedes the delegation of authority under Section 1557 to the Health Resources and Services Administration (HRSA) on April 21, 2016 in 81 FR 25680 (April 29, 2016).

List of Subjects

42 CFR Part 438

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

42 CFR Part 440

Civil rights, Discrimination, Grant programs-health, Individuals with disabilities, Medicaid, National origin, Nondiscrimination, Sex discrimination.

42 CFR Part 460

Age discrimination, Aged, Civil rights, Discrimination, Health Incorporation by reference, Individuals with disabilities, Medicare, Medicaid, National origin, Nondiscrimination, Religious discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 86

Civil rights, Colleges and universities, Employment, Administrative practice and procedure, Buildings and facilities, Education of individuals with disabilities, Education, Educational facilities, Educational research, Educational study programs, Equal educational opportunity, Equal employment opportunity, Graduate fellowship program, Grant programs—education, Individuals with disabilities, Investigations, Reporting and recordkeeping requirements, Sex discrimination, State agreement program, Student aid, Women.

45 CFR Part 92

Administrative practice and procedure, Age discrimination, Civil rights, Discrimination, Elderly, Healthcare, Health facilities, Health insurance, Health programs or activities, Individuals with disabilities, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 147

Age discrimination, Civil rights, Discrimination, Healthcare, Health insurance, Individuals with disabilities, National origin, Nondiscrimination, Reporting and recordkeeping requirements, Sex discrimination, State regulation of health insurance.

45 CFR Part 155

Actuarial value, Administration and calculation of advance payments of the premium tax credit, Administrative practice and procedure, Advance payments of premium tax credit, Age discrimination, Civil rights, Cost-sharing reductions, Discrimination, Healthcare access, Health insurance, Individuals with disabilities, National origin, Nondiscrimination, Plan variations, Reporting and recordkeeping requirements, Sex discrimination, State and local governments.

45 CFR Part 156

Administrative appeals, Administrative practice and procedure, Administration and calculation of advance payments of premium tax credit, Advertising, Advisory Committees, Age discrimination, Brokers, Civil rights, Conflict of interest, Consumer protection, Cost-sharing reductions, Discrimination, Grant programs-health, Grants administration,

[387] *See* HHS OCR, Assurance of Compliance Portal, *https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf.*

Healthcare, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, American Indian/Alaska Natives, Individuals with disabilities, Loan programs-health, Organization and functions (Government agencies), Medicaid, National origin, Nondiscrimination, Payment and collections reports, Public assistance programs, Reporting and recordkeeping requirements, Sex discrimination, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

For the reasons set forth in the preamble, the Department of Health and Human Services amends 42 CFR parts 438, 440, and 460 and 45 CFR parts 86, 92, 147, 155, and 156 as follows:

Title 42—Public Health

PART 438—MANAGED CARE

■ 1. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Amend § 438.3 by revising paragraph (d)(4) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(d) * * *

(4) The MCO, PIHP, PAHP, PCCM or PCCM entity will not discriminate against individuals eligible to enroll on the basis of race, color, national origin, sex, or disability and will not use any policy or practice that has the effect of discriminating on the basis of race, color, or national origin, sex, or disability.

* * * * *

■ 3. Amend § 438.206 by revising paragraph (c)(2) to read as follows:

§ 438.206 Availability of services.

* * * * *

(c) * * *

(2) *Access and cultural considerations.* Each MCO, PIHP, and PAHP participates in the State's efforts to promote the delivery of services in a culturally competent manner to all enrollees, including those with limited English proficiency and diverse cultural and ethnic backgrounds, disabilities, and regardless of sex.

* * * * *

PART 440—SERVICES: GENERAL PROVISIONS

■ 4. The authority citation for part 440 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 5. Revise § 440.262 to read as follows:

§ 440.262 Access and cultural conditions.

The State must have methods to promote access and delivery of services in a culturally competent manner to all beneficiaries, including those with limited English proficiency, diverse cultural and ethnic backgrounds, disabilities, and regardless of sex. These methods must ensure that beneficiaries have access to covered services that are delivered in a manner that meets their unique needs.

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 6. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l, 1395eee(f), and 1396u–4(f)).

■ 7. Amend § 460.98 by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

* * * * *

■ 8. Amend § 460.112 by revising paragraph (a) to read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

* * * * *

Title 45—Public Welfare

PART 86—NONDISCRIMINATION ON THE BASIS OF SEX IN EDUCATION PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE

■ 9. The authority citation for part 86 is revised to read as follows:

Authority: 20 U.S.C. 1681 through 1688; Pub. L. 100–259, 102 Stat. 28 (Mar. 22, 1988).

■ 10. Amend § 86.2:

■ a. In paragraph (a), by adding ‘‘, 1687, 1688’’ after ‘‘1686’’; and

■ b. In paragraph (n), by removing the words ‘‘United States Commissioner of Education’’ and adding in their place the words ‘‘Secretary of Education’’.

■ 11. Add § 86.18 to read as follows:

§ 86.18 Amendments to conform to statutory exemptions.

(a) Nothing in this part shall be construed to force or require any individual or hospital or any other institution, program, or activity receiving Federal funds to perform or pay for an abortion.

(b) Nothing in this part shall be construed to require or prohibit any person, or public or private entity, to provide or pay for any benefit or service, including the use of facilities, related to an abortion. Nothing in the preceding sentence shall be construed to permit a penalty to be imposed on any person or individual because such person or individual is seeking or has received any benefit or service related to a legal abortion.

(c) This part shall be construed consistently with, as applicable, the First Amendment to the Constitution, Title IX's religious exemptions (20 U.S.C. 1681(a)(3) and 1687(4)), the Religious Freedom Restoration Act (42 U.S.C. 2000b *et seq.*), and provisions related to abortion in the Church Amendments (42 U.S.C. 300a–7), the Coats-Snowe Amendment (42 U.S.C. 238n), section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), and appropriation rider provisions relating to abortion, to the extent they remain in effect or applicable, such as the Hyde

Amendment (*e.g.,* Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, secs. 506–07), the Helms Amendment (*e.g.,* Continuing Appropriations Act, 2019, Pub. L. 116–6, Div. F, Title III), and the Weldon Amendment (*e.g.,* Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B, sec. 507(d)).

■ 12. Amend § 86.31 by revising paragraph (b) to read as follows:

§ 86.31 Education programs or activities.

* * * * *

(b) *Specific prohibitions.* Except as provided in this subsection, in providing any aid, benefit, or service to a student, a recipient shall not, on the basis of sex:

(1) Treat one person differently from another in determining whether such person satisfies any requirement or condition for the provision of such aid, benefit, or service;

(2) Provide different aid, benefits, or services or provide aid, benefits, or services in a different manner;

(3) Deny any person any such aid, benefit, or service;

(4) Subject any person to separate or different rules of behavior, sanctions, or other treatment;

(5) Apply any rule concerning the domicile or residence of a student or applicant, including eligibility for in-State fees and tuition;

(6) Aid or perpetuate discrimination against any person by providing significant assistance to any agency, organization, or person which discriminates on the basis of sex in providing any aid, benefit or service to students or employees;

(7) Otherwise limit any person in the enjoyment of any right, privilege, advantage, or opportunity.

* * * * *

■ 13. Revise § 86.71 to read as follows:

§ 86.71 Enforcement procedures.

For the purposes of implementing this Part, the procedural provisions applicable to Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d) are hereby adopted and incorporated herein by reference. These procedures may be found at 45 CFR 80.6 through 80.11 and 45 CFR part 81.

■ 14. Revise part 92 to read as follows:

PART 92—NONDISCRIMINATION ON THE BASIS OF RACE, COLOR, NATIONAL ORIGIN, SEX, AGE, OR DISABILITY IN HEALTH PROGRAMS OR ACTIVITIES RECEIVING FEDERAL FINANCIAL ASSISTANCE AND PROGRAMS OR ACTIVITIES ADMINISTERED BY THE DEPARTMENT OF HEALTH AND HUMAN SERVICES UNDER TITLE I OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OR BY ENTITIES ESTABLISHED UNDER SUCH TITLE

Subpart A—General Provisions

Sec.
92.1 Purpose.
92.2 Nondiscrimination requirements.
92.3 Scope of application.
92.4 Assurances.
92.5 Enforcement mechanisms.
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Subpart B—Specific Applications to Health Programs or Activities

92.101 Meaningful access for individuals with limited English proficiency.
92.102 Effective communication for individuals with disabilities.
92.103 Accessibility standards for buildings and facilities.
92.104 Accessibility of information and communication technology.
92.105 Requirement to make reasonable modifications.

Authority: 42 U.S.C. 18116; 5 U.S.C. 301, Pub. L. 100–259, 102 Stat. 28 (Mar. 22 1988); 42 U.S.C. 2000d *et seq.* (Title VI of the Civil Rights Act of 1964, as amended); 29 U.S.C. 794 (Section 504 of the Rehabilitation Act of 1973, as amended); 20 U.S.C. 1681 *et seq.* (Title IX of the Education Amendments of 1972, as amended); 42 U.S.C. 6101 *et seq.;* (Age Discrimination Act of 1975, as amended); *Lau* v. *Nichols,* 414 U.S. 563 (1974).

Subpart A—General Provisions

§ 92.1 Purpose.

The purpose of this part is to provide for the enforcement of section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. 18116, prohibiting discrimination under any health program or activity receiving Federal financial assistance, or under any program or activity administered by an Executive agency, or by any entity established, under Title I of such law, on the grounds of race, color, national origin, sex, age, or disability, except as provided in Title I of such law (or any amendment thereto). Section 1557 requires the application of the enforcement mechanisms under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), and Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) for purposes of violations of Section 1557 and this part.

§ 92.2 Nondiscrimination requirements.

(a) Except as provided in Title I of the Patient Protection and Affordable Care Act (or any amendment thereto), an individual shall not, on any of the grounds set forth in paragraph (b) of this section, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the U.S. Department of Health and Human Services; or under any program or activity administered by the Department under such Title; or under any program or activity administered by any entity established under such Title.

(b) The grounds are the grounds prohibited under the following statutes:

(1) Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*) (race, color, national origin);

(2) Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*) (sex);

(3) The Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*) (age); or

(4) Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794) (disability).

§ 92.3 Scope of application.

(a) Except as otherwise provided in this part, this part applies to

(1) Any health program or activity, any part of which is receiving Federal financial assistance (including credits, subsidies, or contracts of insurance) provided by the Department;

(2) Any program or activity administered by the Department under Title I of the Patient Protection and Affordable Care Act; or

(3) Any program or activity administered by any entity established under such Title.

(b) As used in this part, ''health program or activity'' encompasses all of the operations of entities principally engaged in the business of providing healthcare that receive Federal financial assistance as described in paragraph (a)(1) of this section. For any entity not principally engaged in the business of providing healthcare, the requirements applicable to a ''health program or activity'' under this part shall apply to such entity's operations only to the extent any such operation receives Federal financial assistance as described in paragraph (a)(1) of this section.

(c) For purposes of this part, an entity principally or otherwise engaged in the

business of providing health insurance shall not, by virtue of such provision, be considered to be principally engaged in the business of providing healthcare.

(d) Any provision of this part held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event the provision shall be severable from this part and shall not affect the remainder thereof or the application of the provision to other persons not similarly situated or to other, dissimilar circumstances.

§ 92.4 Assurances.

(a) *Assurances.* An entity applying for Federal financial assistance to which this part applies shall, as a condition of any application for Federal financial assistance, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the entity's health programs or activities will be operated in compliance with section 1557 and this part. A health insurance issuer seeking certification to participate in an Exchange or a State seeking approval to operate a State Exchange to which section 1557 or this part applies shall, as a condition of certification or approval, submit an assurance, on a form specified by the Director of the Department's Office for Civil Rights, that the health program or activity will be operated in compliance with section 1557 and this part. An applicant or entity may incorporate this assurance by reference in subsequent applications to the Department for Federal financial assistance or requests for certification to participate in an Exchange or approval to operate a State Exchange.

(b) *Duration of obligation.* The duration of the assurances required by this subpart is the same as the duration of the assurances required in the Department's regulations implementing section 504 at 45 CFR 84.5(b).

(c) *Covenants.* When Federal financial assistance is provided in the form of real property or interest, the same conditions apply as those contained in the Department's regulations implementing section 504 at 45 CFR 84.5(c), except that the nondiscrimination obligation applies to discrimination on all bases covered under section 1557 and this part.

§ 92.5 Enforcement mechanisms.

(a) The enforcement mechanisms provided for, and available under, Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), including under the Department's regulations implementing those statutes, shall apply for purposes of violations of § 92.2 of this part.

(b) The Director of the Office for Civil Rights has been delegated the authority to enforce 42 U.S.C. 18116 and this part, which includes the authority to handle complaints, initiate and conduct compliance reviews, conduct investigations, supervise and coordinate compliance within the Department, make enforcement referrals to the Department of Justice, in coordination with the Office of the General Counsel and the relevant component or components of the Department, and take other appropriate remedial action as the Director deems necessary, in coordination with the relevant component or components of the Department, and as allowed by law to overcome the effects of violations of 42 U.S.C. 18116 or of this part.

§ 92.6 Relationship to other laws.

(a) Nothing in this part shall be construed to invalidate or limit the rights, remedies, procedures, or legal standards available to individuals aggrieved under Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d *et seq.*), Title VII of the Civil Rights Act of 1964 (42 U.S.C. 2000e *et seq.*), Title IX of the Education Amendments of 1972 (20 U.S.C. 1681 *et seq.*), the Age Discrimination Act of 1975 (42 U.S.C. 6101 *et seq.*), or Section 504 of the Rehabilitation Act of 1973 (29 U.S.C. 794), or to supersede State laws that provide additional protections against discrimination on any basis described in § 92.2 of this part.

(b) Insofar as the application of any requirement under this part would violate, depart from, or contradict definitions, exemptions, affirmative rights, or protections provided by any of the statutes cited in paragraph (a) of this section or provided by the Architectural Barriers Act of 1968 (42 U.S.C. 4151 *et seq.*); the Americans with Disabilities Act of 1990, as amended by the Americans with Disabilities Act Amendments Act of 2008 (42 U.S.C. 12181 *et seq.*), Section 508 of the Rehabilitation Act of 1973, as amended (29 U.S.C. 794d), the Coats-Snowe Amendment (42 U.S.C. 238n), the Church Amendments (42 U.S.C. 300a–7), the Religious Freedom Restoration Act (42 U.S.C. 2000bb *et seq.*), Section 1553 of the Patient Protection and Affordable Care Act (42 U.S.C. 18113), Section 1303 of the Patient Protection and Affordable Care Act (42 U.S.C. 18023), the Weldon Amendment (Consolidated Appropriations Act, 2019, Pub. L. 115–245, Div. B sec. 209 and sec. 506(d) (Sept. 28, 2018)), or any related, successor, or similar Federal laws or regulations, such application shall not be imposed or required.

Subpart B—Specific Applications to Health Programs or Activities

§ 92.101 Meaningful access for individuals with limited English proficiency.

(a) Any entity operating or administering a health program or activity subject to this part shall take reasonable steps to ensure meaningful access to such programs or activities by limited English proficient individuals.

(b) *Specific applications*—(1) *Enforcement discretion.* In evaluating whether any entity to which paragraph (a) of this section applies has complied with paragraph (a) of this section, the Director of the Department's Office for Civil Rights may assess how such entity balances the following four factors:

(i) The number or proportion of limited English proficient individuals eligible to be served or likely to be encountered in the eligible service population;

(ii) The frequency with which LEP individuals come in contact with the entity's health program, activity, or service;

(iii) The nature and importance of the entity's health program, activity, or service; and

(iv) The resources available to the entity and costs.

(2) *Language assistance services requirements.* Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of language assistance services, such services must be provided free of charge, be accurate and timely, and protect the privacy and independence of the individual with limited English proficiency. Language assistance services may include:

(i) Oral language assistance, including interpretation in non-English languages provided in-person or remotely by a qualified interpreter for an individual with limited English proficiency, and the use of qualified bilingual or multilingual staff to communicate directly with individuals with limited English proficiency; and

(ii) Written translation, performed by a qualified translator, of written content in paper or electronic form into languages other than English.

(3) *Specific requirements for interpreter and translation services.* (i) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of interpreter services, they must be provided by an interpreter who:

(A) Adheres to generally accepted interpreter ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in speaking and understanding at least spoken English and the spoken language in need of interpretation; and

(C) Is able to interpret effectively, accurately, and impartially, both receptively and expressly, to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(ii) Where paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, requires the provision of translation services for written content (in paper or electronic form), they must be provided by a translator who:

(A) Adheres to generally accepted translator ethics principles, including client confidentiality;

(B) Has demonstrated proficiency in writing and understanding at least written English and the written language in need of translation; and

(C) Is able to translate effectively, accurately, and impartially to and from such language(s) and English, using any necessary specialized vocabulary, terminology and phraseology.

(iii) If remote audio interpreting services are required to comply with paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, the entity to which section 1557 applies (as defined in § 92.3 of this part) shall provide:

(A) Real-time, audio over a dedicated high-speed, wide-bandwidth video connection or wireless connection that delivers high-quality audio without lags or irregular pauses in communication;

(B) A clear, audible transmission of voices; and

(C) Adequate training to users of the technology and other involved individuals so that they may quickly and efficiently set up and operate the remote interpreting services.

(4) *Restricted use of certain persons to interpret or facilitate communication.* If an entity is required by paragraph (a) of this section, in light of the entity's individualized assessment of the four factors set forth in paragraph (b)(1) of this section, to provide interpretation services, such entity shall not:

(i) Require an individual with limited English proficiency to provide his or her own interpreter;

(ii) Rely on an adult accompanying an individual with limited English proficiency to interpret or facilitate communication, except

(A) In an emergency involving an imminent threat to the safety or welfare of an individual or the public, where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(B) Where the individual with limited English proficiency specifically requests that the accompanying adult interpret or facilitate communication, the accompanying adult agrees to provide such assistance, and reliance on that adult for such assistance is appropriate under the circumstances;

(iii) Rely on a minor child to interpret or facilitate communication, except in an emergency involving an imminent threat to the safety or welfare of an individual or the public, where there is no qualified interpreter for the individual with limited English proficiency immediately available; or

(iv) Rely on staff other than qualified bilingual/multilingual staff to communicate directly with individuals with limited English proficiency.

(c) *Acceptance of language assistance services is not required.* Nothing in this section shall be construed to require an individual with limited English proficiency to accept language assistance services.

§ 92.102 Effective communication for individuals with disabilities.

(a) Any entity operating or administering a program or activity under this part shall take appropriate steps to ensure that communications with individuals with disabilities are as effective as communications with others in such programs or activities, in accordance with the standards found at 28 CFR 35.160 through 35.164. Where the regulatory provisions referenced in this section use the term ''public entity,'' the term ''entity'' shall apply in its place.

(b) A recipient or State Exchange shall provide appropriate auxiliary aids and services, including interpreters and information in alternate formats, to individuals with impaired sensory, manual, or speaking skills, where necessary to afford such persons an equal opportunity to benefit from the service in question.

(1) Auxiliary aids and services include:

(i) Interpreters on-site or through video remote interpreting (VRI) services, as defined in 28 CFR 35.104 and 36.303(f); note takers; real-time computer-aided transcription services; written materials; exchange of written notes; telephone handset amplifiers; assistive listening devices; assistive listening systems; telephones compatible with hearing aids; closed caption decoders; open and closed captioning, including real-time captioning; voice, text, and video-based telecommunication products and systems, text telephones (TTYs), videophones, and captioned telephones, or equally effective telecommunications devices; videotext displays; accessible information and communication technology; or other effective methods of making aurally delivered information available to individuals who are deaf or hard of hearing; and

(ii) Readers; taped texts; audio recordings; Braille materials and displays; screen reader software; magnification software; optical readers; secondary auditory programs; large print materials; accessible information and communication technology; or other effective methods of making visually delivered materials available to individuals who are blind or have low vision.

(2) When an entity is required to provide an interpreter under paragraph (b) of this section, the interpreting service shall be provided to individuals free of charge and in a timely manner, via a remote interpreting service or an onsite appearance, by an interpreter who

(i) Adheres to generally accepted interpreter ethics principles, including client confidentiality; and

(ii) Is able to interpret effectively, accurately, and impartially, both receptively and expressively, using any necessary specialized vocabulary, terminology and phraseology.

(3) An interpreter for an individual with a disability for purposes of this section can include, for example, sign language interpreters, oral transliterators (individuals who represent or spell in the characters of another alphabet), and cued language transliterators (individuals who represent or spell by using a small number of handshapes).

(c) Disability means, with respect to an individual, a physical or mental impairment that substantially limits one or more major life activities of such individual; a record of such an impairment; or being regarded as having such an impairment, as defined and construed in the Rehabilitation Act, 29 U.S.C. 705(9)(B), which incorporates the definition of disability in the Americans

with Disabilities Act (ADA), as amended (42 U.S.C. 12102 *et seq.*). Where this part cross-references regulatory provisions that use the term ''handicap,'' ''handicap'' means ''disability'' as defined in this section.

§ 92.103 Accessibility standards for buildings and facilities.

(a) Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange shall comply with the 2010 Standards, if the construction or alteration was commenced after July 18, 2016, except that if a facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange, was not covered by the 2010 Standards prior to July 18, 2016, such facility or part of a facility shall comply with the 2010 Standards if the construction was commenced after January 18, 2018. Departures from particular technical and scoping requirements by the use of other methods are permitted where substantially equivalent or greater access to and usability of the facility is provided. All newly constructed or altered buildings or facilities subject to this section shall comply with the requirements for a ''public building or facility'' as defined in section 106.5 of the 2010 Standards.

(b) Each facility or part of a facility in which health programs or activities under this part are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with the 1991 Standards at appendix D to 28 CFR part 36 or the 2010 Standards shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b) with respect to those facilities, if the construction or alteration was commenced on or before July 18, 2016. Each facility or part of a facility in which health programs or activities are conducted that is constructed or altered by or on behalf of, or for the use of, a recipient or State Exchange in conformance with UFAS shall be deemed to comply with the requirements of this section and with 45 CFR 84.23(a) and (b), if the construction was commenced on or before July 18, 2016 and such facility was not covered by the 1991 Standards or 2010 Standards.

(c) For purposes of this part:

(1) ''1991 Standards'' refers to the 1991 Americans with Disabilities Act Standards for Accessible Design at appendix D to 28 CFR part 36.

(2) ''2010 Standards'' refers to the 2010 ADA Standards for Accessible Design, as defined in 28 CFR 35.104.

(3) ''UFAS'' refers to the Uniform Federal Accessibility Standards as promulgated in 49 FR 31528 (Aug. 7, 1984).

§ 92.104 Accessibility of information and communication technology.

(a) Entities required to comply with § 92.2, unless otherwise exempted by this part, shall ensure that their health programs or activities provided through information and communication technology are accessible to individuals with disabilities, unless doing so would result in undue financial and administrative burdens or a fundamental alteration in the nature of the health programs or activities. When undue financial and administrative burdens or a fundamental alteration exist, the covered entity shall provide information in a format other than an electronic format that would not result in such undue financial and administrative burdens or a fundamental alteration, but would ensure, to the maximum extent possible, that individuals with disabilities receive the benefits or services of the health program or activity that are provided through information and communication technology.

(b) A recipient or State Exchange shall ensure that its health programs or activities provided through websites comply with the requirements of Title II of the Americans with Disabilities Act (42 U.S.C. 12131 through 12165).

(c) For purposes of this part, ''information and communication technology'' (ICT) means information technology and other equipment, systems, technologies, or processes, for which the principal function is the creation, manipulation, storage, display, receipt, or transmission of electronic data and information, as well as any associated content. Examples of ICT include computers and peripheral equipment; information kiosks and transaction machines; telecommunications equipment; customer premises equipment; multifunction office machines; software; applications; websites; videos; and, electronic documents.

§ 92.105 Requirement to make reasonable modifications.

Any entity to which section 1557 applies (as defined in § 92.3 of this part) shall make reasonable modifications to its policies, practices, or procedures when such modifications are necessary to avoid discrimination on the basis of disability, unless the covered entity can demonstrate that making the modifications would fundamentally alter the nature of the health program or activity. For the purposes of this section, the term ''reasonable modifications'' shall be interpreted in a manner consistent with the term as set forth in the regulation promulgated under Title II of the Americans with Disabilities Act, at 28 CFR 35.130(b)(7).

PART 147—HEALTH INSURANCE REFORM REQUIREMENTS FOR THE GROUP AND INDIVIDUAL HEALTH INSURANCE MARKETS

■ 15. The authority citation for part 147 continues to read as follows:

Authority: 42 U.S.C. 18021, 18031, 18041, 18044, 18054, 18061, 18063, 18071, and 18082, 26 U.S.C. 36B, 31 U.S.C. 9701.

■ 16. Amend § 147.104 by revising paragraph (e) to read as follows:

§ 147.104 Guaranteed availability of coverage.

* * * * *

(e) *Marketing.* A health insurance issuer and its officials, employees, agents and representatives must comply with any applicable State laws and regulations regarding marketing by health insurance issuers and cannot employ marketing practices or benefit designs that will have the effect of discouraging the enrollment of individuals with significant health needs in health insurance coverage or discriminate based on an individual's race, color, national origin, present or predicted disability, age, sex, expected length of life, degree of medical dependency, quality of life, or other health conditions.

* * * * *

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

Subpart B—General Standards Related to the Establishment of an Exchange

■ 17. The authority citation for part 155 continues to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18033, 18041–18042, 18051, 18054, 18071, and 18081–18083.

■ 18. Amend § 155.120 by revising paragraph (c)(1)(ii) to read as follows:

§ 155.120 Non-interference with Federal law and non-discrimination standards.

* * * * *

(c) * * *

(1) * * *

(ii) Not discriminate based on race, color, national origin, disability, age, or sex.

* * * * *

■ 19. Amend § 155.220 by revising paragraph (j)(2)(i) to read as follows:

§ 155.220 Ability of States to permit agents and brokers to assist qualified individuals, qualified employers, or qualified employees enrolling in QHPs.

* * * * *

(j) * * *

(2) * * *

(i) Provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex;

* * * * *

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 20. The authority citation for part 156 continues to read as follows:

Authority: 5 U.S.C. 552; 42 U.S.C. 300jj–11 and 300jj–14.

■ 21. Amend § 156.200 by revising paragraph (e) to read as follows:

§ 156.200 QHP issuer participation standards.

* * * * *

(e) *Non-discrimination.* A QHP issuer must not, with respect to its QHP, discriminate on the basis of race, color, national origin, disability, age, or sex.

* * * * *

■ 22. Amend § 156.1230 by revising paragraph (b)(2) to read as follows:

§ 156.1230 Direct enrollment with the QHP issuer in a manner considered to be through the Exchange.

* * * * *

(b) * * *

(2) The QHP issuer must provide consumers with correct information, without omission of material fact, regarding the Federally-facilitated Exchanges, QHPs offered through the Federally-facilitated Exchanges, and insurance affordability programs, and refrain from marketing or conduct that is misleading (including by having a direct enrollment website that HHS determines could mislead a consumer into believing they are visiting *HealthCare.gov*), coercive, or discriminates based on race, color, national origin, disability, age, or sex.

Dated: May 20, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–11758 Filed 6–12–20; 4:15 pm]

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Parts III

Nuclear Regulatory Commission

10 CFR Part 170 and 171

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020; Final Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 170 and 171

[NRC–2017–0228; Docket No. PRM–171–1; NRC–2019–0084]

RIN 3150–AK10

Revision of Fee Schedules; Fee Recovery for Fiscal Year 2020

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending the licensing, inspection, special project, and annual fees charged to its applicants and licensees. These amendments are necessary to implement the Omnibus Budget Reconciliation Act of 1990, as amended (OBRA–90), which requires the NRC to recover approximately 90 percent of its annual budget through fees less certain amounts excluded from this fee-recovery requirement. To mitigate the financial impact and economic disruption caused by the COVID–19 Pandemic, the NRC has suspended billing of annual fees and fees for services for the 90-day period of April through June 2020. Deferred fees will be billed in July 2020.

DATES: This final rule is effective on August 18, 2020.

ADDRESSES: Please refer to Docket ID NRC–2017–0228 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2017–0228. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this final rule.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document. For the convenience of the reader, the ADAMS accession numbers and instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section of this document.

FOR FURTHER INFORMATION CONTACT: Anthony Rossi, Office of the Chief Financial Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–7341; email: *Anthony.Rossi@nrc.gov.*

SUPPLEMENTARY INFORMATION:

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I. Background; Statutory Authority

The NRC's fee regulations are primarily governed by two laws: (1) The Independent Offices Appropriation Act, 1952 (IOAA) (31 U.S.C. 9701), and (2) OBRA–90 (42 U.S.C. 2214). The IOAA generally authorizes and encourages Federal regulatory agencies to recover—to the fullest extent possible—costs attributable to services provided to identifiable recipients. Under OBRA–90, the NRC must recover approximately 90 percent of its budget authority for the fiscal year through fees. In FY 2020, the following appropriated amounts are excluded from the fee-recovery requirement: the development of a regulatory infrastructure for advanced nuclear reactor technologies, international activities, generic homeland security activities, Waste Incidental to Reprocessing, and Inspector General services for the Defense Nuclear Facilities Safety Board. Under OBRA–90, the NRC must use its IOAA authority first to collect service fees for NRC work that provides specific benefits to identifiable applicants and licensees (such as licensing work, inspections, and special projects).

The NRC's regulations in part 170 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Fees for Facilities, Materials, Import and Export Licenses, and Other Regulatory Services Under the Atomic Energy Act of 1954, as amended,'' authorize the fees the agency is required to collect from specific beneficiaries. Because the NRC's fee recovery under the IOAA (10 CFR part 170) will not equal 90 percent of the agency's budget authority for the fiscal year, the NRC also assesses ''annual fees'' under 10 CFR part 171, ''Annual Fees for Reactor Licenses and Fuel Cycle Licenses and Materials Licenses, Including Holders of Certificates of Compliance, Registrations, and Quality Assurance Program Approvals and Government Agencies Licensed by the NRC,'' to recover the remaining amount necessary to meet OBRA–90's fee-recovery requirement.

II. Petition for Rulemaking: (PRM–171–1; NRC–2019–0084)

On February 28, 2019, the NRC received a petition for rulemaking (ADAMS Accession No. ML19081A015) from Dr. Michael D. Meier, on behalf of the Southern Nuclear Operating Company (the petitioner). The petitioner requested that the NRC revise its regulations in 10 CFR part 171 related to the start of the assessment of annual fees for combined license (COL) holders licensed under 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' to align with the commencement of ''commercial operation'' of a licensed nuclear power plant. Specifically, the petitioner requested that the NRC revise the timing of when annual fees commence for COL holders to coincide with when a reactor achieves ''commercial operation,'' rather than when the NRC finds under § 52.103(g) that the acceptance criteria in the COL are met, after which the licensee can operate the facility. The NRC's regulations at § 171.15 currently require a 10 CFR part 52 COL holder to pay the annual fee upon the Commission's finding under § 52.103(g).

Public Comment on PRM–171–1

The NRC published a notice of docketing in the **Federal Register** (84 FR 26774; June 10, 2019), and requested public comment on the issues raised in PRM–171–1. The comment period closed on July 10, 2019. The NRC received five public comment submissions; these comments are available on *www.regulations.gov* under the docket ID NRC–2019–0084. Comments were submitted by Nuclear Energy Institute (NEI), several industry stakeholders, and one non-government organization, and all comments supported the petitioner's request. The NRC has carefully considered the public comments received on PRM–171–1, and

provides this summary and analysis of the issues raised by the commenters.

Comment: Two commenters recommended expanding the scope of the rulemaking to apply to reactors licensed under 10 CFR part 50 and small modular reactors with conforming changes to § 171.19(e)(1).

Response: The NRC agrees with this comment. A power reactor can submit an application under 10 CFR parts 50 and part 52; therefore, the NRC found it reasonable to apply this to change to both 10 CFR parts. Although this comment is beyond the scope of PRM–171–1, the NRC considered this subject in its rulemaking for annual fees under 10 CFR part 171 within the FY 2020 fee rule. The annual fee assessment for 10 CFR part 50 power reactor licensees and 10 CFR part 52 COL holders will begin on the date of the licensee's written notification of successful completion of power ascension testing. The NRC notes that 10 CFR part 50 includes non-power reactor licensees (*e.g.,* test reactors, research reactors) that the commenters did not separately distinguish. The NRC will consider, expanding the scope of 10 CFR part 171 to cover other 10 CFR part 50 licensees in a future rulemaking.

Comment: One commenter stated that, ''[t]his is a drop in the bucket of the overall costs associated with getting the plant online, but is a great first step in removing government from the equation and letting costs be determined by market forces . . . [licensees] could then be able to assess their costs and set prices with the thumb of government pressing less forcefully on the economic scales.''

Response: The NRC disagrees with the commenter's suggestion that fees should be determined by market forces. The NRC is required by statute, OBRA–90, as amended, to recover 90 percent of its budget in fees assessed to licensees, less portions specifically excluded from fee recovery or granted as fee-relief. Starting in FY 2021, the Nuclear Energy Innovation and Modernization Act (NEIMA) will increase the amount of the budget to be recovered to 100 percent, less portions specifically excluded or determined by the Commission as fee-relief. To maintain the cohesiveness of NRC's fee schedules, the Commission has maintained appropriate policies to comply with statutory requirements. The Commission previously addressed this issue in the statement of considerations for the FY 2002 final fee rule (67 FR 42611; June 24, 2002) that ''the NRC has not based its fees on licensees' economic status, market conditions, or the ability of licensees to pass through the costs to its customers.'' In keeping with the agency's independent, non-promotional regulatory role, the NRC's regulations deliberately are not tied to economic viability or profitability, nor has the NRC assessed fees based on these concepts.

No changes were made to the final rule as a result of these comments.

PRM–171–1 Consideration

The petitioner requested that the NRC consider this rule change within the context of its annual fee rulemaking to amend 10 CFR parts 170 and 171 to collect FY 2020 fees. The NRC published a notice in the **Federal Register** (84 FR 65032; November 26, 2019) that granted partial consideration by modifying the timing regarding the assessment of annual fees for 10 CFR part 52 COL holders in the FY 2020 fee rule.

Based on its review of PRM–171–1 and the public comments, the NRC is amending § 171.15(a) to modify the timing regarding the assessment of annual fees for 10 CFR part 52 COL holders. In addition, the NRC is amending the timing regarding the assessment of annual fees to apply to future 10 CFR part 50 power reactor licensees. See the FY 2020 Policy Changes section of this final rule for additional information on the amendment resulting from PRM–171–1.

III. Discussion

FY 2020 Fee Collection—Overview

The NRC is issuing this FY 2020 final fee rule based on Public Law (Pub. L.) 116–93—Further Consolidated Appropriations Act, 2020, (the enacted budget). The final fee rule reflects a budget authority in the amount of $855.6 million, a decrease of $55.4 million from FY 2019. As explained previously, certain portions of the NRC's total budget are excluded from OBRA–90's fee-recovery requirement. Based on the FY 2020 enacted budget, these exclusions total $46.6 million, consisting of $15.5 million for the development of a regulatory infrastructure for advanced nuclear reactor technologies; $14.5 million for international activities; $14.1 million for generic homeland security activities; $1.3 million for Waste Incidental to Reprocessing activities; and $1.2 million for Inspector General services for the Defense Nuclear Facilities Safety Board. Additionally, OBRA–90 requires the NRC to recover approximately 90 percent of the remaining budget authority for the fiscal year—10 percent of the remaining budget authority need not be recovered through fees. The NRC refers to the activities included in this 10-percent as ''fee-relief'' activities.

After accounting for the fee-recovery exclusions, the fee-relief activities, and net billing adjustments (*i.e.,* the sum of unpaid current year invoices (estimated) minus payments for prior year invoices, and current year collections made for the termination of one operating power reactor), the NRC must recover approximately $728.1 million in fees in FY 2020. Of this amount, the NRC estimates that $220.2 million will be recovered through 10 CFR part 170 service fees and approximately $507.9 million will be recovered through 10 CFR part 171 annual fees. Table I summarizes the fee-recovery amounts for the FY 2020 final fee rule using the enacted budget, and taking into account excluded activities, fee-relief activities, and net billing adjustments. For all information presented in the following tables, individual values may not sum to totals due to rounding. Please see the work papers (ADAMS Accession No. ML20142A363) for actual amounts.

Public Law 116–93—Further Consolidated Appropriations Act, 2020, also includes direction for the NRC to use $40.0 million in prior year unobligated carryover funds. The use of carryover funds allows the NRC to accomplish the work needed without additional costs to licensees because, consistent with the requirements of OBRA–90, fees are calculated based on the budget authority enacted for the current fiscal year and not carryover funds.

The Commission has authorized a suspension of billing of 10 CFR part 171 annual fees, and 10 CFR part 170 fees for services, for the 90-day period of April through June 2020. This action includes all annual fees that would have come due during the 90-day period and fees for services that would have been billed in April for services rendered January through March 2020. These deferred fees will be billed in July 2020. The NRC took this action to help mitigate the financial impacts and economic disruptions caused by the COVID–19 Pandemic.

TABLE I—BUDGET AND FEE RECOVERY AMOUNTS [1]

[Dollars in millions]

	FY 2019 final rule	FY 2020 final rule
Total Budget Authority	$911.0	$855.6
Less Excluded Fee Items	−43.4	−46.6
Balance	867.6	808.9
Fee Recovery Percent	90	90
Total Amount to be Recovered	780.8	728.1
Less Estimated Amount to be Recovered through 10 CFR Part 170 Fees	−252.1	−220.2
Estimated Amount to be Recovered through 10 CFR Part 171 Fees	528.7	507.9
10 CFR Part 171 Billing Adjustments		
Unpaid Current Year Invoices (estimated)	4.5	4.5
Less Current Year Collections from a Terminated Reactor—Indian Point Nuclear Generating, Unit 2	0.0	−2.7
Less Payments Received in Current Year for Previous Year Invoices (estimated)	−2.8	−1.7
Adjusted 10 CFR Part 171 Annual Fee Collections Required	$530.5	$507.9

FY 2020 Fee Collection—Professional Hourly Rate

The NRC uses a professional hourly rate to assess fees under 10 CFR part 170 for specific services it provides. The professional hourly rate also helps determine flat fees (which are used for the review of certain types of license applications). This rate would be applicable to all activities for which fees are assessed under §§ 170.21 and 170.31.

The NRC's professional hourly rate is derived by adding budgeted resources for: (1) Mission-direct program salaries and benefits, (2) mission-indirect program support, and (3) agency support (corporate support and the Inspector General). The NRC then subtracts certain offsetting receipts and divides this total by the mission-direct full-time equivalent (FTE) converted to hours (the mission-direct FTE converted to hours is the product of the mission-direct FTE multiplied by the estimated annual mission-direct FTE productive hours). The only budgeted resources excluded from the professional hourly rate are those for mission-direct contract resources, which are generally billed to licensees separately. The following shows the professional hourly rate calculation:

$$\text{Professional Hourly Rate} = \frac{\text{Budgeted Resources}}{\text{Mission-Direct FTE Converted to Hours}} = \frac{\$716.9\text{ million}}{1{,}701 \times 1{,}510} = \$279$$

For FY 2020, the NRC is increasing the professional hourly rate from $278 to $279. The FY 2019 professional hourly rate was $278, as discussed in the statement of considerations for both the FY 2019 proposed and final fee rules. During the development of the FY 2020 proposed fee rule, the NRC staff identified that the amendatory language for 10 CFR 170.20, ''Average cost per professional staff-hour,'' inadvertently was not updated in FY 2019 to reflect the professional hourly rate of $278, which is why the regulatory language in this final rule continues to show the FY 2018 professional hourly rate of $275. The NRC has updated the statement of considerations for the FY 2020 fee rule and the amendatory language to reflect the proposed FY 2020 professional hourly rate of $279.

The slight increase in the FY 2020 professional hourly rate is primarily due to the anticipated decline in number of mission-direct FTE compared to FY 2019. The hourly rate is inversely related to the mission-direct FTE amount, therefore as the number of mission-direct FTE decrease the hourly rate can increase. The number of mission-direct FTE is expected to decline by 109, primarily due to: (1) The anticipated completion of the NuScale small modular reactor (SMR) design certification review; (2) a reduction in workload associated with the Clinch River Nuclear Site (Clinch River) early site permit; (3) the power reactor plant closures of Oyster Creek Nuclear Generating Station (Oyster Creek), Pilgrim Nuclear Power Station (Pilgrim), Three Mile Island (TMI) Nuclear Generating Station, Unit 1 (TMI 1); (4) the expected decline in submissions for fuel facility license renewal applications; (5) the decrease in the number of fuel facility license amendments; (6) the termination of the Mixed-Oxide (MOX) Fuel Fabrication Facility construction authorization; and (7) efficiencies gained within the fuel facilities inspection program. The FY 2020 estimate for annual mission-direct FTE productive hours is 1,510 hours, which is unchanged from FY 2019. This estimate, also referred to as the productive hours assumption, reflects the average number of hours that a mission-direct employee spends on mission-direct work in a given year. This estimate therefore excludes hours charged to annual leave, sick leave, holidays, training, and general administrative tasks. Table II shows the professional hourly rate calculation methodology. The FY 2019 amounts are provided for comparison purposes.

[1] For each table, numbers may not add due to rounding.

TABLE II—PROFESSIONAL HOURLY RATE CALCULATION

[Dollars in millions, except as noted]

	FY 2019 final rule	FY 2020 final rule
Mission-Direct Program Salaries & Benefits	$334.7	$314.6
Mission-Indirect Program Support	$120.6	$110.8
Agency Support (Corporate Support and the IG)	$304.5	$291.5
Subtotal	$759.8	$716.9
Less Offsetting Receipts [2]	$0.0	$0.0
Total Budgeted Resources Included in Professional Hourly Rate	$759.8	$716.9
Mission-Direct FTE (Whole numbers)	1,810	1,701
Annual Mission-Direct FTE Productive Hours (Whole numbers)	1,510	1,510
Mission-Direct FTE Converted to Hours (Mission-Direct FTE multiplied by Annual Mission-Direct FTE Productive Hours) (In Millions)	2,733,100	2,568,510
Professional Hourly Rate (Total Budgeted Resources Included in Professional Hourly Rate Divided by Mission-Direct FTE Converted to Hours) (Whole Numbers)	$278	$279

FY 2020 Fee Collection—Flat Application Fee Changes

The NRC is amending the flat application fees it charges in its schedule of fees in §§ 170.21 and 170.31 to reflect the revised professional hourly rate of $279. The NRC charges these fees to applicants for materials licenses and other regulatory services, as well as holders of materials licenses. The NRC calculates these flat fees by multiplying the average professional staff hours needed to process the licensing actions by the professional hourly rate for FY 2020. As part of its calculations, the NRC analyzes the actual hours spent performing licensing actions and estimates the five-year average professional staff hours that are needed to process licensing actions as part of its biennial review of fees, which is required by Section 205(a) of the Chief Financial Officers Act of 1990 (31 U.S.C. 902(a)(8)). The NRC performed this review in FY 2019 and will perform this review again in FY 2021. The higher professional hourly rate of $279 is the primary reason for the increase in application fees. Please see the work papers for more detail.

The NRC rounds these flat fees in such a way that ensures both convenience for its stakeholders and that any rounding effects are minimal. Accordingly, fees under $1,000 are rounded to the nearest $10, fees between $1,000 and $100,000 are rounded to the nearest $100, and fees greater than $100,000 are rounded to the nearest $1,000.

The licensing flat fees are applicable for certain materials licensing actions (see fee categories 1.C. through 1.D., 2.B. through 2.F., 3.A. through 3.S., 4.B. through 5.A., 6.A. through 9.D., 10.B., 15.A. through 15.L., 15.R., and 16 of § 170.31). Because the enacted budget excludes international activities from the fee-recoverable budget, import and exporting licensing activities, funded through the international activities product line (see fee categories K.1. through K.5. of § 170.21 and fee categories 15.A. through 15.R. of § 170.31) will not be charged flat fees under this final rule. Applications filed on or after the effective date of the FY 2020 final fee rule will be subject to the revised fees in this final rule.

FY 2020 Fee Collection—Fee-Relief and Low-Level Waste Surcharge

As previously noted, OBRA–90 requires the NRC to recover approximately 90 percent of its annual budget authority for the fiscal year. The NRC applies the remaining 10 percent that is not recovered to offset certain budgeted activities—see Table III for a full listing of these ''fee-relief'' activities. If the amount budgeted for these fee-relief activities is greater or less than 10 percent of the NRC's annual budget authority (less the fee-recovery exclusions), then the NRC applies a fee adjustment (either an increase or decrease) to all licensees' annual fees, based on the percentage of the NRC's budgeted resources allocated to each fee class.

In FY 2020, the amount budgeted for fee-relief activities is less than the 10 percent threshold. Therefore, the NRC is assessing a fee-relief credit that decreases all licensees' annual fees. Table III summarizes the fee-relief activities budgeted for FY 2020. The FY 2019 amounts are provided for comparison purposes.

TABLE III—FEE-RELIEF ACTIVITIES

[Dollars in millions]

Fee-relief activities	FY 2019 budgeted resources final rule	FY 2020 budgeted resources final rule
1. Activities not attributable to an existing NRC licensee or class of licensees:.		
a. Agreement State oversight	$11.5	$11.9
b. Scholarships and Fellowships	15.0	16.0
c. Medical Isotope Production Infrastructure	5.4	3.1

[2] The fees collected by the NRC for Freedom of Information Act (FOIA) services and indemnity fees (financial protection required of all licensees for public liability claims at 10 CFR part 140) are subtracted from the budgeted resources amount when calculating the 10 CFR part 170 professional hourly rate, per the guidance in the Office of Management and Budget (OMB) Circular A–25, *User Charges.* The budgeted resources for FOIA activities are allocated under the product for Information Services within the Corporate Support business line. The budgeted resources for indemnity activities are allocated under the Licensing Actions and Research and Test Reactors products within the Operating Reactors business line.

TABLE III—FEE-RELIEF ACTIVITIES—Continued

[Dollars in millions]

Fee-relief activities	FY 2019 budgeted resources final rule	FY 2020 budgeted resources final rule
2. Activities not assessed under 10 CFR part 170 service fees or 10 CFR part 171 annual fees based on existing law or Commission policy:.		
a. Fee exemption for nonprofit educational institutions	9.1	9.0
b. Costs not recovered from small entities under 10 CFR 171.16(c)	8.0	7.6
c. Regulatory support to Agreement States	14.7	12.2
d. Generic decommissioning/reclamation (not related to the power reactor and spent fuel storage fee classes)	12.9	12.0
e. Uranium recovery program and unregistered general licensees	7.2	5.2
f. Potential Department of Defense remediation program Memorandum of Understanding activities	2.1	1.7
g. Non-military radium sites	1.1	0.8
Total fee-relief activities	87.0	79.6
Less 10 percent of the NRC's total FY budget (less the fee recovery exclusions)	−86.8	−80.9
Fee-Relief Adjustment to be Allocated to All Licensees' Annual Fees	0.3	−1.3

Table IV shows how the NRC allocates the $1.3 million fee-relief credit to each licensee fee class. In addition to the fee-relief credit, the NRC assesses a generic low-level waste (LLW) surcharge of $3.4 million. Disposal of LLW occurs at commercially operated LLW disposal facilities that are licensed by either the NRC or an Agreement State. Four existing LLW disposal facilities in the United States accept various types of LLW. All are located in Agreement States and, therefore, are regulated by an Agreement State, rather than the NRC. The NRC allocates this surcharge to its licensees based on data available in the U.S. Department of Energy's (DOE) Manifest Information Management System (MIMS). This database contains information on total LLW volumes disposed by four generator classes: Academic, industrial, medical, and utility. The ratio of waste volumes disposed by these generator classes to total LLW volumes disposed over a period of time is used to estimate the portion of this surcharge that will be allocated to the power reactors, fuel facilities, and materials fee classes. The materials portion is adjusted to account for the large percentage of materials licensees that are licensed by the Agreement States rather than the NRC.

The LLW surcharge amounts have changed since publication of the proposed rule. The DOE updated MIMS with 2020 data; as a result of the update, the LLW surcharge for operating power reactors fee class increased from $2.8 million to $3.0 million and the LLW surcharge decreased from $0.4 million to $0.3 million for fuel facilities; while the LLW surcharge remained stable at $0.1 million for materials users.

Table IV shows the LLW surcharge and fee-relief credit and allocation across the various fee classes.

TABLE IV—ALLOCATION OF FEE-RELIEF ADJUSTMENT AND LLW SURCHARGE, FY 2020

[Dollars in millions]

	LLW surcharge		Fee-relief adjustment		Total
	Percent	$	Percent	$	$
Operating Power Reactors	87.4	2.997	86.4	−1.152	1.845
Spent Fuel Storage/Reactor Decommissioning	0.0	0.000	5.4	−0.071	−0.071
Research and Test Reactors	0.0	0.000	0.5	−0.006	−0.006
Fuel Facilities	10.0	0.343	3.4	−0.045	0.298
Materials Users	2.6	0.089	3.8	−0.051	0.039
Transportation	0.0	0.000	0.5	−0.007	−0.007
Rare Earth Facilities	0.0	0.000	0.0	0.0	0.0
Uranium Recovery	0.0	0.000	0.1	−0.001	−0.001
Total	100.0	3.430	100.0	−1.334	2.096

FY 2020 Fee Collection—Revised Annual Fees

In accordance with SECY–05–0164, ''Annual Fee Calculation Method'' (ADAMS Accession No. ML052580332), the NRC rebaselines its annual fees every year. ''Rebaselining'' entails analyzing the budget in detail and then allocating the budgeted costs to various classes or subclasses of licensees. It also includes updating the number of NRC licensees in its fee calculation methodology.

The NRC revised its annual fees in §§ 171.15 and 171.16 to recover approximately 90 percent of the NRC's FY 2020 enacted budget (less the fee-recovery exclusions and the estimated amount to be recovered through 10 CFR part 170 fees). The total estimated 10 CFR part 170 collections for this final rule are $220.2 million, a decrease of $31.9 million from the FY 2019 final rule (see the specific fee class sections for a discussion of this decrease). The NRC, therefore, must recover $507.9 million through annual fees from its licensees, which is a decrease of $22.6 million from the FY 2019 final rule.

Table V shows the final rebaselined fees for FY 2020 for a representative list of licensee categories. The FY 2019 amounts are provided for comparison purposes.

TABLE V—REBASELINED ANNUAL FEES

[Actual dollars]

Class/category of licenses	FY 2019 final annual fee	FY 2020 final annual fee
Operating Power Reactors	$4,669,000	$4,621,000
+ Spent Fuel Storage/Reactor Decommissioning	152,000	188,000
Total, Combined Fee	4,821,000	4,809,000
Spent Fuel Storage/Reactor Decommissioning	152,000	188,000
Research and Test Reactors (Non-power Reactors)	82,400	81,300
High Enriched Uranium Fuel Facility (Category 1.A.(1)(a))	6,675,000	5,067,000
Low Enriched Uranium Fuel Facility (Category 1.A.(1)(b))	2,262,000	1,717,000
Uranium Enrichment (Category 1.E)	3,513,000	2,208,000
UF_6 Conversion and Deconversion Facility (Category 2.A.(1)	1,417,000	510,000
Basic *In Situ* Recovery Facilities (Category 2.A.(2)(b))	49,200	49,200
Typical Users: Radiographers (Category 3O)	30,200	29,900
All Other Specific Byproduct Material Licensees (Category 3P)	10,000	9,700
Medical Other (Category 7C)	15,300	14,800
Device/Product Safety Evaluation—Broad (Category 9A)	14,300	13,800

The work papers that support this final rule show in detail how the NRC allocates the budgeted resources for each class of licensees and calculates the fees.

Paragraphs a. through h. of this section describe the budgeted resources allocated to each class of licensees and the calculations of the rebaselined fees. For more information about detailed fee calculations for each class, please consult the accompanying work papers for this final rule.

a. Operating Power Reactors

The NRC will collect $439.0 million in annual fees from the operating power reactors fee class in FY 2020, as shown in Table VI. The FY 2019 fees are shown for comparison purposes.

TABLE VI—ANNUAL FEE SUMMARY CALCULATIONS FOR OPERATING POWER REACTORS

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Total budgeted resources	$670.2	$623.9
Less estimated 10 CFR part 170 receipts	−217.7	−186.7
Net 10 CFR part 171 resources	452.5	437.2
Allocated generic transportation	0.2	0.2
Fee-relief adjustment/LLW surcharge	3.4	1.9
Billing adjustment	1.5	2.4
Adjustment: Estimated current year collections from terminated reactor (Indian Point Unit 2)	0.0	−2.7
Total required annual fee recovery	457.6	439.0
Total operating reactors	98	95
Annual fee per reactor	4.669	4.621

In comparison to FY 2019, the resources budgeted for the operating power reactors fee class decreased by $46.3 million due to a decline in FTE that includes, but is not limited to, the following: (1) The closures of Oyster Creek, Pilgrim, and TMI 1; (2) the delay in receipt of the Utah Associated Municipal Power System SMR application; (3) withdrawal of the Blue Castle large light-water reactor application; (4) delay in the submittal of the Advanced Passive 1000 design certification renewal application; (5) the near completion of Phase 4 of the NuScale SMR design certification review; (6) the completion of the Clinch River early site permit technical review; (7) a reduction in license amendment requests for the Vogtle Electric Generating Plant; (8) expected delays in construction and operating license application review activities for Bellefonte Nuclear Station, Units 1 and 2; (9) efficiencies gained from the merger of the Office of Nuclear Reactor Regulation and the Office of New Reactors; and (10) the completion of flooding and integrated assessment work related to lessons learned from the accident at Fukushima Dai-ichi in Japan. In addition, the total budgeted resources decreased due to the utilization of prior year unobligated carryover funding.

The 10 CFR part 170 estimated billings declined primarily due to the following: (1) Decreases in both licensing actions and inspections resulting from the shutdown of the Pilgrim and TMI 1 reactors at the end of FY 2019; (2) the shutdown of Indian Point Nuclear Generating, Unit 2 (Indian Point 2) during FY 2020; (3) the completion of the Advanced Power Reactor-1400 design certification, issued in FY 2019 for Korea Hydro and Nuclear Power Co., LTD.; and (4) the completion

of the NuScale SMR design certification review and the completion of the Clinch River early site permit technical review. This decrease in the 10 CFR part 170 estimated billings is partially offset by increased work to support the Oklo Power LLC COL application for the Aurora micro reactor.

The recoverable budgeted costs are divided equally among the 95 licensed operating power reactors, resulting in an annual fee of $4,621,000 per reactor. As part of the final annual fee, an approximate $2,725,000 current year collection adjustment was included in the operating power reactors calculation due to the shutdown of Indian Point 2 as shown in Table VI. Additionally, each licensed operating power reactor is assessed the FY 2020 spent fuel storage/reactor decommissioning annual fee of $188,000 (see Table VII and the discussion that follows). The combined FY 2020 annual fee for each operating power reactor is $4,809,000.

In FY 2016, the NRC amended its licensing, inspection, and annual fee regulations to establish a variable annual fee structure for light-water SMRs (81 FR 32617). Under the variable annual fee structure, an SMR's annual fee would be calculated as a function of its licensed thermal power rating. Currently, there are no operating SMRs; therefore, the NRC will not assess an annual fee in FY 2020 for this type of licensee.

b. Spent Fuel Storage/Reactor Decommissioning

The NRC will collect $22.9 million in annual fees from 10 CFR part 50 power reactors, and from 10 CFR part 72 licensees that do not hold a 10 CFR part 50 license, to recover the budgeted costs for the spent fuel storage/reactor decommissioning fee class, as shown in Table VII. The FY 2019 fees are shown for comparison purposes.

TABLE VII—ANNUAL FEE SUMMARY CALCULATIONS FOR SPENT FUEL STORAGE/REACTOR DECOMMISSIONING

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Total budgeted resources	$35.6	$37.9
Less estimated 10 CFR part 170 receipts	−17.8	−15.9
Net 10 CFR part 171 resources	17.8	22.1
Allocated generic transportation costs	0.7	0.8
Fee-relief adjustment	0.0	−0.1
Billing adjustments	0.1	0.1
Total required annual fee recovery	18.6	22.9
Total spent fuel storage facilities	122	122
Annual fee per facility	0.152	0.188

In comparison to FY 2019, the resources budgeted for the spent fuel storage/reactor decommissioning fee class increased to support the following: (1) The review of new storage license renewal applications for Holtec HI-Storm 100, TN–32, TN–68, NAC UMS, NAC–MPC, Westinghouse W–150, and GE-Hitachi Morris Operation, which are expected in FY 2020; (2) inspection activities related to site preparation for decommissioning of TMI 1, Pilgrim, Oyster Creek, and Indian Point; and (3) fuel performance research. In addition, budgeted resources for contract costs increased due to a reduction in the utilization of prior year unobligated carryover funding compared to FY 2019.

The 10 CFR part 170 estimated billings for FY 2020 decreased primarily due to the following: (1) The completion of certain follow-up inspections and enforcement activities for San Onofre Nuclear Generating Station; (2) a reduction in the staff's review of the Holtec HI–STORE consolidated interim storage facility application due to the extension of the public comment period on the draft environmental impact statement until the end of July; (3) the completion of the Oyster Creek license transfer application and other licensing activities; and (4) the completion of amendments, partial site release requests, and final status surveys at multiple sites. This decrease in the 10 CFR part 170 estimated billings is partially offset by increased work to support the following: (1) License renewals, amendments, and certificates of compliance (CoCs) at multiple sites, and (2) the staff's review of the Indian Point 1 and TMI 2 license transfer applications. The overall decrease in 10 CFR part 170 estimated billings resulted in an increase in annual fees under 10 CFR part 171.

In addition, the annual fee increased due to the rise in generic transportation costs as a result of two new CoCs in FY 2020.

The required annual fee recovery amount is divided equally among 122 licensees, resulting in an FY 2020 annual fee of $188,000 per licensee.

c. Fuel Facilities

The NRC will collect $18.0 million in annual fees from the fuel facilities fee class, as shown in Table VIII. The FY 2019 fees are shown for comparison purposes.

TABLE VIII—ANNUAL FEE SUMMARY CALCULATIONS FOR FUEL FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Total budgeted resources	$30.0	$23.2
Less estimated 10 CFR part 170 receipts	−7.3	−6.8
Net 10 CFR part 171 resources	22.7	16.5
Allocated generic transportation	1.2	1.1
Fee-relief adjustment/LLW surcharge	0.5	0.3

TABLE VIII—ANNUAL FEE SUMMARY CALCULATIONS FOR FUEL FACILITIES—Continued

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Billing adjustments	0.1	0.1
Total remaining required annual fee recovery	24.5	18.0

In comparison to FY 2019, the resources budgeted for the fuel facilities fee class decreased primarily due to the following: (1) An expected decline in submissions for license renewal applications; (2) the decrease in the number of license amendments; (3) the termination of the MOX Fuel Fabrication Facility construction authorization; (4) efficiencies gained because of changes to the Fuel Facilities Inspection Program and workload projections; and (5) the utilization of prior year unobligated carryover funding in FY 2020. The 10 CFR part 170 estimated billings decreased as a result of the withdrawal of the license application for the MOX Fuel Fabrication Facility.

The NRC will continue allocating annual fees to individual fuel facility licensees based on the effort/fee determination matrix developed in the FY 1999 final fee rule (64 FR 31447; June 10, 1999). To briefly recap, the matrix groups licensees within this fee class into various fee categories. The matrix lists processes conducted at licensed sites and assigns effort factors for the safety and safeguards activities associated with each process (these effort levels are reflected in Table IX). The annual fees are then distributed across the fee class based on the regulatory effort assigned by the matrix. The effort factors in the matrix represent regulatory effort that is not recovered through 10 CFR part 170 fees (*e.g.,* rulemaking, guidance). Regulatory effort for activities that are subject to 10 CFR part 170 fees, such as the number of inspections, is not applicable to the effort factor. In FY 2020, the safety and safeguard factors in the effort factors matrix for Liquid Uranium Hexafluoride (UF6) processes at Uranium Conversion facilities have been reduced from 5 (moderate effort) to 0 (no effort). Currently, there is one uranium conversion facility and it is in a ''ready-idle'' status with no processing operations, and the NRC believes that it will remain in ''ready-idle'' position for FY 2020 and will need to be reassessed on an annual basis. Regulatory oversight of processing operations have been curtailed while the operations are in a ''ready-idle'' status. Therefore, the Liquid UF6 processing at Uranium Conversion facilities safety and safeguards factors in the effort factors matrix have been reduced from a 5 to 0 to reflect the curtailed regulatory oversight of these processes.

TABLE IX—EFFORT FACTORS FOR FUEL FACILITIES, FY 2020

Facility type (fee category)	Number of facilities	Effort factors	
		Safety	Safeguards
High-Enriched Uranium Fuel (1.A.(1)(a))	2	88	91
Low-Enriched Uranium Fuel (1.A.(1)(b))	3	70	21
Limited Operations (1.A.(2)(a))	0	0	0
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	0	0	0
Hot Cell (and others) (1.A.(2)(c))	0	0	0
Uranium Enrichment (1.E.)	1	16	23
UF_6 Conversion and Deconversion (2.A.(1))	1	7	2

In FY 2020, the total remaining amount of annual fees to be recovered, $18.0 million, is comprised of safety activities, safeguards activities, and the fee-relief adjustment/LLW surcharge. For FY 2020, the total budgeted resources to be recovered as annual fees for safety activities are $10.1 million. To calculate the annual fee, the NRC allocates this amount to each fee category based on its percentage of the total regulatory effort for safety activities. Similarly, the NRC allocates the budgeted resources to be recovered as annual fees for safeguards activities, $7.6 million, to each fee category based on its percentage of the total regulatory effort for safeguards activities. Finally, the fuel facilities fee class portion of the fee-relief adjustment/LLW surcharge—$0.3 million—is allocated to each fee category based on its percentage of the total regulatory effort for both safety and safeguards activities. The annual fee per licensee is then calculated by dividing the total allocated budgeted resources for the fee category by the number of licensees in that fee category. The fee for each facility is summarized in Table X.

TABLE X—ANNUAL FEES FOR FUEL FACILITIES

[Actual dollars]

Facility type (fee category)	FY 2019 final annual fee	FY 2020 final annual fee
High-Enriched Uranium Fuel (1.A.(1)(a))	$6,675,000	$5,067,000
Low-Enriched Uranium Fuel (1.A.(1)(b))	2,262,000	1,717,000
Gas Centrifuge Enrichment Demonstration (1.A.(2)(b))	N/A	N/A
Hot Cell (and others) (1.A.(2)(c))	N/A	N/A

TABLE X—ANNUAL FEES FOR FUEL FACILITIES—Continued

[Actual dollars]

Facility type (fee category)	FY 2019 final annual fee	FY 2020 final annual fee
Uranium Enrichment (1.E.)	2,909,000	2,208,000
UF_6 Conversion and Deconversion (2.A.(1))	1,417,000	510,000

d. Uranium Recovery Facilities

The NRC will collect $0.2 million in annual fees from the uranium recovery facilities fee class, which is stable compared to FY 2019, as shown in Table XI. The FY 2019 fees are shown for comparison purposes.

TABLE XI—ANNUAL FEE SUMMARY CALCULATIONS FOR URANIUM RECOVERY FACILITIES

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Total budgeted resources	$1.0	$0.6
Less estimated 10 CFR part 170 receipts	−0.8	−0.4
Net 10 CFR part 171 resources	0.2	0.2
Allocated generic transportation	N/A	N/A
Fee-relief adjustment	0.0	0.0
Billing adjustments	0.0	0.0
Total required annual fee recovery	$0.2	$0.2

In comparison to FY 2019, the budgeted resources and 10 CFR part 170 estimated billings for the uranium recovery fee class decreased due to the expected reduction in support for adjudicatory actions, the uncertainty associated with the construction of the NuFuels Crownpoint site in NM and Powertech Dewey Burdock site in SD, and Cameco's continuation to cease U.S. uranium recovery operations at its Crow Butte facility in Crawford, NE. Budgeted resources also decreased to include additional uranium recovery resources in the fee-relief category, ''*In Situ* leach rulemaking and unregistered general licenses,'' in order to ensure the equitability and the stability of annual fees.

The NRC regulates DOE's Title I and Title II activities under Uranium Mill Tailings Radiation Control Act (UMTRCA) [3] and the annual fee assessed to DOE includes the costs specifically budgeted for the NRC's UMTRCA Title I and II activities, as well as 10 percent of the remaining budgeted costs for this fee class. The NRC described the overall methodology for determining fees for UMTRCA in the FY 2002 fee rule (67 FR 42625; June 24, 2002), and the NRC continues to use this methodology. The DOE's UMTRCA annual fee decreased compared to FY 2019 due to an increase in the 10 CFR part 170 estimated billings for processing groundwater corrective action plans site reviews, the anticipated workload increases at various DOE UMTRCA sites, and the fee-relief credit. The NRC assesses the remaining 90 percent of its budgeted costs to the remaining licensee in this fee class, as described in the work papers. This is reflected in Table XII:

TABLE XII—COSTS RECOVERED THROUGH ANNUAL FEES; URANIUM RECOVERY FEE CLASS

[Actual dollars]

Summary of costs	FY 2019 final annual fee	FY 2020 final annual fee
DOE Annual Fee Amount (UMTRCA Title I and Title II) General Licenses:		
UMTRCA Title I and Title II budgeted costs less 10 CFR part 170 receipts	$115,888	$114,577
10 percent of generic/other uranium recovery budgeted costs	5,431	5,573
10 percent of uranium recovery fee-relief adjustment	33	−107
Total Annual Fee Amount for DOE (rounded)	121,000	120,000
Annual Fee Amount for Other Uranium Recovery Licenses:		
90 percent of generic/other uranium recovery budgeted costs less the amounts specifically budgeted for UMTRCA Title I and Title II activities	48,880	50,153
90 percent of uranium recovery fee-relief adjustment	294	−959
Total Annual Fee Amount for Other Uranium Recovery Licenses	49,173	49,194

[3] The Congress established the two programs, Title I and Title II, under UMTRCA to protect the public and the environment from hazards associated with uranium milling. The UMTRCA Title I program is for remedial action at abandoned mill tailings sites where tailings resulted largely from production of uranium for weapons programs. The NRC also regulates DOE's UMTRCA Title II program, which is directed toward uranium mill sites licensed by the NRC or Agreement States in or after 1978.

Further, for any non-DOE licensees, the NRC will continue using a matrix to determine the effort levels associated with conducting generic regulatory actions for the different licensees in the uranium recovery fee class; this is similar to the NRC's approach for fuel facilities, described previously. The matrix methodology for uranium recovery licensees first identifies the licensee categories included within this fee class (excluding DOE). These categories are: conventional uranium mills and heap leach facilities, uranium *in situ* recovery (ISR) and resin ISR facilities, mill tailings disposal facilities, and uranium water treatment facilities. The matrix identifies the types of operating activities that support and benefit these licensees, along with each activity's relative weight (for more information, see the work papers). Currently, there is only one remaining non-DOE licensee which is a Basic *In Situ* Recovery facility. Table XIII displays the benefit factors for the non-DOE licensee in that fee category:

TABLE XIII—BENEFIT FACTORS FOR URANIUM RECOVERY LICENSES

Fee category	Number of licensees	Benefit factor per licensee	Total value	Benefit factor percent total
Conventional and Heap Leach mills (2.A.(2)(a))	0	0	0	0
Basic *In Situ* Recovery facilities (2.A.(2)(b))	1	190	190	100.0
Expanded *In Situ* Recovery facilities (2.A.(2)(c))	0	0	0	0
Section 11e.(2) disposal incidental to existing tailings sites (2.A.(4))	0	0	0	0
Total	1	190	190	100.0

The annual fee for the remaining non-DOE licensee is calculated by allocating 100 percent of the budgeted resources, as summarized in Table XIV.

TABLE XIV—ANNUAL FEES FOR URANIUM RECOVERY LICENSEES

(Other than DOE)

[Actual dollars]

Facility type (fee category)	FY 2019 final annual fee	FY 2020 final annual fee
Conventional and Heap Leach mills (2.A.(2)(a))	N/A	N/A
Basic *In Situ* Recovery facilities (2.A.(2)(b))	$49,200	$49,200
Expanded *In Situ* Recovery facilities (2.A.(2)(c))	N/A	N/A
Section 11e.(2) disposal incidental to existing tailings sites (2.A.(4))	N/A	N/A

e. Research and Test Reactors (non-power reactors)

The NRC will collect $0.325 million in annual fees from the research and test reactor licensee class, as shown in Table XV. The FY 2019 fees are shown for comparison purposes.

TABLE XV—ANNUAL FEE SUMMARY CALCULATIONS FOR RESEARCH AND TEST REACTORS

[Actual dollars]

Summary fee calculations	FY 2019 final	FY 2020 final
Total budgeted resources	$834,280	$3,317,830
Less estimated 10 CFR part 170 receipts	−538,000	−3,030,000
Net 10 CFR part 171 resources	296,280	287,830
Allocated generic transportation	30,971	30,713
Fee-relief adjustment	284	−6,183
Billing adjustments	1,901	12,980
Total required annual fee recovery	329,436	325,341
Total research and test reactors	4	4
Total annual fee per reactor (rounded)	82,400	81,300

In comparison to FY 2019, the budgeted resources for the research and test reactors increased primarily within the medical isotope production facilities due to the submittal of the SHINE Medical Technologies, Inc. (SHINE) operating license application.

The 10 CFR part 170 estimated billings also increased due to the following: (1) The submittal of SHINE's operating license application for a medical production facility; (2) the review of Aerotest Operations, Inc.'s request to amend its operating license to possession only; and (3) reviews of the

National Institute of Standards and Technology and GE-Hitachi Nuclear Energy America's, LLC Nuclear Test Reactor license amendments for security plan reviews.

The annual fee-recovery amount is divided equally among the four research and test reactors subject to annual fees and results in an FY 2020 annual fee of $81,300 for each licensee.

f. Rare Earth

The NRC has not allocated any budgeted resources to this fee class; therefore, the NRC is not assessing an annual fee for this fee class in FY 2020.

g. Materials Users

The NRC will collect $34.1 million in annual fees from materials users licensed under 10 CFR parts 30, 40, and 70, as shown in Table XVI. The FY 2019 fees changes are shown for comparison purposes.

TABLE XVI—ANNUAL FEE SUMMARY CALCULATIONS FOR MATERIALS USERS

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Total budgeted resources for licensees not regulated by Agreement States	$36.0	$33.7
Less estimated 10 CFR part 170 receipts	−1.1	−1.0
Net 10 CFR part 171 resources	35.0	32.8
Allocated generic transportation	1.2	1.2
Fee-relief adjustment/LLW surcharge	0.1	0.0
Billing adjustments	0.1	0.1
Total required annual fee recovery	36.4	34.1

The formula for calculating 10 CFR part 171 annual fees for the various categories of materials users is described in detail in the work papers. Generally, the calculation results in a single annual fee that includes 10 CFR part 170 costs, such as amendments, renewals, inspections, and other licensing actions specific to individual fee categories.

The total annual fee recovery of $34.1 million for FY 2020 shown in Table XVI consists of $26.6 million for general costs and $7.5 million for inspection costs. To equitably and fairly allocate the $34.1 million required to be collected among approximately 2,500 diverse materials users licensees, the NRC continues to calculate the annual fees for each fee category within this class based on the 10 CFR part 170 application fees and estimated inspection costs for each fee category. Because the application fees and inspection costs are indicative of the complexity of the materials license, this approach provides a proxy for allocating the generic and other regulatory costs to the diverse fee categories. This fee-calculation method also considers the inspection frequency (priority), which is indicative of the safety risk and resulting regulatory costs associated with the categories of licenses.

The NRC will decrease annual fees for licensees in this fee class in FY 2020 due to the following: (1) The utilization of prior year unobligated carryover funding in FY 2020; (2) reductions of regional resources for the Nuclear Regulatory Apprenticeship Network (formerly the Nuclear Safety Professional Development Program); (3) budget estimates that are better aligned with projected workload; and (4) a decline in the generic transportation costs for materials users. The decline in annual fees for materials users is offset by a reduction of materials users licensees from FY 2019.

A constant multiplier is established to recover the total general costs (including allocated generic transportation costs) of $26.6 million. To derive the constant multiplier, the general cost amount is divided by the sum of all fee categories (application fee plus the inspection fee divided by inspection priority) then multiplied by the number of licensees. This calculation results in a constant multiplier of 1.27 for FY 2020. The average inspection cost is the average inspection hours for each fee category multiplied by the professional hourly rate of $279. The inspection priority is the interval between routine inspections, expressed in years. The inspection multiplier is established in order to recover the $7.5 million in inspection costs. To derive the inspection multiplier, the inspection costs amount is divided by the sum of all fee categories (inspection fee divided by inspection priority) then multiplied by the number of licensees. This calculation results in an inspection multiplier of 1.48 for FY 2020. The unique category costs are any special costs that the NRC has budgeted for a specific category of licenses. Please see the work papers for more detail about this classification.

The annual fee assessed to each licensee also takes into account a share of the approximately $0.051 million fee-relief credit assessment allocated to the materials users fee class (see Table IV, ''Allocation of Fee-Relief Adjustment and LLW Surcharge, FY 2020,'' in Section IV, ''Discussion,'' of this document), and for certain categories of these licensees, a share of the approximately $0.089 million in LLW surcharge costs allocated to the fee class. The annual fee for each fee category is shown in the revision to § 171.16(d).

h. Transportation

The NRC will collect $1.0 million in annual fees to recover generic transportation budgeted resources in FY 2020, as shown in Table XVII. The FY 2019 fees are shown for comparison purposes.

TABLE XVII—ANNUAL FEE SUMMARY CALCULATIONS FOR TRANSPORTATION

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Total Budgeted Resources	$8.0	$7.2

TABLE XVII—ANNUAL FEE SUMMARY CALCULATIONS FOR TRANSPORTATION—Continued

[Dollars in millions]

Summary fee calculations	FY 2019 final	FY 2020 final
Less Estimated 10 CFR part 170 Receipts	−3.7	−2.8
Net 10 CFR part 171 Resources	4.3	4.4
Less Generic Transportation Resources	−3.3	−3.4
Fee-relief adjustment/LLW surcharge	0.0	0.0
Billing adjustments	0.0	0.0
Total required annual fee recovery	1.0	1.0

In comparison to FY 2019, the total budgeted resources for generic transportation activities decreased due to the following: (1) The utilization of prior year unobligated carryover funding; (2) a reduction in FTE due to decreases in maintenance work associated with the Storage and Transportation Information Management System; and (3) the decline in DOE's percentage of total CoCs as a result of two new CoCs benefitting other fee classes. The 10 CFR part 170 estimated billings decreased primarily due to the issuance of CoCs for NAC International, Inc. and Industrial Nuclear Company, LLC in FY 2019.

Consistent with the policy established in the NRC's FY 2006 final fee rule (71 FR 30721; May 30, 2006), the NRC recovers generic transportation costs unrelated to DOE by including those costs in the annual fees for licensee fee classes. The NRC continues to assess a separate annual fee under § 171.16, fee category 18.A., for DOE transportation activities. The amount of the allocated generic resources is calculated by multiplying the percentage of total CoCs used by each fee class (and DOE) by the total generic transportation resources to be recovered.

This resource distribution to the licensee fee classes and DOE is shown in Table XVIII. Note that for the research and test reactors fee class, the NRC allocates the distribution to only those licensees that are subject to annual fees. Although four CoCs benefit the entire research and test reactor class, only 4 out of 31 research and test reactors are subject to annual fees. Consequently, the number of CoCs used to determine the proportion of generic transportation resources allocated annual fees for the research and test reactors fee class has been adjusted to 0.7 so these licensees are charged a fair and equitable portion of the total fees. For more information, see the work papers.

TABLE XVIII—DISTRIBUTION OF TRANSPORTATION RESOURCES, FY 2020

[Dollars in millions]

Licensee fee class/DOE	Number of CoCs benefiting fee class or DOE	Percentage of total CoCs	Allocated generic transportation resources
Materials Users	25.0	27.3	1.2
Operating Power Reactors	5.0	5.5	0.2
Spent Fuel Storage/Reactor Decommissioning	16.0	17.5	0.8
Research and Test Reactors	0.7	0.7	0.0
Fuel Facilities	24.0	26.2	1.2
Sub-Total of Generic Transportation Resources	70.7	77.1	3.4
DOE	21.0	22.9	1.0
Total	91.7	100.0	4.4

The NRC assesses an annual fee to DOE based on the 10 CFR part 71 CoCs it holds. The NRC, therefore, does not allocate these DOE-related resources to other licensees' annual fees because these resources specifically support DOE.

FY 2020—Policy Changes

The NRC is making two policy changes for FY 2020:

Removing the Fee Exceptions in § 170.21, Footnote 1 and § 170.31, Footnote 2

The NRC is eliminating the fee exceptions set forth in footnote 1 to § 170.21 ''Schedule of Fees for Production and Utilization Facilities, Review of Standard Referenced Design Approvals, Special Projects, Inspections, and Import and Export Licenses,'' and footnote 2 to § 170.31, ''Schedule of Fees for Materials Licenses and Other Regulatory Services, Including Inspections, and Import and Export Licenses.'' These footnotes contain parallel language stating that the NRC ''will not charge fees under 10 CFR part 170 for orders related to civil penalties or other civil sanctions issued by the Commission under § 2.202 or for amendments resulting specifically from the requirements of these orders.''

Currently, footnote 1 to § 170.21 and footnote 2 to § 170.31 provide an exception to the general rule that the NRC recovers review and inspection costs through fees assessed to individuals under 10 CFR part 170. The current language excludes the following activities from 10 CFR part 170 fees if an order relates to a civil penalty or

other sanction: (1) Subsequent NRC inspection or review work to ensure compliance with the terms of the order, and (2) subsequent NRC review costs if the order requires the licensee to seek a license amendment. The current language also states, however, that where an order is ''unrelated to civil penalties or other civil sanctions,'' the NRC will follow its normal practice of assessing fees under 10 CFR part 170.

The language in these footnotes comes from the NRC's FY 2005 fee rule (70 FR 30526; May 26, 2005). Before 2005, the NRC excluded work in connection with *all* orders from 10 CFR part 170 fees. In the FY 2005 fee rule, the NRC amended the footnotes to narrow the exceptions to just those orders that ''relate'' to civil penalties or civil sanctions. The NRC made this change because, after September 11, 2001, it had imposed additional security requirements on multiple licensees through orders. As a result of these orders, the NRC performed extensive follow-up activities that, because of the pre-existing broad exceptions in footnotes 1 and 2, were exempt from 10 CFR part 170 fees. Because these activities were exempt from 10 CFR part 170 fees, the NRC recovered the associated costs through annual fees under 10 CFR part 171, even though the work benefited specific licensees (70 FR 30528–30535; May 26, 2005).

Through the FY 2005 fee rule, the NRC attempted to allocate costs more fairly by ensuring that the beneficiaries of its review and inspection services associated with orders of the type issued after September 11, 2001, paid for those services through 10 CFR part 170 fees. At the same time, the NRC retained an exception for orders that relate to a civil penalty or civil sanction. The NRC also explained in the FY 2005 fee rule that it was maintaining its longstanding policy of not charging 10 CFR part 170 fees for the *preparation* of any order. The costs associated with preparing an order would continue to be recovered through annual fees under 10 CFR part 171.

The authority for assessing the 10 CFR part 171 fees comes from the same statute that provides the authority for the NRC's 10 CFR part 170 fee schedule. The IOAA requires that the NRC assess fees fairly and equitably, and it authorizes the NRC to collect fees whenever the agency provides ''a service or thing of value'' to a recipient. In addition, OBRA–90 (or, in future fiscal years, NEIMA) and Office of Management and Budget (OMB) Circular A–25, ''User Charges,'' require that the NRC recover fees from persons who derive a direct benefit from the agency's services.

Even if an order related to a civil penalty or civil sanction has some public benefit, the services the NRC provides in connection with the order, such as inspections and document-review activities, primarily benefit a specific licensee. These services primarily benefit the licensee because they enable the licensee to maintain its NRC license in good standing and continue to operate its facility. Furthermore, regardless of whether the NRC issues an order in a safety, security, or enforcement context, the NRC's follow-up services related to the order—inspections, document review and analysis, and other services—benefit the licensee by contributing to public confidence in the safe operation of the licensee's facility. Charging 10 CFR part 170 fees for services related to all orders is therefore most consistent with the NRC's obligations under the governing fee-recovery statutes and OMB Circular A–25. Transferring the cost of these services to other members of a licensee's fee class, on the other hand, could therefore be viewed as unfair and inconsistent with the governing fee-recovery statutes and OMB Circular A–25.

Accordingly, in this final rule, the NRC is removing the fee exceptions (*i.e.,* the first two sentences) from § 170.21, footnote 1 and § 170.31, footnote 2. Removing the exceptions promotes fairness and equity in the NRC's fees rules, consistent with the IOAA, ensures that licensees who receive special benefits in the form of NRC services pay for those services, consistent with OMB Circular A–25. Removing the exceptions also simplifies the NRC's fee schedules. If there are circumstances in which charging 10 CFR part 170 fees for follow-up activities related to an order would be unfair, the NRC retains the ability under § 170.11 to grant a fee exemption for those services, either on its own initiative or upon request.

Removing the fee exceptions will not, however, change the NRC's longstanding policy regarding the recovery of costs associated with preparing an order. Consistent with this policy, such costs will continue to be recovered through annual fees under 10 CFR part 171.

Amending § 171.15 Regarding the Assessment of Annual Fees for 10 CFR Part 52 Combined License Holders and Future 10 CFR Part 50 Power Reactor Licensees

Based on its review of PRM–171–1 and the public comments, the NRC is amending § 171.15(a) so that the assessment of annual fees for 10 CFR part 52 COL holders commences upon successful completion of power ascension testing, rather than after the Commission makes a finding under § 52.103(g). This approach will also apply this approach to future 10 CFR part 50 power reactor licensees.

Currently, § 171.15 requires a 10 CFR part 52 COL holder to begin paying the annual fee once the Commission finds under § 52.103(g) that all acceptance criteria in the COL are met. Similarly, 10 CFR part 50 licensees begin paying annual fees upon issuance of an operating license. The timing of annual fees reflects the NRC's historical position that a nuclear power reactor licensee receives the benefits of its license, and thus should begin paying annual fees, when the NRC authorizes the licensee to use nuclear materials (*i.e.,* begin operating the reactor).

The NRC is firmly committed to the application of fairness and equity in the assessment of fees to licensees. The NRC recognizes that, subsequent to the § 52.103(g) finding for 10 CFR part 52 COL holders, and issuance of the operating license for 10 CFR part 50 power reactor licensees, fuel must be loaded, and power ascension testing must be completed to provide assurance that the facility is fully operational. As part of this process, 10 CFR part 52 COL holders must provide written notification to the NRC that successful power ascension testing is completed. This notification is the trigger that enables operation at a steady-state reactor core power level equal to 100 percent of reactor thermal power as defined in the facility's final safety analysis report.

As a result, the NRC recognizes that it would be more fair and equitable to change the timing of when annual fees commence for 10 CFR part 52 licensees from when the Commission issues a § 52.103(g) finding to a time that aligns more closely with the licensee's facility becoming fully operational. For that reason, the NRC will defer charging annual fees until after the licensee's start-up and initial-testing phase. The NRC will begin charging annual fees only after the licensee has notified the NRC in writing that it has successfully completed power ascension testing. For similar reasons, the NRC is also applying this change to 10 CFR part 50 power reactor licensees.

Because only current 10 CFR part 52 COLs contain a standard license condition that requires written notification be submitted to the NRC upon successful completion of power ascension testing, the NRC will consider adding a similar license condition to

future 10 CFR part 50 operating licenses and 10 CFR part 52 COLs to ensure that they promptly notify the NRC of successful completion of power ascension testing. Upon successful completion of testing and the required notification to the NRC, the power reactor would be fully operational. The annual fee assessment for 10 CFR part 50 power reactor licensees and 10 CFR part 52 COL holders would therefore begin on the date of the licensee's written notification of successful completion of power ascension testing.

Accordingly, the NRC is amending § 171.15(a) so that annual fees commence not upon issuance of the operating license for 10 CFR part 50 power reactors and issuance of the § 52.103(g) finding for 10 CFR part 52 COL holders, but upon written notification to the NRC of successful completion of power ascension testing and making conforming changes to § 171.3, ''Scope,'' and § 171.17, ''Proration.'' The NRC finds this rule change amendment to be reasonable, fair, and equitable, and supported by the public comments the NRC received on PRM–171–1 and on the proposed rule. Finally, the NRC will consider expanding this approach to other 10 CFR part 50 licensees in a future rulemaking.

FY 2020—Administrative Change

The NRC is making one administrative change:

Add a footnote to the table in § 171.16(d) for additional clarity.

The NRC is adding a footnote to the table in § 171.16(d) to clarify that licensees that are subject to annual fees under fee categories 4.A., 4.B. or 4.C. are not subject to annual fees under 3.N. for waste disposal services authorized on the same license.

Update on the Fees Transformation Initiative

In the Staff Requirements Memorandum, dated October 19, 2016, (ADAMS Accession No. ML16293A902) for SECY–16–0097, ''Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule,'' (ADAMS Accession No. ML16194A365), the Commission directed staff to explore, as a voluntary pilot, whether the NRC could establish a flat fee structure for routine licensing matters in the area of uranium recovery, and to accelerate the process improvements for setting fees, including the transition to an electronic billing system. In addition, the Commission also directed the staff to begin the fees transformation activities listed in SECY–16–0097 as ''Process Changes Recommended for Future Consideration—FY 2018 and Beyond,'' which includes one remaining item to complete regarding the rulemaking to update the NRC's small business size standards in § 2.810, ''NRC Size Standards.''

With respect to the uranium recovery flat fee pilot initiative, the NRC explored the feasibility of establishing a flat fee structure for routine licensing matters and inspection activities. The NRC provided a report to Congress on January 9, 2020, describing the results of the pilot initiative and the decision to maintain the current NRC fee billing structure for 10 CFR part 170 fees for service for uranium recovery licensing matters. For more information, the report to Congress can be found at ADAMS Accession No. ML20010D684.

With respect to the NRC's transition to an electronic billing system (eBilling), eBilling went live with a phased implementation on October 1, 2019, which included 9 licensees with 65 dockets. As of May 12, 2020, eBilling currently has 111 licensees with 381 dockets enrolled. Outreach to additional licensees will continue throughout FY 2020 in order to increase enrollment and ensure awareness.

Finally, in order to obtain sufficient information to update the NRC's small business size standard in § 2.810, the NRC conducted a financial survey of materials licensees to determine whether changes to the size standards are needed. The NRC published a document in the **Federal Register** (85 FR 6225; February 4, 2020) announcing the survey, and requested response by due date of April 30, 2020. The survey results will be analyzed to determine if changes are needed to the current nuclear industry-specific size standards in § 2.810.

For more information, please see our fees transformation accomplishments schedule, located on our license fees website at: *https://www.nrc.gov/about-nrc/regulatory/licensing/fees-transformation-accomplishments.html.*

IV. Public Comment Analysis

Overview of Public Comments

The NRC published a proposed rule on February 18, 2020 (85 FR 9328) and requested public comment on its proposed revisions to 10 CFR parts 170 and 171. By the close of the comment period, the NRC received eight written comment submissions on the FY 2020 proposed rule. In general, the commenters were supportive of the specific proposed regulatory changes. Some commenters expressed concerns about broader fee-policy issues related to transparency, the overall size of the budget, fairness of fees, and budget formulation.

The commenters are listed in Table XIX.

TABLE XIX—FY 2020 PROPOSED FEE RULE COMMENTER SUBMISSIONS

Commenter	Affiliation	ADAMS accession No.
David Shafer	U.S. Department of Energy (DOE)	ML20056F131
Jeffrey Fulks	Honeywell International—Metropolis Works (MTW)	ML20073J763
Jennifer Uhle	NEI	ML20077K338
Matthew Ostdiek	Rendezvous Engineering, P.C. (RE)	ML20077M622
Fred Schuman	Mid River Asphalt, Inc	ML20083K042
Camilla Zozula	Westinghouse Electric Company (WEC)	ML20083K046
Cheryl Gayheart	Southern Nuclear Operating Company (SNC)	ML20083K048
Bradley Fewell	Exelon Generation Company (Exelon)	ML20084K871

Information about obtaining the complete text of the comment submissions is available in Section XIV, ''Availability of Documents,'' of this document.

V. Public Comments and NRC Responses

The NRC has carefully considered the public comments received on the proposed rule. The comments have been organized by topic. Comments from multiple commenters raising similar specific concerns were combined to capture the common essential issues raised by the commenters. Comments from a single commenter have been quoted to ensure accuracy; brackets

within those comments are used to show changes that have been made to the quoted comments. The NRC responses are preceded by a short summary of the issues raised by the commenters.

A. Budget Formulation

Comment: ''The NRC staff provided a very thorough public briefing about the proposed fee rule on March 5, 2020, including the business line budget utilization of the $40M in carryover funds. Approximately 50 [percent] of the carryover funding was utilized in the Operating and New Reactor business lines, consistent with the business line budgeting information provided in the briefing. However, the fee class budget distribution provided in the briefing shows 86 [percent] of the fee/receipt recoverable budget is allocated to Power Reactors. The **Federal Register** publication of the proposed fee rule notes that the $40M in carryover results in reduced fees to licensees. In light of the NRC's distribution of its fee-recoverable appropriation, how did the NRC determine the percentage of carryover that would be applied to reduce operating reactor fees?'' (Exelon)

Response: One commenter requested that the NRC explain its process to determine the percentage of carryover that was applied to reduce the operating power reactors fees. There is not a separate process to determine the percentage of carryover that would be applied to reduce the fee classes budgeted resources. When determining how to allocate the $40.0 million in carryover funds based on Congressional direction, the NRC used its appropriation funding categories—or control points—and allocated the carryover funds to appropropriate funding categories relative to the percentages of total enacted funding. This allocation was performed without distinguishing the specific fee classes during this process. The fee class distribution is determined as part of the normal fee allocation process after budget allocations are determined. During the March 5, 2020, public meeting, the NRC discussed the allocation process and demonstrated the reconciliation of the FY 2020 business line budgets to the specific fee classes. To increase transparency, NRC has included these reconciliations in the work papers for this final rule. In addition, the work papers include a chart, illustrating the utilization of carryover funding in FY 2019 and FY 2020 by business line and the subsequent allocations for the development of the fee rule.

No changes were made to the final rule as a result of this comment.

Comment: ''Related to the use of carryover funds, the $40M amount is very large by historical standards, the FY2019 carryover was $20M. Again, referencing the business line carryover utilization provided in the March 5 briefing, $13M, approximately one third of carryover funding was used to defray corporate support costs. NRC has struggled to contain corporate support costs and is required under NEIMA to reduce these costs to less than 30 [percent], to the maximum extent practicable. Exelon is concerned that without continued use of carryover funds in future years, corporate support will drive licensee fees higher, with uncertain safety benefit. We request that the work papers address the potential for increased industry fees to cover NRC corporate support.'' (Exelon)

Response: The agency remains focused on innovative strategies that result in savings, while not jeopardizing the corporate activities necessary to accomplish the agency's mission. The NRC has made significant progress in reducing corporate support in recent years. When compared to the FY 2014 enacted budget, the FY 2021 budget request for corporate support represents a decrease of $74.7 million, or approximately 22 percent. It should be noted that the NRC's annual fee rule and supporting work papers are published so that the public and licensees can understand how fees are calculated based on the budget authority enacted for the current fiscal year, not future fiscal years. The FY 2021 Congressional Budget Justification (CBJ), alternatively, provides the agency's explanation and justification for the resources being requested for the next fiscal year to allow the agency to complete its mission, the CBJ provides the reasoning for changes in the agency resource requests, and is the appropriate source for the agency's explanation and justification for the Corporate Support budget. The NRC's goal is to provide transparency in the fee rule and work papers between fees at the final appropriated budget requirements.

No changes were made to the final rule as a result of this comment.

B. Public Participation in Budget Formulation

Comment: Two commenters expressed a desire for industry to be involved with the NRC directly during the development of the NRC's budget to better determine the sufficiency of the budget and to accurately determine the necessary annual fees. They emphasized the need for the NRC staff to work with industry in an open and transparent fashion regarding the prioritization of annual fee expenditures and the utilization of indirect resources. (NEI and WEC)

Response: The NRC seeks information from licensees and other entities relevant to projected workload, through public meetings and other forms of public outreach, to better inform NRC's budget formulation workload assumptions. However, the NRC is an independent safety regulator, and it would not be appropriate for regulated entities, non-government organizations, and members of the public to be involved in the NRC's budget formulation. In addition, OMB establishes the Executive Branch budget process through OMB Circular No. A–11, ''Preparation, Submission, and Execution of the Budget.'' Section 22.1 of OMB Circular No. A–11 requires that pre-decisional budget deliberations remain confidential until the release of the CBJ.

No changes were made to this final rule as a result of these comments.

C. Work Papers

Comment: ''In prior year comments, we have identified a lack of transparency in the basis for the budget as an area of concern. We acknowledge that several steps have been taken to improve both the types and clarity of information provided in the fee rule work papers and Congressional Budget Justification. There has been a marked improvement in the level of detail provided to stakeholders on the NRC budget, however, we urge that additional steps be taken. In particular, we believe that additional detail should be provided on budgeted work activities, including a level of planned effort for each activity, how this level compares with the prior year, and the rationale for the change. Such detail would enable licensees to better evaluate and understand significant budget changes. Additional information should be provided to enable a better understanding of which actions are recovered through service fees and which actions are recovered through annual fees. We also believe that stakeholders would benefit greatly from an expansion on the narrative discussion in the fee rule work paper explaining significant increases/decreases in product line budget items.'' (NEI)

Response: The fee rule and its supporting work papers, are published so the public and licensees can understand how fees are determined for a fee class and a fee category. Consistent with requirements of OBRA–90, license

fees are calculated by business lines, product lines, and products based on the budget authority enacted for the current fiscal year. The NRC provides those business lines, product lines, and products in the fee rule work papers. The CBJ provides the agency explanation and justification for the resources being requested for the budget year, including increases and decreases, and the reason for changes in the agency budget request as compared to the prior year, at the business line and product line levels; it also includes the prior year actual amounts at the business line and product line levels.

The commenter is correct that the work papers currently do not distinguish by specific budget line items which fees are recovered through user and annual fees. The fee rule work papers do not draw this distinction because it has been impractical for the NRC to determine in advance what precise percentage of fees for a given business line will be recovered through 10 CFR part 170 user fees versus 10 CFR part 171 annual fees. With respect to 10 CFR part 170 user fees, the NRC staff time spent on licensing and inspection actions is subject to change, depending on the novelty and complexity of the license application under review or the facility being inspected. Similarly, with respect to 10 CFR part 171 annual fees, the nature of the generic research, safety, environmental, or safeguards activities also may vary considerably, given changes in Commission priorities, external events, interactions with Agreement States, other Federal agencies, state, local and tribal governments, the regulated industry, and members of the public.

The NRC notes that the CBJ includes a statement in each business line chapter to indicate which product lines impact fees for services versus annual fees. For all the business lines, except for the nuclear materials users business line, typically resources budgeted in the Licensing and Oversight Product Lines typically affect fees for services, and all other resources affect annual fees. For the nuclear materials users business line, almost all budgeted resources impact annual fees. The NRC is planning for the implementation of NEIMA in FY 2021 and is considering adding additional detail in the fee rule and associated work papers to enhance the transparency of how fees are determined.

The NRC disagrees with the comment recommending that NRC expand the narrative to explain the significant increases and decreases. The NRC has provided improved and detailed explanation in the fee rule of the changes in budgetary resources, changes to 10 CFR part 170 estimated billings, and the impact on annual fees. The budgetary resources by each fee class by business line, product line, and product in the work papers, which show the specific fee class budget increases and decreases. For example, in the FY 2020 proposed fee rule the operating power reactors fee class displayed numerous activities within the licensing and oversight product lines (*i.e.,* delayed construction and operating license application review activities), that affected the fee class budget and caused it to decline from the previous year. To increase transparency, the NRC incorporated a reconciliation of the FY 2020 CBJ resources by business line to the associated fee class in the FY 2020 proposed fee rule work papers. For the first time, stakeholders can trace the CBJ business line budgets to the resources recovered within each fee class budget by product line.

No changes were made to this final rule as a result of this comment.

Comment: ''The work papers supporting the FY2020 proposed rule show a detailed breakdown of the products and product lines included in the calculation of the Part 171 Operating Power Reactors annual per-reactor fee, including significant amounts for various research activities. Research for Operating Reactors is shown as $24M in contract dollars, and 128 FTEs. While some research appears explainable for the existing fleet of reactors, *e.g.,* ''Aging & Materials,'' other descriptors are more cryptic, *e.g.,* ''Engineering Research,'' ''Systems Analysis,'' or ''Risk Analysis'' ($16M contract dollars budgeted for these three.) And others that might appear applicable, *e.g.,* ''Digital I&C'' have no resources budgeted. It would be helpful to have in the work papers, perhaps as a separate paragraph or table in the Operating Power Reactors section, a brief description of the major efforts for each research Product, the goal of the research, expected completion date, safety issue to be resolved by the research, whether related to specific licensing actions, etc., so that Licensees and the public have confidence that these research dollars are being used to directly support the NRC mission.'' (Exelon)

Response: The commenter is requesting additional detail in the work papers in order to better understand the specific budgeted research efforts. The CBJ is the appropriate source for the agency's explanation and justification for the agency's research budget, not the fee rule, which implements the final results of the budget process. The NRC's goal is to provide transparency in the fee rule and work papers between fees at the final appropriated budget requirements. The fee rule and the supporting work papers are published in order for the public and licensees to understand how fees are determined for a fee class and a fee category.

With respect to the commenter's request to expand the fee rule work papers to provide additional information on all research activities with the specific goal of the research, expected completion date, safety issue to be resolved by the research, and whether it is related to specific licensing actions, the NRC does not believe such a change to the fee rule work papers is necessary. The CBJ, which serves a different purpose than the fee rule work papers, provides the overview of the specific research activities being conducted by the NRC during FY 2020. Some examples of NRC research activities discussed in the CBJ include but are not limited to: Seismic and structural stability; probabilistic risk assessment; digital instrumentation and controls and electrical systems; accident tolerant fuel; fuel performance research; and materials performance. Additional information on the regulatory research program, including NUREG–1925, Revision 4, ''Research Activities FY 2018–FY 2020,'' and the ''FY 2020–22 Planned Research Activities,'' are available on the NRC's public website at *https://www.nrc.gov/about-nrc/regulatory/research.html.* Additional information regarding the costs associated with research can be derived by comparing the work papers from the proposed fee rule to the final fee rule, which would allow the impact associated with budget changes, including the use of carryover, to be identified between fiscal years. Work papers for the proposed and final fee rules for the last several years can be readily accessed at *https://www.nrc.gov/about-nrc/regulatory/licensing/fees.html.*

No changes were made to this final rule as a result of this comment.

Comment: ''As Exelon has noted in reviewing proposed fee rules for prior years, this trade-off between Part 170 and Part 171 fees divorces the reactor fee from any actual health and safety benefit to be achieved via the Part 171 fee collection. That is, an increase in per-reactor fee does not necessarily mean greater NRC focus is needed to ensure safety. Exelon notes that under [NEIMA], the reactor fee is limited ''to the maximum extent practicable.'' Exelon recommends that the work papers address this aspect of the fees so that safety benefit derived from increased Part 171 fees can be better

understood. If the fee reflects only the budgeting process and not any change in the need for NRC oversight, that clarity would also be useful for the industry in prioritizing resource allocations.'' (Exelon)

Response: The NRC's annual budget request reflects the agency's continued commitment to protecting public health and safety and ensuring the long-term safety and security of nuclear power facilities and nuclear materials, which includes mission-direct, mission-indirect, and agency-support resources, as well as resources that are excluded from the NRC's fee recoverable budget.

Beginning in FY 2021, the NRC will be required to collect 100 percent of its annual budget authority (less certain excluded items), to the maximum extent practicable. Additionally, in accordance with Section 102(b)(3)(B)(i) of NEIMA, the operating power reactors fee class annual fee, to the maximum extent practicable, shall not exceed the operating power reactor annual fee amount established in the FY 2015 final fee rule, adjusted for inflation. On its own initiative, the NRC included an estimate of the operating power reactors annual fee in Appendix C, Estimated Operating Power Reactors Annual Fee,'' of the FY 2021 CBJ, with the intent to increase transparency. The NRC developed this estimate based on the NRC staff's allocation of the FY 2021 budget request to fee collections under 10 CFR part 170, and allocations within the operating power reactors fee class under 10 CFR part 171. In addition, the estimated annual fee assumes 93 operating power reactors in FY 2021 and applies various data assumptions from the FY 2019 final fee rule. Collectively, these actions help mitigate impacts on the remaining licensees from licensees that leave a fee class by helping the NRC continue to develop budgets that account for regulating a fee class with a declining number of licensees. Though the FY 2021 estimated operating power reactor fee class annual fee is included in the FY 2021 CBJ, it is subject to changes in those data assumptions as the NRC will conduct an annual rulemaking for FY 2021 fees by publishing a proposed and final rule in order to assess fees. Fee rule estimates during budget formulation are subject to the changes that will occur in the two-year interval between formulation and final appropriation impacting the fee rule.

The commenter is correct that the NRC's FY 2020 work papers do not include the allocation of the FY 2021 budget. The NRC's fee rule and supporting work papers are published in order for the public and licensees to understand how fees are calculated based on the budget authority enacted for the current fiscal year and not future fiscal years. The FY 2021 CBJ, which serves a different purpose than the fee rule work papers, provides the agency's explanation and justification for the resources being requested for the next fiscal year to allow the agency to complete its mission, and it provides the reasoning for changes in the agency resource requests. The NRC is planning for the implementation of NEIMA in FY 2021, and strives to enhance transparency for the annual fee rule and supporting work papers each year.

No changes were made to this final rule as a result of this comment.

D. Operating Reactors Decline in the Budget and 10 CFR Part 170 Estimated Billings

Comment: Several commenters expressed concern regarding the declining fraction of fees recovered under 10 CFR part 170 (service fees) relative to 10 CFR part 171 (annual fees), as well as the NRC's overall budget for the operating power reactors fee class. The commenters noted that these fees were being borne by a decreasing number of facilities with a decreasing number of licensing actions and completion of NRC reviews and certifications. The commenters noted that the high percentage of activities covered by annual fees places an increased importance on transparency of indirect services covered under 10 CFR part 171 fees, and they encourage a continued focus on enhancing transparency. (NEI and Exelon)

Response: The relationship between 10 CFR part 170 (service fees) relative to 10 CFR part 171 (annual fees) is workload driven. The activities covered by 10 CFR part 171 annual fees are necessary for NRC to accomplish its safety mission as described and justified in the CBJ. The amount of user fees collected under 10 CFR part 170 depends on a number of different factors including the professional hourly rate, licensee and applicant decisions to pursue licensing actions, and the number of hours necessary to resolve any licensing actions. Due to OBRA–90 requirements, examining changes in the 10 CFR part 170 fees and the 10 CFR part 171 fees separately may not account for the overall decreases in the fee class budget or the realized efficiencies. Over the last seven years, the fee class budget for operating power reactors has decreased from $734.7 million in FY 2013 to $623.9 million in FY 2020. This represents a reduction of $110.8 million, or 15 percent as a result of the decreasing number of nuclear power reactor licensees, application delays and withdrawals, reduced license amendments, efficiencies gained in office mergers, and long-term project completions.

Over this same period, the 10 CFR part 170 estimated billings for the operating power reactors fee class have declined from $303.8 million in FY 2013 to $186.7 million in FY 2020, which represents a decline of $117.1 million or 38.5 percent. These changes in the budgetary resources and the 10 CFR part 170 estimated billings, ultimately adjust the amount of fee recoverable resources that is required to be collected through 10 CFR part 171 annual fees. As compared to FY 2013, the operating power reactors fee class annual fee has increased from $424.2 million in FY 2013 to $439.0 million in FY 2020, which represents an increase of $14.8 million or 3.5 percent.

With respect to enhancing transparency, the NRC continues to review its budget and will pursue additional efficiency improvements to ensure that its budgetary request accurately reflects the anticipated workload. The NRC considers projected operating power plant closures and other external factors when estimating workload changes in a manner that allows the agency to meet its statutory responsibilities as the industry changes. However, a reduction in the budget is not linearly proportional as there is a cost for the infrastructure that must be maintained independent of the number of operating power reactors in the fleet.

The implementation of NEIMA in FY 2021, will include a cap on annual fees for operating reactors; the NRC continues to evaluate resource requirements and adjustments that can be made to refine the operating power reactors budget. Finally, the NRC remains committed to providing enhanced transparency throughout the development of the annual fee rule and supporting work papers.

No changes were made to this final rule as a result of these comments.

E. Fairness of Fees

Comment: ''The work papers also show that approximately 17% of the Nuclear Reactor Safety program budget used in determining the annual Operating Reactor fee comes from the New Reactors product line. Exelon suggests that the new reactor budget be broken out separately, to be paid by those entities pursuing new reactors. Alternately, the work papers should clarify in some detail how new reactor spending benefits the operating reactor fleet.'' (Exelon)

Response: The NRC disagrees with the proposed recommendation. To the extent that the NRC's reactor safety work directly benefits a licensee or applicant, the NRC then assesses 10 CFR part 170 user fees upon that licensee or applicant. As a result, existing operating reactor licensees are not paying any fees for new reactor work that directly benefits an entity engaged in new reactor activities. As for the portion of the new reactor work that is not collected through 10 CFR part 170 user fees, OBRA–90, as amended, requires that the NRC allocate the costs for this work fairly and equitably. Because the NRC's generic new reactor activities yield indirect benefits for existing operating reactor licensees, the NRC's current system of allocating all operating reactor costs to existing licensees satisfies OBRA–90's requirements.

While there are generic activities that may preferentially benefit new reactor vendors or licensees, there are activities that appear to be focused on new reactors but have a direct benefit to the operating power reactor licensees. For example, if an existing licensee sought to obtain NRC approval for a design change to a safety significant structure at an operating plant, then the NRC may use guidance that was developed for new reactor applications to analyze the design change. One example is the vendor quality assurance inspection program that develops and maintains the infrastructure for vendor inspections and quality assurance reviews supporting both new and operating reactors. While inspections and allegations specific to operating reactors are funded by operating reactors, many of the vendor inspections and allegations funded by the new reactor program are at vendors that also supply parts for operating reactors. Moreover, entities holding licenses for currently operating reactors may also be, either now or in the future, applicants for new nuclear power plant licenses. Finally, all power plant licensees indirectly benefit from rulemaking or other generic activities that enhance and develop the new reactor licensing framework because these generic activities help to establish and maintain the regulatory infrastructure at the NRC. This provides existing nuclear reactor licensees with regulatory predictability that is useful for business planning purposes.

Along these same lines, the NRC performs generic activities related to license renewal. These costs are spread among all holders of power reactor operating licenses without regard to whether the operating license holder intends to seek renewal. This is because a stable and efficient regulatory regime for license renewal indirectly benefits all existing power plants even if an existing power reactor has no immediate plans to seek license renewal. The same is true for new reactor licensing activities.

Ultimately, identification of fee classes is a matter of drawing practical distinctions. By virtue of being a generic activity without a specific, concrete beneficiary, all the activities that fall in the 10 CFR part 171 annual fee category could be theoretically parsed into an almost infinite amount of fee classes. For example, if the NRC were to base fees on distinctions such as whether generic work benefited boiling-water reactors versus pressurized-water reactors or coastal versus inland reactors, the exercise would result in distinctions that are both artificial and unduly burdensome from an administrative and recordkeeping standpoint. Therefore, the NRC's decision to draw the fee class line in a way that encompasses generic new reactor work satisfies OBRA–90's requirement that costs be allocated fairly and that, ''[t]o the maximum extent practicable, the charges shall have a reasonable relationship to the cost of providing regulatory services.''

No change was made to this final rule in response to this comment.

F. Fuel Facilities Matrix

Comment: ''The Metropolis facility has been secured in an idle state due to market conditions. The idle state conditions prohibits the production or the creation of liquid UF6 per Honeywell Request for Relaxation Security Order dated April 30, 2018. The NRC approved the request for Relaxation of Security Order in a letter dated March 11, 2019, due to the removal of UF6 from the process equipment. NRC recently acknowledged an 80% reduction in inspection effort due to the idle condition as stated in the NRC Inspection Report 4–339/2020–005 Honeywell Metropolis Works License Performance Review dated March 2, 2020. In the current idle state, MTW will not have liquid UF6 on site, or implement safeguards related to liquid UF6. Therefore, MTW asks that the effort factor for liquid UF6 be revised from 5 to 0 and the safeguards factor for liquid UF6 also be revised from a 5 to 0 to appropriately reflect the effort during the current idle state condition.'' (MTW)

Response: Currently, there is one uranium conversion facility, and it is in a ''ready-idle'' status with no processing operations. The NRC believes that this facility will remain in ''ready-idle'' position for FY 2020 and will need to be reassessed on an annual basis. Regulatory oversight of processing operations have been curtailed while the operations are shut down. Therefore, the safety and safeguards factors for ''Liquid UF6 processing at Uranium Conversion facilities'' in the effort factors matrix have been reduced from 5 to 0 to reflect the curtailed regulatory oversight of these processes.

G. Fuel Facilities Fee Class

Comment: ''We note that annual fees for Category I Fuel Cycle Facilities (listed under Category ''High-Enriched Uranium Fuel'') still exceed operating power reactor fees by roughly half a million dollars ($4.9M vs. $4.5M, respectively). We continue to encourage the NRC to adjust the Category I Fuel Cycle Facility regulatory effort, and in turn fees, to be commensurate with the facility risk profile.'' (NEI)

Response: The resources budgeted for each business line reflect the regulatory effort. In this final rule the total required annual fee recovery for the operating power reactor business line is $439.0 million, and the total annual fee recovery for the fuel facility business line is $18.0 million. The lower amount is commensurate with the lower risk at fuel facilities. This amount must be recovered from the 7 existing fuel facilities in the business line. For the Category I fuel facilities, the processes in the matrix are surrogates for the actual processes because the actual processes are classified.

No changes were made to this final rule because of this comment.

Comment: Two commenters welcomed the reductions in the fuel facilities fee class budgetary resources and annual fees in FY 2020, but felt that it is imperative that the OCFO staff take into consideration the Office of Nuclear Materials Safety and Safeguards' (NMSS) ongoing Fuel Cycle Smarter Program initiative, which will likely identify further reductions in FY 2021 fee-billable inspection hours. For planning purposes, a commensurate business line reduction in FY 2021 should closely reflect any final ''Smarter Programs'' inspection decisions (final reports are anticipated in Spring 2020). In the absence of such adjustments, fuel cycle facilities will experience an unnecessary increase in annual fees for FY 2021. (NEI and WEC)

Response: The fuel facilities business line is responsible for ensuring the safety and security of fuel cycle and greater than critical mass facilities. The business line leads the licensing and oversight of these facilities, as well as domestic material control and

accounting and international safeguards implementation activities for the NRC. The business line also supports rulemaking and environmental review activities for fuel facilities. The NRC has taken steps to right-size the fuel facilities budget to ensure that it reflects the reduced workload in the business line. A peak workload was experienced in FY 2012 and since then, the fee class budget has decreased from $54.4 million in FY 2012 to $18.0 million in FY 2020. This represents a reduction of $36.4 million, or 67 percent within the fee class budget. The FY 2020 fuel facilities fee class budget decreased primarily due to an expected decline in license renewal applications, the decrease in the number of license amendments, the termination of the MOX Fuel Fabrication Facility construction authorization, and efficiencies gained because of changes to the Fuel Facilities Inspection Program, and workload projections.

In a public meeting conducted on March 5, 2020, on the FY 2020 proposed fee rule, the NRC provided an overview of the fuel facilities business line budget, major activities, the budget planning process (*e.g.,* workload forecasting, types of work, and inspection activities), the reconciliation from the fuel facilities business line to the fee class budget, and the five-year trend of 10 CFR part 170 user fees and 10 CFR part 171 annual fees. Slides from this public meeting are available at ADAMS Accession No. ML20064G525.

Regarding the assertion that the NRC should reduce the fuel facilities business line budget, the NRC continues to actively evaluate resource requirements, both in terms of overall budget numbers and FTEs, to address changes that occur between budget formulation and execution. The NRC will continue to assess resource requirements and evaluate programmatic efficiencies that could result in additional resource reductions, but a reduction in the budget is not linearly proportional as there is a cost for the infrastructure that must be maintained independent of the number of operational fuel facilities.

In this final rule, the fees assessed to the licensees and applicants by the NRC must conform to OBRA–90, which requires the NRC to collect approximately 90 percent of its FY 2020 budget authority (less certain excluded items) through both user fees and annual fees. The NRC can assess these annual fees only to licensees or certificate holders, and the annual fee schedule must be fair and equitably allocate annual fees among the NRC's many licensees. To ensure compliance with OBRA–90, the NRC makes continual organizational improvements to align the resources needed to support its regulatory activities. These actions help mitigate impacts on the remaining licensees from licensees that leave a fee class by helping the NRC continue to develop budgets that account for regulating a fee class with a declining number of licensees.

Beyond FY 2020, the NRC will continue to look for efficiencies within the fuel facilities program. Going forward, the fuel facilities business line is focusing efforts to align the agency's program of work in the fuel facilities area to workload projections and continuing to risk-inform the regulatory framework for these activities while maintaining adequate protection consistent with our principles of good regulation.

On April 26, 2019, the NRC created two working groups tasked with building smarter Fuel Cycle licensing and oversight programs. The working groups were tasked with conducting a holistic assessment of the fuel cycle licensing and oversight programs for the purpose of improving the effectiveness and efficiency of the programs. The working groups included experienced supervisors and staff members looking for areas of transformation and innovation while adhering to the key principles of good regulation that guide the manner in which we conduct our work and make decisions.

The NRC believes that the implementation of the recommendations resulting from this effort will ensure focus on the areas of greatest safety benefit using the appropriate level of effort. Implementation of the recommendations will begin in FY 2021 and the results will be reflected in future rulemakings.

No changes were made to this final rule because of these comments.

H. Uranium Mill Tailings Radiation Control Act (Work Papers)

Comment: ''The U.S. Department of Energy (DOE) has reviewed the proposed 10 CFR parts 170 and 171 fee schedule for FY 2020. The DOE finds that the basis for the total annual fee amount and the level of effort to support the general licenses for [UMTRCA] sites is not presented in the proposed rule or associated work papers. Additionally, the bases for allocation percentages for DOE and other uranium recovery licensees and the generic/other uranium recovery costs in the proposed rule and work papers are not presented. The DOE requests that the US NRC clarify the rationale for the various fee components that are used to determine the total charge. This will help DOE evaluate whether the proposed NRC scope is consistent with anticipated DOE activities and establish the basis for DOE's estimate of annual uranium licensee fees in its budget request.'' (DOE)

Response: The NRC described the overall methodology for determining fees for uranium recovery facilities, including DOE, in the 2002 fee rule (67 FR 42625; June 24, 2002), and the NRC continues to use this methodology. As the NRC explained in the FY 2020 proposed fee rule, the NRC recovers fees from DOE through both user fees charged under 10 CFR part 170 for specific UMTRCA oversight activities and annual fees charged under 10 CFR part 171 for generic and other costs related to UMTRCA and other uranium recovery activities. As shown in the work papers referenced in the proposed fee rule, the NRC calculated the total amount of budgeted resources for UMTRCA activities related to DOE sites in the FY 2020 budget by computing the cost of staff hours budgeted to conduct the work (in terms of full-time equivalent, or FTE) and the budgeted contract costs. The total amount of budgeted resources was reduced by the amount expected to be recovered by 10 CFR part 170 user fees for site-specific UMTRCA activities. The NRC estimated the amount of 10 CFR part 170 user fees by analyzing billing data and the actual contractual work charged to DOE for the previous four quarters. The estimate, therefore, reflects any recent reductions in NRC oversight activities. The remainder of the UMTRCA budgeted amount related to DOE sites is charged to DOE for generic activities. In addition to those generic costs, DOE was charged for 10 percent of the overall generic costs attributable to the uranium recovery program. In other words, the DOE fee includes the costs of generic activities related to DOE sites and 10 percent of the overall generic costs attributable to the uranium recovery program. The remaining 90 percent of the overall generic costs is charged to the other members of the uranium recovery fee class. The work papers also provided information on all the values of the effort/benefit factors used in the uranium recovery matrix for FY 2020.

No changes were made to this final rule because of this comment.

I. Small Entity Size Standards

Comment: ''Regarding small entity size standards, the NRC should consider establishing lower licensing fees by creating one or more additional ranges between the $520,000 and $7,000,000

gross annual receipts range. A fee rate schedule with more steps for small businesses would help reduce the license fee burden on the smaller entities and address small business concerns.'' (RE)

Response: To reduce the significance of the annual fees on a substantial number of small entities, the NRC established the maximum small entity fee in FY 1991. In FY 1992, the NRC introduced a second lower tier to the small entity fee. Because the NRC's methodology for small entity size standards has been approved by the Small Business Administration, the NRC did not modify its current methodology for this rulemaking. However, as one of the ongoing Fees Transformation initiatives, the NRC conducted a financial survey of materials licensees to determine whether changes to the size standards are needed. The NRC published a document in the **Federal Register** (85 FR 6225; February 4, 2020) announcing the survey, with a requested due date of April 30, 2020, to complete the survey. The survey results will be analyzed to determine if changes are needed to the current NRC nuclear industry-specific small entity size standards in § 2.810.

No change was made to this final rule in response to this comment.

J. Comments Generally Supporting Actions of the Agency

Several commenters expressed comments generally in favor of actions that the agency is taking with respect to fees, billing, and other aspects of the fee rule process. Comments expressed support for the public meetings NRC held on the proposed fee rule; improved efficiency and clarity of the fee and invoicing process; NRC's eBilling system; the policy change to modify the timing of when annual fees commence for power reactor licensees; actions to decrease and right-size the fuel facilities budget to right-size the budget to reflect a reduced workload; and other improvements made as part of the Fees Transformation Initiative. No change was made to this final rule in response to this comment.

K. Comments on Matters Not Related to This Rulemaking

Several commenters raised issues outside the scope of the FY 2020 fee rule. Commenters raised concerns with the agency's budgeting process and requested public participation on the agency's budget formulation process. A few commenters requested expediting efficiency efforts and engaging industry regarding additional efficiencies and risk-informing the current regulatory program. These matters are outside the scope of this final rule. The primary purpose of the rule is to update the NRC's fee schedules to recover approximately 90 percent of the NRC's budgeted authority for the current fiscal year, and to make other necessary corrections or appropriate changes to specific aspects of the NRC's fee regulations in order to ensure compliance with OBRA–90.

The NRC understands the importance of examining and improving the efficiency of its operations and the prioritization of its regulatory activities. Accordingly, the NRC has undertaken, and continues to undertake, a number of significant initiatives aimed at improving the efficiency of NRC operations and enhancing the agency's approach to regulating. Though comments raising these issues are not within the scope of this final rule, the NRC will consider this input in its future program operations.

VI. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[4] the NRC has prepared a regulatory flexibility analysis related to this final rule. The regulatory flexibility analysis is available as indicated in Section XIV, Availability of Documents, of this document.

VII. Regulatory Analysis

Under OBRA–90, the NRC is required to recover approximately 90 percent of its budget authority in FY 2020. The NRC established fee methodology guidelines for 10 CFR part 170 in 1978, and established additional fee methodology guidelines for 10 CFR part 171 in 1986. In subsequent rulemakings, the NRC has adjusted its fees without changing the underlying principles of its fee policy to ensure that the NRC continues to comply with the statutory requirements for cost recovery in OBRA–90.

In this final rule, the NRC continues this longstanding approach. Therefore, the NRC did not identify any alternatives to the current fee structure guidelines and did not prepare a regulatory analysis for this final rule.

VIII. Backfitting and Issue Finality

The NRC has determined that the backfit rule, § 50.109, does not apply to this final rule and that a backfit analysis is not required. A backfit analysis is not required because these amendments do not require the modification of, or addition to, systems, structures, components, or the design of a facility, or the design approval or manufacturing license for a facility, or the procedures or organization required to design, construct, or operate a facility.

IX. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act, as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

X. National Environmental Policy Act

The rule is limited to amending the NRC's administrative requirements in 10 CFR parts 170 and 171. Therefore, this action is categorically excluded from needing environmental review, as described in § 51.22(c)(1). Consequently, neither an environmental impact statement nor an environmental assessment has been prepared for this final rule.

XI. Paperwork Reduction Act

This final rule does not contain a collection of information as defined in the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and, therefore, is not subject to the requirements of the Paperwork Reduction Act of 1995.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XII. Congressional Review Act

This final rule is a rule as defined in the Congressional Review Act of 1996 (5 U.S.C. 801–808). The Office of Management and Budget has found it to be a major rule as defined in the Congressional Review Act.

XIII. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this final rule, the NRC is amending the licensing, inspection, and annual fees charged to its licensees and applicants, as necessary, to recover approximately 90 percent of its budget authority in FY 2020, as required by

[4] 5 U.S.C. 603. The RFA, 5 U.S.C. 601–612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996, Public Law 104–121, Title II, 110 Stat. 847 (1996).

OBRA–90. This action does not constitute the establishment of a standard that contains generally applicable requirements.

XIV. Availability of Guidance

The Small Business Regulatory Enforcement Fairness Act requires all Federal agencies to prepare a written compliance guide for each rule for which the agency is required by 5 U.S.C. 604 to prepare a regulatory flexibility analysis. The NRC, in compliance with the law, prepared the ''Small Entity Compliance Guide'' for the FY 2019 proposed fee rule. The NRC plans to continue to use this compliance guide for FY 2020 and has relabeled the compliance guide to reflect the current fiscal year. The FY 2020 version of the compliance guide is available as indicated in Section XIV, Availability of Documents, of this document. The next compliance guide will be developed when the NRC completes the next small entity biennial review in FY 2021.

XV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Documents	Adams Accession No./web link
SECY–05–0164, ''Annual Fee Calculation Method,'' dated September 15, 2005	ML052580332.
SECY–16–0097, ''Fee Setting Improvements and Fiscal Year 2017 Proposed Fee Rule,'' dated August 15, 2016.	ML16194A365.
Staff Requirements Memorandum for SECY–16–0097, dated October 19, 2016	ML16293A902.
NUREG–1100, Volume 35, ''Congressional Budget Justification: Fiscal Year 2020'' (February 2019).	ML19065A279.
Petition for Rulemaking–171–1, ''Petition to Amend 10 CFR 171.15, ''Reactor Licenses and Independent Spent Fuel Storage Licenses,'' dated February 28, 2019.	ML19081A015.
''Nuclear Power Plant License Fees Upon Commencing Commercial Operation,'' partial consideration in the rulemaking process (84 FR 65032; November 26, 2019).	ML19304B492.
FY 2020 Final Rule Work Papers	ML20142A363.
''Uranium Recovery Flat Fee Pilot Initiative: A Report for the Senate Committee on Environment and Public Works and the House Committee on Energy and Commerce''.	ML20010D684.
FY 2020 Final Fee Rule	ML20114E208.
FY 2020 Regulatory Flexibility Analysis	ML20120A537.
FY 2020 U.S. Nuclear Regulatory Commission Small Entity Compliance Guide	ML19318G044.
NRC Form 526, ''Certification of Small Entity Status for the Purposes of Annual Fees Imposed under 10 CFR Part 171''.	*https://www.nrc.gov/reading-rm/doc-collections/forms/nrc526.pdf.*
OMB Circular A–25, ''User Charges''	*https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a025/a025.html.*
Fees Transformation Accomplishments	*https://www.nrc.gov/about-nrc/regulatory/licensing/fees-transformation-accomplishments.html.*

List of Subjects

10 CFR Part 170

Byproduct material, Import and export licenses, Intergovernmental relations, Non-payment penalties, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Source material, Special nuclear material.

10 CFR Part 171

Annual charges, Approvals, Byproduct material, Holders of certificates, Intergovernmental relations, Nonpayment penalties, Nuclear materials, Nuclear power plants and reactors, Registrations, Source material, Special nuclear material.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR parts 170 and 171:

PART 170—FEES FOR FACILITIES, MATERIALS, IMPORT AND EXPORT LICENSES, AND OTHER REGULATORY SERVICES UNDER THE ATOMIC ENERGY ACT OF 1954, AS AMENDED

■ 1. The authority citation for part 170 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w) (42 U.S.C. 2014, 2201(w)); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 31 U.S.C. 901, 902, 9701; 44 U.S.C. 3504 note.

§ 170.20 [Amended]

■ 2. In § 170.20, remove the dollar amount ''$275'' and add in its place the dollar amount ''$279''.

■ 3. In § 170.21, in the table, revise the entry for ''K. Import and export licenses'' and footnotes 1 and 6 to read as follows:

§ 170.21 Schedule of fees for production and utilization facilities, review of standard referenced design approvals, special projects, inspections and import and export licenses.

* * * * *

SCHEDULE OF FACILITY FEES

[See footnotes at end of table]

Facility categories and type of fees	Fees[1 2]
* * * * * * *	
K. Import and export licenses[6]	
Licenses for the import and export only of production or utilization facilities or the export only of components for production or utilization facilities issued under 10 CFR part 110.	

SCHEDULE OF FACILITY FEES—Continued

[See footnotes at end of table]

Facility categories and type of fees	Fees[1 2]
1. Application for import or export of production or utilization facilities[4] (including reactors and other facilities) and exports of components requiring Commission and Executive Branch review, for example, actions under 10 CFR 110.40(b).	
Application—new license, or amendment; or license exemption request	N/A.
2. Application for export of reactor and other components requiring Executive Branch review, for example, those actions under 10 CFR 110.41(a).	
Application—new license, or amendment; or license exemption request	N/A.
3. Application for export of components requiring the assistance of the Executive Branch to obtain foreign government assurances.	
Application—new license, or amendment; or license exemption request	N/A.
4. Application for export of facility components and equipment not requiring Commission or Executive Branch review, or obtaining foreign government assurances.	
Application—new license, or amendment; or license exemption request	N/A.
5. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms or conditions or to the type of facility or component authorized for export and, therefore, do not require in-depth analysis or review or consultation with the Executive Branch, U.S. host state, or foreign government authorities.	
Minor amendment to license	N/A.

[1] Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under title 10 of the *Code of Federal Regulations* (*e.g.,* 10 CFR 50.12, 10 CFR 73.5) and any other sections in effect now or in the future, regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form.

[2] Full cost fees will be determined based on the professional staff time and appropriate contractual support services expended. For applications currently on file and for which fees are determined based on the full cost expended for the review, the professional staff hours expended for the review of the application up to the effective date of the final rule will be determined at the professional rates in effect when the service was provided.

* * * * * * *

[4] Imports only of major components for end-use at NRC-licensed reactors are authorized under NRC general import license in 10 CFR 110.27.

* * * * * * *

[6] Because the Further Consolidated Appropriations Act, 2020, excludes international activities from the fee-recoverable budget in FY 2020, import and export licensing actions will not incur fees.

■ 4. In § 170.31, revise the table to read as follows:

§ 170.31 Schedule of fees for materials licenses and other regulatory services, including inspections, and import and export licenses.

* * * * *

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES

[See footnotes at end of table]

Category of materials licenses and type of fees[1]	Fees[2 3]
1. Special nuclear material:[11]	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium)[6] [Program Code(s): 21213]	Full Cost.
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel[6] [Program Code(s): 21210].	Full Cost.
(2) All other special nuclear materials licenses not included in Category 1.A. (1) which are licensed for fuel cycle activities.[6]	
(a) Facilities with limited operations[6] [Program Code(s): 21240, 21310, 21320]	Full Cost.
(b) Gas centrifuge enrichment demonstration facilities.[6] [Program Code(s): 21205]	Full Cost.
(c) Others, including hot cell facilities.[6] [Program Code(s): 21130, 21133]	Full Cost.
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI)[6] [Program Code(s): 23200].	Full Cost.
C. Licenses for possession and use of special nuclear material of less than a critical mass as defined in § 70.4 in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers.[4] Application [Program Code(s): 22140].	$1,300.
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under Category 1.A.[4] Application [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310].	$2,600.
E. Licenses or certificates for construction and operation of a uranium enrichment facility[6] [Program Code(s): 21200]	Full Cost.
F. Licenses for possession and use of special nuclear material greater than critical mass as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel-cycle activities.[4 6] [Program Code(s): 22155].	Full Cost.
2. Source material:[11]	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal.[6] [Program Code(s): 11400].	Full Cost.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
(2) Licenses for possession and use of source material in recovery operations such as milling, *in-situ* recovery, heap-leaching, ore buying stations, ion-exchange facilities, and in processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.[6]	
(a) Conventional and Heap Leach facilities [6] [Program Code(s): 11100]	Full Cost.
(b) Basic *In Situ* Recovery facilities [6] [Program Code(s): 11500]	Full Cost.
(c) Expanded *In Situ* Recovery facilities[6] [Program Code(s): 11510]	Full Cost.
(d) *In Situ* Recovery Resin facilities [6] [Program Code(s): 11550]	Full Cost.
(e) Resin Toll Milling facilities [6] [Program Code(s): 11555]	Full Cost.
(f) Other facilities [6] [Program Code(s): 11700]	Full Cost.
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4) [6] [Program Code(s): 11600, 12000].	Full Cost.
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2) [6] [Program Code(s): 12010].	Full Cost.
B. Licenses which authorize the possession, use, and/or installation of source material for shielding.[7 8] Application [Program Code(s): 11210].	$1,200.
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter. Application [Program Code(s): 11240].	$4,300.
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter. Application [Program Code(s): 11230, 11231].	$2,800.
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. Application [Program Code(s): 11710].	$2,700.
F. All other source material licenses. Application [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810, 11820]	$2,700.
3. Byproduct material: [11]	
A. Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. Application [Program Code(s): 03211, 03212, 03213].	$13,100.
(1). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. Application [Program Code(s): 04010, 04012, 04014].	$17,400.
(2). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. Application [Program Code(s): 04011, 04013, 04015].	$21,700.
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. Application [Program Code(s): 03214, 03215, 22135, 22162].	$3,600.
(1). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. Application [Program Code(s): 04110, 04112, 04114, 04116].	$4,800.
(2). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: more than 20. Application [Program Code(s): 04111, 04113, 04115, 04117].	$6,000.
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 1–5. Application [Program Code(s): 02500, 02511, 02513].	$5,200.
(1). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 6–20. Application [Program Code(s): 04210, 04212, 04214].	$6,900.
(2). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: more than 20. Application [Program Code(s): 04211, 04213, 04215].	$8,700.
D. [Reserved]	N/A.
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units). Application [Program Code(s): 03510, 03520].	$3,200.
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes. Application [Program Code(s): 03511].	$6,500.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials where the source is not exposed for irradiation purposes. Application [Program Code(s): 03521].	$62,300.
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter. The category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. Application [Program Code(s): 03254, 03255, 03257].	$6,700.
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter. Application [Program Code(s): 03250, 03251, 03252, 03253, 03256].	$11,600.
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. Application [Program Code(s): 03240, 03241, 03243].	$2,000.
K. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter. This category does not include specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter. Application [Program Code(s): 03242, 03244].	$1,100.
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5. Application [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613].	$5,500.
(1) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–20. Application [Program Code(s): 04610, 04612, 04614, 04616, 04618, 04620, 04622].	$7,300.
(2) Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: more than 20. Application [Program Code(s): 04611, 04613, 04615, 04617, 04619, 04621, 04623].	$9,100.
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution. Application [Program Code(s): 03620].	$8,300.
N. Licenses that authorize services for other licensees, except: (1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee Categories 4.A., 4.B., and 4.C. Application [Program Code(s): 03219, 03225, 03226].	$8,900.
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: 1–5. Application [Program Code(s): 03310, 03320].	$6,400.
(1). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: 6–20. Application [Program Code(s): 04310, 04312].	$8,500.
(2). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. Number of locations of use: more than 20. Application [Program Code(s): 04311, 04313].	$10,600.
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[9] Number of locations of use: 1–5. Application [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03130, 03140, 03220, 03221, 03222, 03800, 03810, 22130].	$4,700.
(1). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[9] Number of locations of use: 6–20. Application [Program Code(s): 04410, 04412, 04414, 04416, 04418, 04420, 04422, 04424, 04426, 04428, 04430, 04432, 04434, 04436, 04438].	$6,300.
(2). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[9] Number of locations of use: More than 20. Application [Program Code(s): 04411, 04413, 04415, 04417, 04419, 04421, 04423, 04425, 04427, 04429, 04431, 04433, 04435, 04437, 04439].	$7,900.
Q. Registration of a device(s) generally licensed under part 31 of this chapter. Registration	$600.
R. Possession of items or products containing radium-226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section.[5] 1. Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4) or (5) but less than or equal to 10 times the number of items or limits specified. Application [Program Code(s): 02700].	$2,600.
2. Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4) or (5). Application [Program Code(s): 02710].	$2,500.
S. Licenses for production of accelerator-produced radionuclides. Application [Program Code(s): 03210]	$14,300.
4. Waste disposal and processing: [11]	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material. Application [Program Code(s): 03231, 03233, 03236, 06100, 06101].	Full Cost.
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. Application [Program Code(s): 03234].	$6,900.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. Application [Program Code(s): 03232].	$5,000.
5. Well logging: [11]	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies. Application [Program Code(s): 03110, 03111, 03112].	$4,600.
B. Licenses for possession and use of byproduct material for field flooding tracer studies. Licensing [Program Code(s): 03113].	Full Cost.
6. Nuclear laundries: [11]	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material. Application [Program Code(s): 03218].	$22,200.
7. Medical licenses: [11]	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. Number of locations of use: 1–5. Application [Program Code(s): 02300, 02310].	$11,200.
(1). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. Number of locations of use: 6–20. Application [Program Code(s): 04510, 04512].	$14,800.
(2). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. Number of locations of use: more than 20. Application [Program Code(s): 04511, 04513].	$18,500.
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 1–5. Application [Program Code(s): 02110].	$8,700.
(1). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: 6–20. Application [Program Code(s): 04710].	$11,600.
(2). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license. Number of locations of use: more than 20. Application [Program Code(s): 04711].	$14,500.
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices.[10] Number of locations of use: 1–5. Application [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160].	$6,600.
(1). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices.[10] Number of locations of use: 6–20. Application [Program Code(s): 04810, 04812, 04814, 04816, 04818, 04820, 04822, 04824, 04826, 04828].	$8,800.
(2). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices.[10] Number of locations of use: More than 20. Application [Program Code(s): 04811, 04813, 04815, 04817, 04819, 04821, 04823, 04825, 04827, 04829].	$10,900.
8. Civil defense: [11]	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities. Application [Program Code(s): 03710].	$2,600.
9. Device, product, or sealed source safety evaluation:	
A. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution. Application—each device.	$10,900.
B. Safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices. Application—each device.	$9,000.
C. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution. Application—each source.	$5,300.
D. Safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel. Application—each source.	$1,100.
10. Transportation of radioactive material:	
A. Evaluation of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	Full Cost.
2. Other Casks	Full Cost.
B. Quality assurance program approvals issued under part 71 of this chapter.	

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
1. Users and Fabricators. Application	$4,200.
Inspections	Full Cost.
2. Users. Application	$4,200.
Inspections	Full Cost.
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices)..	Full Cost.
11. Review of standardized spent fuel facilities.	Full Cost.
12. Special projects: Including approvals, pre-application/licensing activities, and inspections. Application [Program Code: 25110].	Full Cost.
13. A. Spent fuel storage cask Certificate of Compliance.	Full Cost.
B. Inspections related to storage of spent fuel under § 72.210 of this chapter	Full Cost.
14. Decommissioning/Reclamation: [11]	
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including master materials licenses (MMLs). The transition to this fee category occurs when a licensee has permanently ceased principal activities. [Program Code(s): 03900, 11900, 21135, 21215, 21325, 22200].	Full Cost.
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, regardless of whether or not the sites have been previously licensed.	Full Cost.
15. Import and Export licenses: [12]	
Licenses issued under part 110 of this chapter for the import and export only of special nuclear material, source material, tritium and other byproduct material, and the export only of heavy water, or nuclear grade graphite (fee categories 15.A. through 15.E.).	
A. Application for export or import of nuclear materials, including radioactive waste requiring Commission and Executive Branch review, for example, those actions under 10 CFR 110.40(b). Application—new license, or amendment; or license exemption request.	N/A.
B. Application for export or import of nuclear material, including radioactive waste, requiring Executive Branch review, but not Commission review. This category includes applications for the export and import of radioactive waste and requires the NRC to consult with domestic host state authorities (i.e., Low-Level Radioactive Waste Compact Commission, the U.S. Environmental Protection Agency, etc.). Application—new license, or amendment; or license exemption request.	N/A.
C. Application for export of nuclear material, for example, routine reloads of low enriched uranium reactor fuel and/or natural uranium source material requiring the assistance of the Executive Branch to obtain foreign government assurances. Application—new license, or amendment; or license exemption request.	N/A.
D. Application for export or import of nuclear material not requiring Commission or Executive Branch review, or obtaining foreign government assurances. Application—new license, or amendment; or license exemption request.	N/A.
E. Minor amendment of any active export or import license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign government authorities. Minor amendment.	N/A.
Licenses issued under part 110 of this chapter for the import and export only of Category 1 and Category 2 quantities of radioactive material listed in appendix P to part 110 of this chapter (fee categories 15.F. through 15.R.).	
Category 1 (Appendix P, 10 CFR Part 110) Exports:	
F. Application for export of appendix P Category 1 materials requiring Commission review (e.g. exceptional circumstance review under 10 CFR 110.42(e)(4)) and to obtain one government-to-government consent for this process. For additional consent see fee category 15.I. Application—new license, or amendment; or license exemption request.	N/A.
G. Application for export of appendix P Category 1 materials requiring Executive Branch review and to obtain one government-to-government consent for this process. For additional consents see fee category 15.I. Application—new license, or amendment; or license exemption request.	N/A.
H. Application for export of appendix P Category 1 materials and to obtain one government-to-government consent for this process. For additional consents see fee category 15.I. Application—new license, or amendment; or license exemption request.	N/A.
I. Requests for each additional government-to-government consent in support of an export license application or active export license. Application—new license, or amendment; or license exemption request.	N/A.
Category 2 (Appendix P, 10 CFR Part 110) Exports:	
J. Application for export of appendix P Category 2 materials requiring Commission review (e.g. exceptional circumstance review under 10 CFR 110.42(e)(4)). Application—new license, or amendment; or license exemption request.	N/A.
K. Applications for export of appendix P Category 2 materials requiring Executive Branch review. Application—new license, or amendment; or license exemption request.	N/A.
L. Application for the export of Category 2 materials. Application—new license, or amendment; or license exemption request.	N/A.
M. [Reserved]	N/A.
N. [Reserved]	N/A.
O. [Reserved]	N/A.
P. [Reserved]	N/A.
Q. [Reserved]	N/A.
Minor Amendments (Category 1 and 2, Appendix P, 10 CFR Part 110, Export):	
R. Minor amendment of any active export license, for example, to extend the expiration date, change domestic information, or make other revisions which do not involve any substantive changes to license terms and conditions or to the type/quantity/chemical composition of the material authorized for export and, therefore, do not require in-depth analysis, review, or consultations with other Executive Branch, U.S. host state, or foreign authorities. Minor amendment.	N/A.

TABLE 1 TO § 170.31—SCHEDULE OF MATERIALS FEES—Continued

[See footnotes at end of table]

Category of materials licenses and type of fees [1]	Fees [2 3]
16. Reciprocity:	
Agreement State licensees who conduct activities under the reciprocity provisions of 10 CFR 150.20. Application	$2,100.
17. Master materials licenses of broad scope issued to Government agencies. Application [Program Code(s): 03614]	Full Cost.
18. Department of Energy.	
A. Certificates of Compliance. Evaluation of casks, packages, and shipping containers (including spent fuel, high-level waste, and other casks, and plutonium air packages).	Full Cost.
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities	Full Cost.

[1] *Types of fees*—Separate charges, as shown in the schedule, will be assessed for pre-application consultations and reviews; applications for new licenses, approvals, or license terminations; possession-only licenses; issuances of new licenses and approvals; certain amendments and renewals to existing licenses and approvals; safety evaluations of sealed sources and devices; generally licensed device registrations; and certain inspections. The following guidelines apply to these charges:

(a) *Application and registration fees.* Applications for new materials licenses and export and import licenses; applications to reinstate expired, terminated, or inactive licenses, except those subject to fees assessed at full costs; applications filed by Agreement State licensees to register under the general license provisions of 10 CFR 150.20; and applications for amendments to materials licenses that would place the license in a higher fee category or add a new fee category must be accompanied by the prescribed application fee for each category.

(1) Applications for licenses covering more than one fee category of special nuclear material or source material must be accompanied by the prescribed application fee for the highest fee category.

(2) Applications for new licenses that cover both byproduct material and special nuclear material in sealed sources for use in gauging devices will pay the appropriate application fee for fee category 1.C. only.

(b) *Licensing fees.* Fees for reviews of applications for new licenses, renewals, and amendments to existing licenses, pre-application consultations and other documents submitted to the NRC for review, and project manager time for fee categories subject to full cost fees are due upon notification by the Commission in accordance with § 170.12(b).

(c) *Amendment fees.* Applications for amendments to export and import licenses must be accompanied by the prescribed amendment fee for each license affected. An application for an amendment to an export or import license or approval classified in more than one fee category must be accompanied by the prescribed amendment fee for the category affected by the amendment, unless the amendment is applicable to two or more fee categories, in which case the amendment fee for the highest fee category would apply.

(d) *Inspection fees.* Inspections resulting from investigations conducted by the Office of Investigations and nonroutine inspections that result from third-party allegations are not subject to fees. Inspection fees are due upon notification by the Commission in accordance with § 170.12(c).

(e) *Generally licensed device registrations under 10 CFR 31.5.* Submittals of registration information must be accompanied by the prescribed fee.

[2] Fees will be charged for approvals issued under a specific exemption provision of the Commission's regulations under title 10 of the *Code of Federal Regulations* (*e.g.,* 10 CFR 30.11, 40.14, 70.14, 73.5, and any other sections in effect now or in the future), regardless of whether the approval is in the form of a license amendment, letter of approval, safety evaluation report, or other form. In addition to the fee shown, an applicant may be assessed an additional fee for sealed source and device evaluations as shown in fee categories 9.A. through 9.D.

[3] Full cost fees will be determined based on the professional staff time multiplied by the appropriate professional hourly rate established in § 170.20 in effect when the service is provided, and the appropriate contractual support services expended.

[4] Licensees paying fees under categories 1.A., 1.B., and 1.E. are not subject to fees under categories 1.C., 1.D. and 1.F. for sealed sources authorized in the same license, except for an application that deals only with the sealed sources authorized by the license.

[5] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

[6] Licensees subject to fees under fee categories 1.A., 1.B., 1.E., or 2.A. must pay the largest applicable fee and are not subject to additional fees listed in this table.

[7] Licensees paying fees under 3.C., 3.C.1, or 3.C.2 are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[8] Licensees paying fees under 7.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[9] Licensees paying fees under 3.N. are not subject to paying fees under 3.P., 3.P.1, or 3.P.2 for calibration or leak testing services authorized on the same license.

[10] Licensees paying fees under 7.B., 7.B.1, or 7.B.2 are not subject to paying fees under 7.C., 7.C.1, or 7.C.2. for broad scope licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

[11] A materials license (or part of a materials license) that transitions to fee category 14.A is assessed full-cost fees under 10 CFR part 170, but is not assessed an annual fee under 10 CFR part 171. If only part of a materials license is transitioned to fee category 14.A, the licensee may be charged annual fees (and any applicable 10 CFR part 170 fees) for other activities authorized under the license that are not in decommissioning status.

[12] Because the Further Consolidated Appropriations Act, 2020, excludes international activities from the fee-recoverable budget in FY 2020, import and export licensing actions will not be charged fees.

PART 171—ANNUAL FEES FOR REACTOR LICENSES AND FUEL CYCLE LICENSES AND MATERIALS LICENSES, INCLUDING HOLDERS OF CERTIFICATES OF COMPLIANCE, REGISTRATIONS, AND QUALITY ASSURANCE PROGRAM APPROVALS AND GOVERNMENT AGENCIES LICENSED BY THE NRC

■ 5. The authority citation for part 171 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 161(w), 223, 234 (42 U.S.C. 2014, 2201(w), 2273, 2282); Energy Reorganization Act of 1974, sec. 201 (42 U.S.C. 5841); 42 U.S.C. 2214; 44 U.S.C. 3504 note.

■ 6. Revise § 171.3 to read as follows:

§ 171.3 Scope.

The regulations in this part apply to any person holding an operating license for a test reactor or research reactor issued under part 50 of this chapter, and to any person holding an operating license for a power reactor licensed under 10 CFR part 50 or a combined license issued under 10 CFR part 52 that has provided notification to the NRC that the licensee has successfully completed power ascension testing. The regulations in this part also apply to any person holding a materials license as defined in this part, a Certificate of Compliance, a sealed source or device registration, a quality assurance program approval, and to a Government agency as defined in this part. Notwithstanding the other provisions in this section, the regulations in this part do not apply to uranium recovery and fuel facility licensees until after the Commission verifies through inspection that the

facility has been constructed in accordance with the requirements of the license.

■ 7. In § 171.15, revise paragraphs (a), (b)(1), (b)(2) introductory text, (c)(1), (c)(2) introductory text, (d)(1) introductory text, (d)(2) and (3), and (f) to read as follows:

§ 171.15 Annual fees: Reactor licenses and independent spent fuel storage licenses.

(a) Each person holding an operating license for a test or research reactor; each person holding an operating license for a power reactor licensed under 10 CFR part 50 or a combined license under 10 CFR part 52 that has provided notification to the NRC that the licensee has successfully completed power ascension testing; each person holding a 10 CFR part 50 or 10 CFR part 52 power reactor license that is in decommissioning or possession only status, except those that have no spent fuel onsite; and each person holding a 10 CFR part 72 license who does not hold a 10 CFR part 50 or 10 CFR part 52 license and provides notification in accordance with 10 CFR 72.80(g), shall pay the annual fee for each license held during the Federal fiscal year in which the fee is due. This paragraph (a) does not apply to test or research reactors exempted under § 171.11(b).

(b)(1) The FY 2020 annual fee for each operating power reactor that must be collected by September 30, 2020, is $4,621,000.

(2) The FY 2020 annual fees are comprised of a base annual fee for power reactors licensed to operate, a base spent fuel storage/reactor decommissioning annual fee, and associated additional charges (fee-relief adjustment). The activities comprising the spent fuel storage/reactor decommissioning base annual fee are shown in paragraphs (c)(2)(i) and (ii) of this section. The activities comprising the FY 2020 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2020 base annual fee for operating power reactors are as follows:

* * * * *

(c)(1) The FY 2020 annual fee for each power reactor holding a 10 CFR part 50 license or combined license issued under 10 CFR part 52 that is in a decommissioning or possession-only status and has spent fuel onsite, and for each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license or a 10 CFR part 52 combined license, is $188,000.

(2) The FY 2020 annual fee is comprised of a base spent fuel storage/reactor decommissioning annual fee (which is also included in the operating power reactor annual fee shown in paragraph (b) of this section) and a fee-relief adjustment. The activities comprising the FY 2020 fee-relief adjustment are shown in paragraph (d)(1) of this section. The activities comprising the FY 2020 spent fuel storage/reactor decommissioning rebaselined annual fee are:

* * * * *

(d)(1) The fee-relief adjustment allocated to annual fees includes a surcharge for the activities listed in paragraph (d)(1)(i) of this section, plus the amount remaining after total budgeted resources for the activities included in paragraphs (d)(1)(ii) and (iii) of this section are reduced by the appropriations the NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (d)(1)(ii) and (iii) of this section for a given fiscal year, annual fees will be reduced. The activities comprising the FY 2020 fee-relief adjustment are as follows:

* * * * *

(2) The total FY 2020 fee-relief adjustment allocated to the operating power reactor class of licenses is a $1,152,477 fee-relief credit, not including the amount allocated to the spent fuel storage/reactor decommissioning class. The FY 2020 operating power reactor fee-relief adjustment to be assessed to each operating power reactor is approximately a $12,131 fee-relief credit. This amount is calculated by dividing the total operating power reactor fee-relief credit, $1,152,477, by the number of operating power reactors (95).

(3) The FY 2020 fee-relief adjustment allocated to the spent fuel storage/reactor decommissioning class of licenses is a $71,443 fee-relief credit. The FY 2020 spent fuel storage/reactor decommissioning fee-relief adjustment to be assessed to each operating power reactor, each power reactor in decommissioning or possession-only status that has spent fuel onsite, and to each independent spent fuel storage 10 CFR part 72 licensee who does not hold a 10 CFR part 50 license, is a $586 fee-relief credit. This amount is calculated by dividing the total fee-relief credit by the total number of power reactors licenses, except those that permanently ceased operations and have no fuel onsite, and 10 CFR part 72 licensees who do not hold a 10 CFR part 50 license.

* * * * *

(f) The FY 2020 annual fees for licensees authorized to operate a research or test (non-power) reactor licensed under 10 CFR part 50, unless the reactor is exempted from fees under § 171.11(b), are as follows:

Research reactor	$81,300
Test reactor	$81,300

■ 8. In § 171.16, revise paragraphs (c), (d), and (e) introductory text to read as follows:

§ 171.16 Annual fees: Materials licensees, holders of certificates of compliance, holders of sealed source and device registrations, holders of quality assurance program approvals, and government agencies licensed by the NRC.

* * * * *

(c) A licensee who is required to pay an annual fee under this section, in addition to 10 CFR part 72 licenses, may qualify as a small entity. If a licensee qualifies as a small entity and provides the Commission with the proper certification along with its annual fee payment, the licensee may pay reduced annual fees as shown in following table. Failure to file a small entity certification in a timely manner could result in the receipt of a delinquent invoice requesting the outstanding balance due and/or denial of any refund that might otherwise be due. The small entity fees are as follows:

NRC small entity classification	Maximum annual fee per licensed category
Small Businesses Not Engaged in Manufacturing (Average gross receipts over last 3 completed fiscal years):	
$485,000 to $7 million	$4,500
Less than $485,000	900
Small Not-For-Profit Organizations (Annual Gross Receipts):	
$485,000 to $7 million	4,500

NRC small entity classification	Maximum annual fee per licensed category
Less than $485,000	900
Manufacturing Entities that Have An Average of 500 Employees or Fewer:	
35 to 500 employees	4,500
Fewer than 35 employees	900
Small Governmental Jurisdictions (Including publicly supported educational institutions) (Population):	
20,000 to 49,999	4,500
Fewer than 20,000	900
Educational Institutions that are not State or Publicly Supported, and have 500 Employees or Fewer:	
35 to 500 employees	4,500
Fewer than 35 employees	900

(d) The FY 2020 annual fees are comprised of a base annual fee and an allocation for fee-relief adjustment. The activities comprising the FY 2020 fee-relief adjustment are shown for convenience in paragraph (e) of this section. The FY 2020 annual fees for materials licensees and holders of certificates, registrations, or approvals subject to fees under this section are shown in the following table:

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
1. Special nuclear material:	
A. (1) Licenses for possession and use of U–235 or plutonium for fuel fabrication activities.	
(a) Strategic Special Nuclear Material (High Enriched Uranium) [15] [Program Code(s): 21213]	$5,067,000
(b) Low Enriched Uranium in Dispersible Form Used for Fabrication of Power Reactor Fuel [15] [Program Code(s): 21210]	1,717,000
(2) All other special nuclear materials licenses not included in Category 1.A.(1) which are licensed for fuel cycle activities.	
(a) Facilities with limited operations [15] [Program Code(s): 21310, 21320]	N/A
(b) Gas centrifuge enrichment demonstration facility [15] [Program Code(s): 21205]	N/A
(c) Others, including hot cell facility [15] [Program Code(s): 21130, 21133]	N/A
B. Licenses for receipt and storage of spent fuel and reactor-related Greater than Class C (GTCC) waste at an independent spent fuel storage installation (ISFSI) [11 15] [Program Code(s): 23200]	N/A
C. Licenses for possession and use of special nuclear material of less than a critical mass, as defined in § 70.4 of this chapter, in sealed sources contained in devices used in industrial measuring systems, including x-ray fluorescence analyzers. [Program Code(s): 22140]	2,800
D. All other special nuclear material licenses, except licenses authorizing special nuclear material in sealed or unsealed form in combination that would constitute a critical mass, as defined in § 70.4 of this chapter, for which the licensee shall pay the same fees as those under Category 1.A. [Program Code(s): 22110, 22111, 22120, 22131, 22136, 22150, 22151, 22161, 22170, 23100, 23300, 23310]	7,000
E. Licenses or certificates for the operation of a uranium enrichment facility [15] [Program Code(s): 21200]	2,208,000
F. Licenses for possession and use of special nuclear materials greater than critical mass, as defined in § 70.4 of this chapter, for development and testing of commercial products, and other non-fuel cycle activities.[4] [Program Code: 22155]	5,100
2. Source material:	
A. (1) Licenses for possession and use of source material for refining uranium mill concentrates to uranium hexafluoride or for deconverting uranium hexafluoride in the production of uranium oxides for disposal.[15] [Program Code: 11400]	510,000
(2) Licenses for possession and use of source material in recovery operations such as milling, in-situ recovery, heap-leaching, ore buying stations, ion-exchange facilities and in-processing of ores containing source material for extraction of metals other than uranium or thorium, including licenses authorizing the possession of byproduct waste material (tailings) from source material recovery operations, as well as licenses authorizing the possession and maintenance of a facility in a standby mode.	
(a) Conventional and Heap Leach facilities.[15] [Program Code(s): 11100]	N/A
(b) Basic *In Situ* Recovery facilities.[15] [Program Code(s): 11500]	49,200
(c) Expanded *In Situ* Recovery facilities [15] [Program Code(s): 11510]	N/A
(d) *In Situ* Recovery Resin facilities.[15] [Program Code(s): 11550]	[5] N/A
(e) Resin Toll Milling facilities.[15] [Program Code(s): 11555]	[5] N/A
(f) Other facilities [6] [Program Code(s): 11700]	[5] N/A
(3) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal, except those licenses subject to the fees in Category 2.A.(2) or Category 2.A.(4).[15] [Program Code(s): 11600, 12000]	[5] N/A
(4) Licenses that authorize the receipt of byproduct material, as defined in Section 11e.(2) of the Atomic Energy Act, from other persons for possession and disposal incidental to the disposal of the uranium waste tailings generated by the licensee's milling operations, except those licenses subject to the fees in Category 2.A.(2).[15] [Program Code(s): 12010]	N/A
B. Licenses which authorize the possession, use, and/or installation of source material for shielding.[16 17] Application [Program Code(s): 11210]	3,100
C. Licenses to distribute items containing source material to persons exempt from the licensing requirements of part 40 of this chapter. [Program Code: 11240]	7,700
D. Licenses to distribute source material to persons generally licensed under part 40 of this chapter. [Program Code(s): 11230 and 11231]	6,000

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
E. Licenses for possession and use of source material for processing or manufacturing of products or materials containing source material for commercial distribution. [Program Code: 11710]	7,400
F. All other source material licenses. [Program Code(s): 11200, 11220, 11221, 11300, 11800, 11810, 11820]	9,100
3. Byproduct material:	
A. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. [Program Code(s): 03211, 03212, 03213]	27,900
(1). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. [Program Code(s): 03211, 03212, 03213]	37,100
(2). Licenses of broad scope for the possession and use of byproduct material issued under parts 30 and 33 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: More than 20. [Program Code(s): 04011, 04013, 04015]	46,300
B. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 1–5. [Program Code(s): 03214, 03215, 22135, 22162]	11,300
(1). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: 6–20. [Program Code(s): 04110, 04112, 04114, 04116]	15,000
(2). Other licenses for possession and use of byproduct material issued under part 30 of this chapter for processing or manufacturing of items containing byproduct material for commercial distribution. Number of locations of use: More than 20. [Program Code(s): 04111, 04113, 04115, 04117]	18,700
C. Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 1–5. [Program Code(s): 02500, 02511, 02513]	10,500
(1). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: 6–20. [Program Code(s): 04210, 04212, 04214]	13,800
(2). Licenses issued under §§ 32.72 and/or 32.74 of this chapter that authorize the processing or manufacturing and distribution or redistribution of radiopharmaceuticals, generators, reagent kits, and/or sources and devices containing byproduct material. This category does not apply to licenses issued to nonprofit educational institutions whose processing or manufacturing is exempt under § 170.11(a)(4). Number of locations of use: More than 20. [Program Code(s): 04211, 04213, 04215]	17,400
D. [Reserved]	[5] N/A
E. Licenses for possession and use of byproduct material in sealed sources for irradiation of materials in which the source is not removed from its shield (self-shielded units) [Program Code(s): 03510, 03520]	11,700
F. Licenses for possession and use of less than or equal to 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes [Program Code(s): 03511]	10,700
G. Licenses for possession and use of greater than 10,000 curies of byproduct material in sealed sources for irradiation of materials in which the source is exposed for irradiation purposes. This category also includes underwater irradiators for irradiation of materials in which the source is not exposed for irradiation purposes [Program Code(s): 03521]	85,200
H. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material that require device review to persons exempt from the licensing requirements of part 30 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter [Program Code(s): 03254, 03255, 03257]	10,700
I. Licenses issued under subpart A of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require device evaluation to persons exempt from the licensing requirements of part 30 of this chapter, except for specific licenses authorizing redistribution of items that have been authorized for distribution to persons exempt from the licensing requirements of part 30 of this chapter [Program Code(s): 03250, 03251, 03252, 03253, 03256]	16,900
J. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material that require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter [Program Code(s): 03240, 03241, 03243]	4,100
K. Licenses issued under subpart B of part 32 of this chapter to distribute items containing byproduct material or quantities of byproduct material that do not require sealed source and/or device review to persons generally licensed under part 31 of this chapter, except specific licenses authorizing redistribution of items that have been authorized for distribution to persons generally licensed under part 31 of this chapter [Program Code(s): 03242, 03244]	3,000
L. Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 1–5. [Program Code(s): 01100, 01110, 01120, 03610, 03611, 03612, 03613]	15,000
(1). Licenses of broad scope for possession and use of product material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: 6–20. [Program Code(s): 04610, 04612, 04614, 04616, 04618, 04620, 04622]	19,800

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
(2). Licenses of broad scope for possession and use of byproduct material issued under parts 30 and 33 of this chapter for research and development that do not authorize commercial distribution. Number of locations of use: More than 20. [Program Code(s): 04611, 04613, 04615, 04617, 04619, 04621, 04623]	24,700
M. Other licenses for possession and use of byproduct material issued under part 30 of this chapter for research and development that do not authorize commercial distribution [Program Code(s): 03620]	14,400
N. Licenses that authorize services for other licensees, except: (1) Licenses that authorize only calibration and/or leak testing services are subject to the fees specified in fee Category 3.P.; and (2) Licenses that authorize waste disposal services are subject to the fees specified in fee categories 4.A., 4.B., and 4.C.[21] [Program Code(s): 03219, 03225, 03226]	18,100
O. Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license Number of locations of use: 1–5. [Program Code(s): 03310, 03320]	29,900
(1). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license. Number of locations of use: 6–20. [Program Code(s): 04310, 04312]	40,000
(2). Licenses for possession and use of byproduct material issued under part 34 of this chapter for industrial radiography operations. This category also includes the possession and use of source material for shielding authorized under part 40 of this chapter when authorized on the same license. Number of locations of use: More than 20. [Program Code(s): 04311, 04313]	49,800
P. All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[18] Number of locations of use: 1–5. [Program Code(s): 02400, 02410, 03120, 03121, 03122, 03123, 03124, 03140, 03130, 03220, 03221, 03222, 03800, 03810, 22130]	9,700
(1). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[18] Number of locations of use: 6–20. [Program Code(s): 04410, 04412, 04414, 04416, 04418, 04420, 04422, 04424, 04426, 04428, 04430, 04432, 04434, 04436, 04438]	13,000
(2). All other specific byproduct material licenses, except those in Categories 4.A. through 9.D.[18] Number of locations of use: More than 20. [Program Code(s): 04411, 04413, 04415, 04417, 04419, 04421, 04423, 04425, 04427, 04429, 04431, 04433, 04435, 04437, 04439]	16,300
Q. Registration of devices generally licensed under part 31 of this chapter	[13] N/A
R. Possession of items or products containing radium–226 identified in 10 CFR 31.12 which exceed the number of items or limits specified in that section:[14].	
(1). Possession of quantities exceeding the number of items or limits in 10 CFR 31.12(a)(4), or (5) but less than or equal to 10 times the number of items or limits specified [Program Code(s): 02700]	7,000
(2). Possession of quantities exceeding 10 times the number of items or limits specified in 10 CFR 31.12(a)(4) or (5) [Program Code(s): 02710]	7,300
S. Licenses for production of accelerator-produced radionuclides [Program Code(s): 03210]	30,300
4. Waste disposal and processing:	
A. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of contingency storage or commercial land disposal by the licensee; or licenses authorizing contingency storage of low-level radioactive waste at the site of nuclear power reactors; or licenses for receipt of waste from other persons for incineration or other treatment, packaging of resulting waste and residues, and transfer of packages to another person authorized to receive or dispose of waste material. [Program Code(s): 03231, 03233, 03235, 03236, 06100, 06101]	31,900
B. Licenses specifically authorizing the receipt of waste byproduct material, source material, or special nuclear material from other persons for the purpose of packaging or repackaging the material. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. [Program Code(s): 03234]	18,100
C. Licenses specifically authorizing the receipt of prepackaged waste byproduct material, source material, or special nuclear material from other persons. The licensee will dispose of the material by transfer to another person authorized to receive or dispose of the material. [Program Code(s): 03232]	10,200
5. Well logging:	
A. Licenses for possession and use of byproduct material, source material, and/or special nuclear material for well logging, well surveys, and tracer studies other than field flooding tracer studies. [Program Code(s): 03110, 03111, 03112]	14,300
B. Licenses for possession and use of byproduct material for field flooding tracer studies. [Program Code(s): 03113]	[5] N/A
6. Nuclear laundries:	
A. Licenses for commercial collection and laundry of items contaminated with byproduct material, source material, or special nuclear material. [Program Code(s): 03218]	34,000
7. Medical licenses:	
A. Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 1–5. [Program Code(s): 02300, 02310]	25,300
(1). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 6–20. [Program Code(s): 04510, 04512]	33,600

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
(2). Licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, or special nuclear material in sealed sources contained in gamma stereotactic radiosurgery units, teletherapy devices, or similar beam therapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: More than 20. [Program Code(s): 04511, 04513]	42,000
B. Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 1–5. [Program Code(s): 02110]	30,800
(1). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: 6–20. [Program Code(s): 04710]	41,100
(2). Licenses of broad scope issued to medical institutions or two or more physicians under parts 30, 33, 35, 40, and 70 of this chapter authorizing research and development, including human use of byproduct material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9] Number of locations of use: More than 20. [Program Code(s): 04711]	51,200
C. Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9 19] Number of locations of use: 1-5. [Program Code(s): 02120, 02121, 02200, 02201, 02210, 02220, 02230, 02231, 02240, 22160]	14,800
(1). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9 19] Number of locations of use: 6–20. [Program Code(s): 04810, 04812, 04814, 04816, 04818, 04820, 04822, 04824, 04826, 04828]	19,700
(2). Other licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices. This category also includes the possession and use of source material for shielding when authorized on the same license.[9 19] Number of locations of use: More than 20. [Program Code(s): 04811, 04813, 04815, 04817, 04819, 04821, 04823, 04825, 04827, 04829]	24,500
8. Civil defense:	
A. Licenses for possession and use of byproduct material, source material, or special nuclear material for civil defense activities. [Program Code(s): 03710]	7,000
9. Device, product, or sealed source safety evaluation:	
A. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material, except reactor fuel devices, for commercial distribution	13,800
B. Registrations issued for the safety evaluation of devices or products containing byproduct material, source material, or special nuclear material manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel devices	11,400
C. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, except reactor fuel, for commercial distribution	6,700
D. Registrations issued for the safety evaluation of sealed sources containing byproduct material, source material, or special nuclear material, manufactured in accordance with the unique specifications of, and for use by, a single applicant, except reactor fuel	1,400
10. Transportation of radioactive material:	
A. Certificates of Compliance or other package approvals issued for design of casks, packages, and shipping containers.	
1. Spent Fuel, High-Level Waste, and plutonium air packages	[6] N/A
2. Other Casks	[6] N/A
B. Quality assurance program approvals issued under part 71 of this chapter.	
1. Users and Fabricators	[6] N/A
2. Users	[6] N/A
C. Evaluation of security plans, route approvals, route surveys, and transportation security devices (including immobilization devices)	[6] N/A
11. Standardized spent fuel facilities	[6] N/A
12. Special Projects [Program Code(s): 25110]	[6] N/A
13. A. Spent fuel storage cask Certificate of Compliance	[6] N/A
B. General licenses for storage of spent fuel under 10 CFR 72.210	[12] N/A
14. Decommissioning/Reclamation:	
A. Byproduct, source, or special nuclear material licenses and other approvals authorizing decommissioning, decontamination, reclamation, or site restoration activities under parts 30, 40, 70, 72, and 76 of this chapter, including master materials licenses (MMLs). The transition to this fee category occurs when a licensee has permanently ceased principal activities. [Program Code(s): 03900, 11900, 21135, 21215, 21325, 22200]	[7 20] N/A
B. Site-specific decommissioning activities associated with unlicensed sites, including MMLs, whether or not the sites have been previously licensed	[7] N/A

SCHEDULE OF MATERIALS ANNUAL FEES AND FEES FOR GOVERNMENT AGENCIES LICENSED BY NRC—Continued

[See footnotes at end of table]

Category of materials licenses	Annual fees [1 2 3]
15. Import and Export licenses	[8] N/A
16. Reciprocity	[8] N/A
17. Master materials licenses of broad scope issued to Government agencies.[15] [Program Code(s): 03614]	312,000
18. Department of Energy:	
A. Certificates of Compliance	[10] 1,007,000
B. Uranium Mill Tailings Radiation Control Act (UMTRCA) activities [Program Code(s): 03237, 03238]	120,000

[1] Annual fees will be assessed based on whether a licensee held a valid license with the NRC authorizing possession and use of radioactive material during the current FY. The annual fee is waived for those materials licenses and holders of certificates, registrations, and approvals who either filed for termination of their licenses or approvals or filed for possession only/storage licenses before October 1 of the current FY, and permanently ceased licensed activities entirely before this date. Annual fees for licensees who filed for termination of a license, downgrade of a license, or for a possession-only license during the FY and for new licenses issued during the FY will be prorated in accordance with the provisions of § 171.17. If a person holds more than one license, certificate, registration, or approval, the annual fee(s) will be assessed for each license, certificate, registration, or approval held by that person. For licenses that authorize more than one activity on a single license (*e.g.,* human use and irradiator activities), annual fees will be assessed for each category applicable to the license.

[2] Payment of the prescribed annual fee does not automatically renew the license, certificate, registration, or approval for which the fee is paid. Renewal applications must be filed in accordance with the requirements of parts 30, 40, 70, 71, 72, or 76 of this chapter.

[3] Each FY, fees for these materials licenses will be calculated and assessed in accordance with § 171.13 and will be published in the FEDERAL REGISTER for notice and comment.

[4] Other facilities include licenses for extraction of metals, heavy metals, and rare earths.

[5] There are no existing NRC licenses in these fee categories. If NRC issues a license for these categories, the Commission will consider establishing an annual fee for this type of license.

[6] Standardized spent fuel facilities, 10 CFR parts 71 and 72 Certificates of Compliance and related Quality Assurance program approvals, and special reviews, such as topical reports, are not assessed an annual fee because the generic costs of regulating these activities are primarily attributable to users of the designs, certificates, and topical reports.

[7] Licensees in this category are not assessed an annual fee because they are charged an annual fee in other categories while they are licensed to operate.

[8] No annual fee is charged because it is not practical to administer due to the relatively short life or temporary nature of the license.

[9] Separate annual fees will not be assessed for pacemaker licenses issued to medical institutions that also hold nuclear medicine licenses under fee categories 7.A, 7.A.1, 7.A.2, 7.B., 7.B.1, 7.B.2, 7.C, 7.C.1, or 7.C.2.

[10] This includes Certificates of Compliance issued to the U.S. Department of Energy that are not funded from the Nuclear Waste Fund.

[11] See § 171.15(c).

[12] See § 171.15(c).

[13] No annual fee is charged for this category because the cost of the general license registration program applicable to licenses in this category will be recovered through 10 CFR part 170 fees.

[14] Persons who possess radium sources that are used for operational purposes in another fee category are not also subject to the fees in this category. (This exception does not apply if the radium sources are possessed for storage only.)

[15] Licensees subject to fees under categories 1.A., 1.B., 1.E., 2.A., and licensees paying fees under fee category 17 must pay the largest applicable fee and are not subject to additional fees listed in this table.

[16] Licensees paying fees under 3.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[17] Licensees paying fees under 7.C. are not subject to fees under 2.B. for possession and shielding authorized on the same license.

[18] Licensees paying fees under 3.N. are not subject to paying fees under 3.P., 3.P.1, or 3.P.2 for calibration or leak testing services authorized on the same license.

[19] Licensees paying fees under 7.B., 7.B.1, or 7.B.2 are not subject to paying fees under 7.C., 7.C.1, or 7.C.2 for broad scope license licenses issued under parts 30, 35, 40, and 70 of this chapter for human use of byproduct material, source material, and/or special nuclear material, except licenses for byproduct material, source material, or special nuclear material in sealed sources contained in teletherapy devices authorized on the same license.

[20] No annual fee is charged for a materials license (or part of a materials license) that has transitioned to this fee category because the decommissioning costs will be recovered through 10 CFR part 170 fees, but annual fees may be charged for other activities authorized under the license that are not in decommissioning status.

[21] Licensees paying fees under 4.A., 4.B. or 4.C. are not subject to paying fees under 3.N. licenses that authorize services for other licensees authorized on the same license.

(e) The fee-relief adjustment allocated to annual fees includes the budgeted resources for the activities listed in paragraph (e)(1) of this section, plus the total budgeted resources for the activities included in paragraphs (e)(2) and (3) of this section, as reduced by the appropriations the NRC receives for these types of activities. If the NRC's appropriations for these types of activities are greater than the budgeted resources for the activities included in paragraphs (e)(2) and (3) of this section for a given fiscal year, a negative fee-relief adjustment (or annual fee reduction) will be allocated to annual fees. The activities comprising the FY 2020 fee-relief adjustment are as follows:

* * * * *

■ 9. In § 171.17, revise paragraphs (a) introductory text and (a)(1) and (2) to read as follows:

§ 171.17 Proration.

* * * * *

(a) Reactors, 10 CFR part 72 licensees who do not hold 10 CFR part 50 or 10 CFR part 52 licenses, and materials licenses with annual fees of $100,000 or greater for a single fee category. The NRC will base the proration of annual fees for terminated and downgraded licenses on the fee rule in effect at the time the action is official. The NRC will base the determinations on the proration requirements under paragraphs (a)(2) and (3) of this section.

(1) *New licenses.* (i) The annual fees for new licenses for power reactors that are subject to fees under this part, for which the licensee has notified the NRC on or after October 1 of a fiscal year (FY) that the licensee has successfully completed power ascension testing, are prorated on the basis of the number of days remaining in the FY. Thereafter, the full annual fee is due and payable each subsequent FY.

(ii) The annual fees for new licenses for non-power reactors, 10 CFR part 72 licensees who do not hold 10 CFR part 50 or 10 CFR part 52 licenses, and

materials licenses with annual fees of $100,000 or greater for a single fee category for the current FY, that are subject to fees under this part and are granted a license to operate on or after October 1 of a FY, are prorated on the basis of the number of days remaining in the FY. Thereafter, the full annual fee is due and payable each subsequent FY.

(2) *Terminations.* The base operating power reactor annual fee for operating reactor licensees who have requested amendment to withdraw operating authority permanently during the FY will be prorated based on the number of days during the FY the license was in effect before docketing of the certifications for permanent cessation of operations and permanent removal of fuel from the reactor vessel or when a final legally effective order to permanently cease operations has come into effect. The spent fuel storage/reactor decommissioning annual fee for reactor licensees who permanently cease operations and have permanently removed fuel from the site during the FY will be prorated on the basis of the number of days remaining in the FY after docketing of both the certifications of permanent cessation of operations and permanent removal of fuel from the site. The spent fuel storage/reactor decommissioning annual fee will be prorated for those 10 CFR part 72 licensees who do not hold a10 CFR part 50 or 10 CFR part 52 license who request termination of the 10 CFR part 72 license and permanently cease activities authorized by the license during the FY based on the number of days the license was in effect before receipt of the termination request. The annual fee for materials licenses with annual fees of $100,000 or greater for a single fee category for the current FY will be prorated based on the number of days remaining in the FY when a termination request or a request for a possession-only license is received by the NRC, provided the licensee permanently ceased licensed activities during the specified period.

* * * * *

Dated: June 5, 2020.

For the Nuclear Regulatory Commission.

Cherish K. Johnson,

Chief Financial Officer.

[FR Doc. 2020–13031 Filed 6–18–20; 8:45 am]

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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, 447, et al.

Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 433, 438, 447 and 456

[CMS–2482–P]

RIN 0938–AT82

Medicaid Program; Establishing Minimum Standards in Medicaid State Drug Utilization Review (DUR) and Supporting Value-Based Purchasing (VBP) for Drugs Covered in Medicaid, Revising Medicaid Drug Rebate and Third Party Liability (TPL) Requirements

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would advance CMS' efforts to support state flexibility to enter into innovative value-based purchasing arrangements (VBPs) with manufacturers, and to provide manufacturers with regulatory support to enter into VBPs with payers, including Medicaid. To ensure that the regulatory framework is sufficient to support such arrangements and to promote transparency, flexibility, and innovation in drug pricing without undue administrative burden, we are proposing new regulatory policies and clarifying certain already established policies to assist manufacturers and states in participating in VBPs in a manner that is consistent with the law and maintains the integrity of the Medicaid Drug Rebate Program (MDRP). This proposed rule also proposes revisions to regulations regarding: Authorized generic sales when manufacturers calculate average manufacturer price (AMP); pharmacy benefit managers (PBM) accumulator programs and their impact on AMP and best price; state and manufacturer reporting requirements to the MDRP; new Medicaid Drug Utilization Review (DUR) provisions designed to reduce opioid related fraud, misuse and abuse; the definitions of CMS-authorized supplemental rebate agreement, line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, innovator multiple source drug for purposes of the MDRP; payments for prescription drugs under the Medicaid program; and coordination of benefits (COB) and third party liability (TPL) rules related to the special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program (CHIP).

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 20, 2020.

ADDRESSES: In commenting, please refer to file code CMS–2842–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2482–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2482–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Ruth Blatt, (410) 786–1767, for issues related to the definition of line extension, new formulation, oral solid dosage form, single source drug, multiple source drug, and innovator multiple source drug.

Cathy Sturgill, (410) 786–3345, for issues related to Third Party Liability.

Michael Forman, (410) 786–2666 and Whitney Swears (410) 786–6543 for issues related to Drug Utilization Review.

Christine Hinds, (410) 786–4578, for issues related to Value-based Purchasing.

Joanne Meneeley, (410) 786–1361, for issues related to State Drug Utilization Data (SDUD) certification.

Christine Hinds, (410) 786–4578, for issues related to Authorized Generics and Inflation Rebates.

Charlotte Amponsah (410) 786–1092, for issues related to Manufacturer-sponsored Patient Assistance Programs.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional benefit under section 1905(a)(12) of the Social Security Act (the Act). Section 1903(a) of the Act provides for federal financial participation (FFP) in state expenditures for these drugs. In the case of a state that provides for medical assistance for covered outpatient drugs, as provided under section 1902(a)(54) of the Act, the state must comply with the requirements of section 1927 of the Act. Section 1927 of the Act governs the Medicaid Drug Rebate program (MDRP) and payment for covered outpatient drugs (CODs), which are defined in section 1927(k)(2) of the Act. In general, for payment to be made available for CODs under section 1903(a) of the Act, manufacturers must enter into a National Drug Rebate Agreement (NDRA) as set forth in section 1927(a) of the Act. See also section 1903(i)(10) of the Act. The MDRP is authorized under section 1927 of the Act, and is a program that includes CMS, state Medicaid agencies, and participating drug manufacturers that helps to partially offset the federal and state costs of most outpatient prescription drugs dispensed to Medicaid beneficiaries. The MDRP provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, drug utilization reviews (DUR), and requirements for states for CODs.

The Covered Outpatient Drugs final rule with comment period (COD final rule) was published in the February 1, 2016 **Federal Register** (81 FR 5170) and became effective on April 1, 2016. The COD final rule implemented provisions of section 1927 of the Act that were added by the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively referred to as the Affordable Care Act) pertaining to Medicaid reimbursement for CODs. It also revised other requirements related to CODs, including key aspects of Medicaid coverage and payment and the MDRP under section 1927 of the Act. The regulations implemented through the COD final rule, and those proposed in this notice of proposed rulemaking are consistent with the Secretary's authority set forth in section 1102 of the Act to publish regulations that are necessary to the efficient administration of the Medicaid program.

A. Changes to Coordination of Benefits/Third Party Liability Regulation Due to Bipartisan Budget Act (BBA) 2018

Medicaid is the payer of last resort, which means that other available

resources—known as third party liability, or TPL—must be used before Medicaid pays for services received by a Medicaid-eligible individual. Title XIX of the Act requires state Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid. Section 53102 of the Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018) amended the TPL provision at section 1902(a)(25) of the Act. Specifically, section 1902(a)(25)(A) of the Act requires that states take all reasonable measures to ascertain legal liability of third parties to pay for care and services available under the plan. That provision further specifies that a third party is any individual, entity, or program that is or may be liable to pay all or part of the expenditures for medical assistance furnished under a state plan. Section 1902(a)(25)(A)(i) of the Act specifies that the state plan must provide for the collection of sufficient information to enable the state to pursue claims against third parties. Examples of liable third parties include: Private insurance companies through employment-related or privately purchased health insurance; casualty coverage resulting from an accidental injury; payment received directly from an individual who has voluntarily accepted or been assigned legal responsibility for the health care of one or more Medicaid recipients; fraternal groups, unions, or state workers' compensation commissions; and medical support provided by a parent under a court or administrative order.

Effective February 9, 2018, section 53102(a)(1) of the Bipartisan Budget Act of 2018 amended section 1902(a)(25)(E) of the Act to require a state to use standard coordination of benefits cost avoidance when processing claims for prenatal services which now included labor and delivery and postpartum care claims. Additionally, effective October 1, 2019, section 53102(a)(1) of the Bipartisan Budget Act of 2018 amended section 1902(a)(25)(E) of the Act, to require a state to make payments without regard to third party liability for pediatric preventive services unless the state has made a determination related to cost-effectiveness and access to care that warrants cost avoidance for 90 days.

Section 53102(b)(2) of the Bipartisan Budget Act of 2018 delays the implementation date from October 1, 2017 to October 1, 2019 of the Bipartisan Budget Act of 2013 provision, which allowed for payment up to 90 days after a claim is submitted that is associated with medical support enforcement instead of 30 days under previous law. Medical support is a form of child support that is often provided through an absent parent's employers health insurance plan.

Effective April 18, 2019, section 7 of the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16) amended section 202(a)(2) of the Bipartisan Budget Act of 2013 to allow 100 days instead of 90 days to pay claims related to medical support enforcement under section 1902(a)(25)(F)(i) of the Act.

B. Changes to the Calculation of Average Manufacturer Price (AMP) Regarding Authorized Generic Drugs Due to the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019

On September 27, 2019, the President signed into law the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Health Extenders Act) (Pub. L. 116–59), which made changes to sections 1927(k)(1) and 1927(k)(11) of the Act, revising how manufacturers calculate the average manufacturer price (AMP) for a covered outpatient drug, for which the manufacturer permits an authorized generic to be sold and redefines the definition of wholesaler. Manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own new drug application (NDA) approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall no longer include sales of these authorized generics in the calculation of AMP, regardless of the relationship between the brand name manufacturer and the manufacturer of the authorized generic.

Specifically, section 1603 of the Health Extenders Act, which is titled ''Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program; Excluding Manufacturers from Definition Of Wholesaler,'' amended the statute as follows:

- Section 1927(k)(1)(C) of the Act to replace the term ''Inclusion'' with ''Exclusion'' in the title and further amended subparagraph (C) to state that, in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under the manufacturer's new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.
- The definition of wholesaler at section 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

Typically, an authorized generic is a product that a manufacturer (primary manufacturer) allows another manufacturer (secondary manufacturer) to sell under the primary manufacturer's FDA approved NDA but under a different National Drug Code (NDC) number. The authorized generic is typically the primary manufacturer's brand product offered at a lower price point. Primary manufacturers may sell the authorized generic product to the secondary manufacturer they are allowing to sell an authorized generic of their brand product, and such sales are commonly referred to as transfer sales. Under the amendments made to section 1927 of the Act, a primary manufacturer that sells the authorized generic version of the brand drug to the secondary manufacturer can no longer include the price of the transfer sale of the authorized generic to the secondary manufacturer in its calculation of AMP for the brand product. The exclusion of these transfer sales from the primary manufacturer's brand drug AMP will likely result in higher AMPs for the brand drugs and a potential increase to a manufacturer's Medicaid drug rebates to states.

The amendments to section 1927 authorized under section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers must reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). To assist manufacturers, CMS provided guidance in Manufacturer Release #111 [1] and Manufacturer Release #112.[2] Furthermore, in accordance with 42 CFR 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

C. Changes as Result of the Bipartisan Budget Act of 2015

Under the Medicaid program, states may provide coverage of prescribed drugs as an optional service under section 1905(a)(12) of the Act. Section 1903(a) of the Act provides for FFP in state expenditures for these drugs. Section 1927 of the Act governs the MDRP and payment for CODs, which are defined in section 1927(k)(2) of the

[1] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-111.pdf.*

[2] *https://www.medicaid.gov/prescription-drugs/downloads/mfr-rel-112.pdf.*

Act. In general, for payment to be made available under section 1903(a) of the Act for CODs, manufacturers must enter into an NDRA as set forth in section 1927(a) and (b) of the Act. Section 1927 of the Act provides specific requirements for rebate agreements, drug pricing submission and confidentiality requirements, the formulas for calculating rebate payments, and requirements for states for CODs. Section 602 of the Bipartisan Budget Act of 2015 (BBA 2015) (Pub. L. 114–74, enacted November 2, 2015) amended section 1927(c)(3) of the Act to require that manufacturers pay additional rebates on their non-innovator multiple source (N) drugs if the average manufacturer prices of an N drug increase at a rate that exceeds the rate of inflation. This provision of BBA 2015 was effective beginning with the January 1, 2017 quarter, or in other words, beginning with the unit rebate amounts (URAs) that are calculated for the January 1 2017 quarter. This additional inflation adjusted rebate requirement for N drugs was discussed in Manufacturer Release Nos. 97 (Manufacturer Release 97) and 101(Manufacturer Release 101).

D. Current Medicaid Drug Rebate Program and Value-Based Purchasing Arrangements (VBP)

In the preamble of the COD final rule, in response to a comment (81 FR 5253), we recognized the importance of VBPs, especially when such arrangements benefit patients. We acknowledged that, given the uniqueness of each VBP arrangement, we had to consider how to provide more specific guidance on the matter, including how such arrangements affect a manufacturer's calculation of its best price and Medicaid drug rebate obligations. Thereafter, we released a state and manufacturer notice on July 14, 2016 (available at State Release 176 [3] and Manufacturer Release 99 [4]) to inform states and manufacturers on how to seek guidance from us on their specific VBP, as well as to encourage states to consider entering into VBP as a means to address high cost drug treatments.

Since the release, manufacturers and states have shown an increased interest in VBP as a possible option for better managing and predicting drug spending, which helps to assure that manufacturers have some vested interest in assuring positive patient outcomes from the use of their drugs. To this end, CMS has approved several state plan amendments submitted by states that allow states to negotiate supplemental rebates under CMS-authorized rebate agreements with drug manufacturers based on evidence or outcomes-based measures for a patient or beneficiary based on use of the drug. In addition, manufacturers have approached us with their issues and questions regarding the impact of various types of VBP proposals on their MDRP price reporting obligations (that is, AMP and best price), as well as the regulatory challenges they encounter when structuring and implementing VBP. Finally, manufacturers have noted MDRP reporting challenges with VBP programs, whose evidence or outcomes-based measures extend beyond 3 years, particularly given that manufacturers have limited ability to make changes to reporting metrics outside the 12-quarter MDRP reporting period. This proposed regulation would address some of the manufacturer concerns with regards to these MDRP requirements.

E. Definition of Line Extension, New Formulation, and Oral Solid Dosage Form for Alternative Unit Rebate Amount

Section 2501(d) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, enacted March 23, 2010), as amended by section 1206 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152, enacted March 30, 2010) (collectively referred to as the Affordable Care Act) added section 1927(c)(2)(C) of the Act effective for drugs paid for by a state on or after January 1, 2010. This provision establishes an alternative formula for calculating the URA for a line extension of a single source drug or innovator multiple source drug that is an oral solid dosage form. We refer to the URA calculated under the alternative formula as the ''alternative URA''. Additionally, the Affordable Care Act defined ''line extension'' to mean, with respect to a drug, a new formulation of the drug, such as an extended release formulation. Section 1927(c)(2)(C) of the Act was further amended by section 705 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) (Pub. L. 114–198, enacted July 22, 2016) to exclude from that definition an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation. The determination of whether a drug is excluded because it is an abuse deterrent formulation is explained in at Manufacturer Release 102.[5] The CARA amendment applies to drugs paid for by a state in calendar quarters beginning on or after the July 22, 2016 date of enactment of CARA (that is, beginning with 4Q 2016). Finally, section 1927(c)(2)(C) of the Act was further amended by section 53104 of the BBA of 2018, which provided a technical correction such that the rebate for a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form shall be the greater of either (1) the standard rebate (calculated as a base rebate amount plus an additional inflation-based rebate) or (2) the base rebate amount increased by the alternative formula described in section 1927(c)(2)(C)(iii)(I) through (III) of the Act. We refer to the additional inflation-based rebate as the ''additional rebate.'' Additionally, as we have previously used the term ''initial brand name listed drug'' in the ''Medicaid Program; Covered Outpatient Drugs'' proposed rule published in the February 2, 2012 **Federal Register** (77 FR 5318, 5323 through 5324) (hereinafter referred to as the February 2, 2012 proposed rule), the Covered Outpatient Drugs final rule with comment published on February 1, 2016 (81 FR 5197), and 42 CFR 447.509(a)(4)(iii) to refer to the initial single source drug or innovator multiple source drug, we continue to do so in this proposed rule. The BBA of 2018 amendment applies to rebate periods beginning on or after October 1, 2018.

We proposed a definition of ''line extension'' in the February 2, 2012 proposed rule (77 FR 5323 through 5324) and received numerous comments from stakeholders. In the COD final rule, we did not finalize the proposed definition and requested additional comments with a 60-day comment period that closed on April 1, 2016. The additional comments received, although instructive of the public's thoughts at the time, were not informed by the then-current statutory framework. Therefore, we did not finalize a definition of ''line extension'' in the April 1, 2019 final rule (84 FR 12132). We reiterated in the April 1, 2019 final rule that manufacturers are to rely on the statutory definition of ''line extension'' at section 1927(c)(2)(C) of the Act, and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension. We also stated that if we later decide to develop

[3] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-176.pdf.*

[4] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-099.pdf.*

[5] *https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/mfr-releases/mfr-rel-102.pdf.*

a regulatory definition of ''line extension,'' we would do so through our established Administrative Procedures Act (APA) compliant rulemaking process and issue a proposed rule. For the reasons discussed in section II.C. of this proposed rule, we are proposing definitions of ''line extension'', ''new formulation'', and ''oral solid dosage form''.

The line extension provision has been in effect since January 1, 2010, and the Drug Data Reporting for Medicaid (DDR) system was modified in 2016 to implement the data reporting requirements for line extensions. However, we have found that some manufacturers are unclear about their line extension reporting obligations, for example, whether a particular drug satisfies the statutory definition of line extension and the identification of the initial brand name listed drug. Therefore, in addition to proposing definitions of ''line extension'', ''new formulation'', and ''oral solid dosage form'', we are providing clarification below regarding manufacturers' reporting obligations.

Details regarding how to calculate the additional rebate (calculated as a percentage of AMP) and the alternative URA can be found in the ''Medicaid Program; Covered Outpatient Drug; Line Extension Definition; and Change to the Rebate Calculation for Line Extension Drugs'' final rule and interim final rule with comment period that was published in the April 1, 2019 **Federal Register** (84 FR 12133) (hereinafter referred to as the April 1, 2019 final rule). We note that under § 447.509(a)(4)(iii), manufacturers are required to calculate the alternative URA if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. As noted later in section II.C. of this proposed rule, although a drug that meets the definition of a line extension should be identified as such in DDR, a manufacturer is not required to calculate the alternative URA unless the manufacturer of the line extension also manufactures, or has a corporate relationship with the manufacturer of, the initial brand name listed drug.

To apply the alternative formula described in section 1927(c)(2)(C)(iii)(I) through (III) of the Act for each line extension and rebate period, the manufacturer must determine which NDC represents the initial brand name listed drug that will be used to calculate the alternative URA. First, the manufacturer must identify all potential initial brand name listed drugs by their respective NDCs by considering all strengths of the initial brand name listed drug in accordance with section 1927(c)(2)(C)(iii)(II) of the Act. Additionally, only those potential initial brand name listed drugs that are manufactured by the manufacturer of the line extension or by a manufacturer with which the line extension manufacturer has a corporate relationship should be considered. Then, the manufacturer must evaluate the additional rebate (calculated as a percentage of AMP) for each potential initial brand name listed drug. The potential initial brand name listed drug that has the highest additional rebate (calculated as a percentage of AMP) is the initial brand name listed drug that must be identified in DDR and used to calculate the alternative URA for the rebate period.

Section 1927(c)(2)(C)(i) of the Act requires the manufacturer to calculate the alternative formula for each quarter in order to determine the initial drug for each quarter that has the highest additional rebate (calculated as a percentage of AMP). Therefore, the manufacturer must re-evaluate the additional rebate (calculated as a percentage of AMP) for each potential initial brand name listed drug each quarter. Because the additional rebate (calculated as a percentage of AMP) for any potential initial brand name listed drug may change from one quarter to the next, the initial brand name listed drug used for the alternative URA calculation may also change from one quarter to the next. Additionally, the NDC for the initial brand name listed drug must be active in MDRP for the quarter, that is, an NDC that is produced or distributed by a manufacturer with an active NDRA and the NDC does not have a termination date that occurred in a rebate period earlier than the rebate period for which the calculation is being performed. Because drugs may come on and off the market, an initial brand name listed drug that was used to calculate the alternative URA for one quarter may not be active in MDRP for the next quarter. However, a different initial brand name listed drug may be active in MDRP and available to use to calculate the alternative URA for the next quarter.

F. Impact of Certain Manufacturer Sponsored Patient Assistance Programs (''PBM Accumulator Programs'') on Best Price and Average Manufacturer Price (AMP)

Manufacturer-sponsored patient assistance programs can be helpful to patients in obtaining necessary medications. However, pharmacy benefit managers (PBMs) contend that manufacturer-sponsored assistance programs steer consumers towards more expensive medications when there may be more cost saving options available to health plans. Therefore, as a cost saving measure, PBMs have encouraged health plans in some cases to not allow the manufacturer assistance provided under such programs to be applied towards a patient's health plan deductible for a brand name drug not on a plan's formulary. This proposed regulation would provide instruction to manufacturers on how to consider the implementation of such programs when determining best price and AMP for purposes of the MDRP.

G. State Drug Utilization Data (SDUD) Reported to Medicaid Drug Rebate Program

Section 1927(b)(2)(A) of the Act requires each State agency to report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each Medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary. In accordance with this requirement, states are required to send state drug utilization data (SDUD) using OMB-approved Rebate Invoice Form, the CMS–R–144 (the data fields and descriptions are included as Exhibit X in this proposed rule) to manufacturers and transmit a copy of this report to CMS.

While many states subject their SDUD on the CMS–R–144 to edits in order to uncover outliers/inaccuracies in the invoices to manufacturers before sending copies to CMS, some states send unedited copies of the SDUD to CMS, resulting in discrepancies that do not conform with the statutory requirement at section 1927(b)(2)(A) of the Act. The statute requires such reporting to be in a form consistent with a standard reporting format established by the Secretary, and we believe that such a copy means that the data submitted on the invoice (CMS–R–144) to the manufacturer must be accurate and identical to the report (copy) states send to CMS. Further, we expect that when states send SDUD updates or changes to manufacturers, they transmit those changes to us concurrently in a copy to CMS. However, in some cases,

states fail to submit these updates causing the data to be mismatched. This results in states not complying with section 1927(b)(2)(A) of the Act and CMS not having an accurate account of rebates billed in the MDRP.

H. Changes Related to the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

The epidemic of opioid overdose, misuse, and addiction is a critical public health issue that affects the lives of millions of Americans. Research shows the opioid overdose epidemic has a disproportionate impact on Medicaid beneficiaries and the consequences have been tragic. In 2017, 47,600 people in America died of an opioid overdose per the Centers for Disease Control and Prevention (CDC).[6] Inappropriate opioid prescribing can result in costly medical complications such as abuse, misuse, overdoses, falls and fractures, drug to drug interactions and neonatal conditions. The use of multiple opioids is associated with a higher risk of mortality, with mortality risk increasing in direct relation to the number of opioids prescribed concurrently.[7] [8] Beneficiaries who receive multiple opioids may lack coordinated care and are at higher risk for opioid overdose.[9] These complications are costly, preventable, and result in avoidable healthcare expenditures.[10] Moreover, according to the National Institute on Drug Abuse (NIDA), research suggests that misuse of prescription pain relievers may actually open the door to heroin use, as four in five new heroin users started out misusing prescription painkillers.[11]

Since 1993, section 1927(g) of the Act has required each state to develop a DUR program targeted, in part, at reducing abuse and misuse of outpatient prescription drugs covered under the State's Medicaid Program. The DUR program operates to assure that prescriptions are appropriate, medically necessary, and are not likely to result in adverse medical events. Each state DUR program consists of prospective drug use review, retrospective drug use review, data assessment of drug use against predetermined standards, and ongoing educational outreach activities.

Consistent with section 1927(g)(3)(D) of the Act, we require each state Medicaid Program to submit to us an annual report on the operation of its Medicaid DUR program with respect to the fee-for-service (FFS) delivery system, including information on prescribing patterns, cost savings generated by the state's DUR program, and the state's DUR program's overall operations, including any new or innovative practices. Additionally, § 438.3(s)(4) and (5) require state contracts with any managed care organization (MCO), prepaid inpatient health plan (PIHP) or prepaid ambulatory health plan (PAHP) that covers covered outpatient drugs to require the MCO, PIHP, or PAHP to operate a DUR program that complies with section 1927(g) of the Act and 42 CFR part 456, subpart K, and to submit detailed information about its DUR program activities annually. For the purposes of this proposed rule, managed care program (MCP) references MCOs, managed care entities (MCEs), PAHPs and PIHPs.

The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271, enacted October 24, 2018) (the SUPPORT for Patients and Communities Act) includes measures to combat the opioid crisis in part by reducing opioid related abuse and misuse by advancing treatment and recovery initiatives, improving prevention, protecting communities, and bolstering efforts to fight deadly illicit synthetic drugs. There are several Medicaid-related DUR provisions for FFS and MCP pharmacy programs contained within section 1004 of the SUPPORT for Patients and Communities Act. These provisions establish drug review and utilization standards in section 1902(a)(85) and (oo) of the Act to supplement existing requirements under section 1927(g) of the Act, in an effort to reduce opioid-related fraud, misuse and abuse. State implementation of these strategies was required by October 1, 2019, and states must include information about their implementation in their annual reports under section 1927(g)(3)(D) of the Act. In turn, the Secretary is required to report to Congress on the information submitted by the states, starting with information from states' FY 2020 reports.

Consistent with section 1927(g) of the Act, the SUPPORT for Patients and Communities Act has the goal of improving the quality of care received by Medicaid recipients by reducing their exposure to hazards resulting from the inappropriate prescribing, gross overuse, or inappropriate or medically unnecessary care. In this context, strategies to assure the appropriate use of opioids are now being implemented in clinical settings, health care systems and public health agencies. Efforts to prevent harms associated with overuse and misuse of opioids must be integrated to ensure patients are receiving appropriate standards of care. We recognize efforts involving multiple stakeholders are needed to address the opioid crisis, to assure the health and well-being of Medicaid beneficiaries, and decrease any related health care expenditures as well as for prevention of future epidemics. We are committed to ensuring there are basic minimum standards implemented through Medicaid DUR programs nationwide to help ensure that prescriptions are appropriate, medically necessary and align with current standards of care, under our authority to implement section 1927(g) of the Act and section 1004 of the SUPPORT for Patients and Communities Act.

I. Single Source Drug, Multiple Source Drug, Innovator Multiple Source Drug

Section 6(c) of the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, enacted April 18, 2019) modified the definitions in section 1927(k) of the Act for single source drug, multiple source drug, and innovator multiple source drug. In this proposed rule, we propose to revise the definitions of these terms at § 447.502 to reflect these statutory changes.

II. Provisions of the Proposed Regulations

A. Third Party Liability: Payment of Claims (§ 433.139)

In 1980, under the authority in section 1902(a)(25)(A) of the Act, we issued regulations at 42 CFR part 433, subpart D establishing requirements for state Medicaid agencies to support the coordination of benefits (COB) effort by identifying TPL. Effective February 9, 2018, section 53102(a)(1) of BBA 2018 amended section 1902(a)(25)(E) of the Act to require states to cost avoid claims

[6] *https://www.cdc.gov/drugoverdose/data/statedeaths.html.*

[7] Ray WA, Chung CP, Murray KT, Hall K, Stein CM. Prescription of Long-Acting Opioids and Mortality in Patients with Chronic Noncancer Pain. JAMA. 2016 Jun 14; 315(22):2415–23.

[8] Baumblatt JA, Wiedeman C, Dunn JR, Schaffner W, et al. High-risk use by patients prescribed opioids for pain and its role in overdose deaths. JAMA Intern Med. 2014 May; 174(5):796–801.

[9] Bonnie, Richard J., et al. Pain Management and the Opioid Epidemic: Balancing Societal and Individual Benefits and Risks of Prescription Opioid Use. The National Academies Press, 2017.

[10] Davis, Cory. ''Naloxone for Community Opioid Overdose Reversal.'' Naloxone for Community Opioid Overdose Reversal | Public Health Law Research, Public Health Law Research (PHLR), 22 June 2015, *http://phlr.org/product/naloxone-community-opioid-overdose-reversal.*

[11] ''Opioid Addiction 2016 Facts & Figures—ASAM Home Page.'' American Society of Addition Medicine, *www.asam.org/docs/default-source/advocacy/opioid-addiction-disease-facts-figures.pdf.*

(for example, when the state Medicaid agency has determined there is a legally liable third party responsible for paying the claim, it will reject (''cost avoid'') the claim) for prenatal care for pregnant women including labor and delivery and postpartum care, and to allow the state Medicaid agency 90 days instead of 30 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments. Effective April 18, 2019, section 7 of the Medicaid Services Investment and Accountability Act of 2019 amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments.

Section 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care. Specifically, we are proposing to delete § 433.139(b)(2). We are also proposing to revise § 433.139(b)(3)(i) by removing ''prenatal care for pregnant women, or'' from pay and chase services, and § 433.139(b)(3)(ii)(B) by removing ''30 days'' and adding ''100 days.''

B. Changes To Address Medicaid Access to Drugs Using Value-Based Purchasing Arrangements (VBP)

In the preamble of the COD final rule, in response to a comment in the COD final rule (81 FR 5253), we recognized the importance of VBP especially when such arrangements benefit Medicaid patients' access to drug treatments. We acknowledged that given the uniqueness of each VBP arrangement, we had to consider how to provide more specific guidance on the matter, including how such arrangements affect a manufacturer's best price and Medicaid drug rebate obligations. Thereafter, we released a state and manufacturer notice on July 14, 2016 (State Release 176 and Manufacturer Release 99) to inform states and manufacturers on how to seek guidance from us on their specific VBPs, as well as encourage states to consider entering into VBPs as a means to address high cost drug treatments.

Since those releases, manufacturers and states have shown an increased interest in VBP as a potential option for better managing and predicting drug spending, which helps to assure that manufacturers have some vested interest in assuring positive patient outcomes from the use of their drugs. However, some manufacturers hesitate to offer VBP arrangements to payers, including Medicaid, because of concerns that the existing Medicaid covered outpatient drug statute and applicable regulations do not specifically address, with respect to price reporting, the purchase or discounting of drugs based on evidence or outcomes-based measures. That is, CMS has not addressed the possible impact of offering VBP arrangements on manufacturer compliance with applicable MDRP price reporting obligations, including best price and AMP reporting.

The Administration supports VBP because it believes it will assist states with providing Medicaid patients access to needed therapies while providing a payment arrangement that allows the state flexibility, including an option to only pay when a therapy actually works. In order for such arrangements to work for Medicaid, we need to consider changes to MDRP regulations to both address manufacturers' concerns with offering Medicaid such innovative payment arrangements, while ensuring the required economies, efficiencies, and quality of care provided under the Medicaid program. If we do not consider such changes, manufacturers may be unwilling to offer VBP to Medicaid, which in turn will mean Medicaid will not have the advantage of accessing these arrangements for some of the drug therapies on the market that could replace other more expensive Medicaid services (such as hospital and physician-based services). In other words, by addressing a number of potential regulatory hurdles in a proposed regulation, states will be able to provide such methods and procedures relating to the utilization of, and payment for care and services as may be necessary to safeguard against unnecessary utilization of such care and services and assure that consistent with section 1902(a)(30)(A) of the Act, Medicaid payments are consistent with efficiency, economy, and quality of care.

One potential regulatory hurdle manufacturers have raised with us is best price reporting. Section 1927(c)(1)(C) of the Act defines best price in relevant part to mean with respect to a single source drug or innovator multiple source drug of a manufacturer *the lowest price available* from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States, with certain exclusions enumerated at sections 1927(c)(1)(C)(i)(I) through (VI) of the Act. One of the issues manufacturers face in determining best price with the advent of VBP arrangements is that a manufacturer's best price can be reset based upon the outcome of a drug treatment for one patient or one unit of the drug because of the VBP. When this occurs, the rebate due for that single use of the drug during a quarter that results in a negative outcome will reset the best price to a significantly lower amount, sometimes zero, prompting a significantly higher rebate (sometimes 100 percent of the drug's AMP).

This being the case, manufacturers have questioned how they should calculate best price and account for these units when an outcome of a VBP arrangement results in ''a lowest price available'' of zero or at a significant discount. Manufacturers have expressed concern to CMS that without further guidance from CMS in regulation regarding the determination of best price in this scenario, the manufacturer could be at risk of understating rebates and may potentially be subject to False Claims Act liability, a risk which further diminishes manufacturer interest in offering VBP payment arrangements in either the commercial or Medicaid market. In turn, this may hinder Medicaid access to the care and services provided as part of these VBP arrangements (for example, to gene therapies and potentially curative orphan drug treatments) that are available in the general population and that are consistent with efficiency, economy, and quality of care in accordance with section 1902(a)(30)(A) of the Act.

We believe this proposed rule proposes changes to the MDRP price reporting (in particular best price) to address the regulatory challenges manufacturers encounter when structuring and implementing VBP, and therefore, gives manufacturers the ability to offer these programs to commercial payers or Medicaid without the negative impact on best price or the potential for MDRP regulatory compliance.

Subpart I—Payment for Drugs

1. Definitions (§ 447.502)

a. Value-Based Purchasing Arrangement (VBP)

A VBP arrangement is not expressly defined or addressed in section 1927 of the Act or the MDRP implementing regulations. In order to address the issues noted above, we are proposing a definition of VBP to apply, as appropriate, in implementation of the MDRP.

More specifically, we are proposing to define VBP at § 447.502 to further clarify for manufacturers how discounts,

rebates, pricing etc. as a result of VBP arrangements should be accounted for in a manufacturer's determination of AMP and best price for an applicable covered outpatient drug.

At this time, manufacturers are permitted to make reasonable assumptions in the absence of applicable statute, regulation or guidance regarding how to treat pricing as a result of VBP. However, because of the uncertainty or lack of assurances as to the propriety of those reasonable assurances, we understand manufacturers may be discouraged from offering VBP to payers including Medicaid. Therefore, we propose to define VBP as an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes (but is not limited to):

- Evidence-based measures, which substantially link the cost of a drug product to existing evidence of effectiveness and potential value for specific uses of that product;
- Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in a patient or a population, or a reduction in other medical expenses.

We have observed that some examples of evidence or outcomes-based measures used by manufacturers in their VBP proposals may be derived by observing and recording the absence of disease over a period of time, reducing a patient's medical spending, or improving a patient's activities of daily living thus resulting in reduced non-medical spending. In response to the proposed definition of VBP, we welcome suggestions for other measures and a rationale for the suggested measures that could be used to reflect value from a drug therapy and considered as we develop a final definition. We also welcome suggestions as to how to interpret ''substantially'' as used in the definition. That is, how much of the drug product's final cost should be associated with the evidence or outcomes based measure in order for the arrangement to be considered a VBP (for example, a drug product cost with less than 90 percent of the discounts/rebates tied to the drug's performance not be considered a VBP arrangement).

b. Bundled Sale

As stated earlier, one of the issues manufacturers contend with in determining best price with the advent of VBP arrangements is that a manufacturer's best price can be reset based upon the outcome of a drug treatment for one patient or one unit of the drug because of the VBP arrangement. When this occurs, the rebate due for that single use of the drug during a quarter that results in a negative outcome will reset the best price to a significantly lower amount, sometimes zero, prompting a significantly higher rebate (sometimes 100 percent of the drug's AMP). We have received stakeholder comments and inquiries regarding how rebates or discounts as part of a VBP arrangement could be considered in a bundled sale when determining best price. Some manufacturers have made reasonable assumptions that such discounts, as a result of a VBP, should be considered part of a bundled sale as defined at § 447.502.

In the COD final rule, we defined bundled sale at § 447.502 as any arrangement regardless of physical packaging under which the rebate, discount, or other price concession is conditioned upon the purchase of the same drug, drugs of different types (that is, at the nine-digit national drug code (NDC) level) or another product or some other performance requirement (for example, the achievement of market share, inclusion or tier placement on a formulary), or where the resulting discounts or other price concessions are greater than those which would have been available had the bundled drugs been purchased separately or outside the bundled arrangement. Specifically, the discounts in a bundled sale, including those discounts resulting from a contingent arrangement, are allocated proportionally to the total dollar value of the units of all drugs or products sold under the bundled arrangement. Also, for bundled sales where multiple drugs are discounted, the current definition indicates that the aggregate value of all the discounts in the bundled arrangement must be proportionally allocated across all the drugs or products in the bundle. (See § 447.502; 81 FR at 5182.) We understand that based on the bundled sale definition, which provides that the rebate, discount or other price concession is conditioned upon the purchase of the same drug, drugs of different types, or another product or some other performance requirement, some manufacturers have made reasonable assumptions to take into account the discounts from a VBP arrangement that has a performance requirement when a measure (such as a performance-based measure) is not met. When manufacturers recognize the VBP arrangement as a bundled sale, the manufacturer, for example, may assume that the discount that resulted from a performance requirement of a single unit is distributed proportionally to the total dollar value of the units of all the drugs sold in the bundled arrangement. This smooths out the discount over all the units sold under the arrangement in the rebate period and does not reset the manufacturer's best price based upon the ultimate price of one unit of a drug.

For example, a manufacturer could structure a VBP arrangement such that to qualify for a patient outcome rebate, the bundled sale VBP arrangement requires the sale of 1,000 units of the same drug at $200 per unit, and if one patient fails to achieve an outcomes-based performance measure the manufacturer agrees to a $100 price concession on that one unit. In this example, because all of the drugs in the bundle were subject to the performance requirement, the manufacturer's scheme qualified as a bundled sale VBP arrangement, and thus, the manufacturer's rebate of $100 on that one unit would be allocated across all units in that bundled sale as follows:

1,000 units × $200 = $200,000 − $100 price concession = ($199,900/1,000 units) = $199.90

Best price could be set at $199.90 if that $100 rebate available in a qualifying bundled sale resulted in the lowest price available from the manufacturer, and not at $100 ($200/unit − $100).

We agree with the applicability of the bundled sale definition in this context because it will permit manufacturers to have a best price that is not based upon the failure of one patient taking the drug. Therefore, in order to facilitate the appropriate application of a bundled sale offered in the context of a VBP arrangement to the best price determination, we are proposing to revise the definition of bundled sale at § 447.502 to add paragraph (3) that states VBP arrangements may qualify as a bundled sale, if the arrangement contains a performance requirement such as an outcome(s) measurement metric. We expect manufacturers, consistent with the manufacturer recording keeping requirements at § 447.510(f), to maintain documentation of the arrangement to support their calculation of AMP and best price.

2. Definitions—Best Price (§ 447.505(a)) and Reporting of Multiple Best Prices, Adjustments to Best Price (§ 447.505(d)(3))

In the preamble to the Covered Outpatient Drug Final Regulation (81 FR 5253), we indicated that we recognized the value of pharmaceutical value based purchasing arrangements in the marketplace, and that we were

considering how to give specific guidance on this matter, including how such arrangements affect a manufacturer's ''best price.'' In addition to CMS, States, manufacturers, and commercial payers all have an interest in making new innovative therapies available to patients, and we have heard that there are challenges with the current interpretation of statutes and regulations with respect to how ''best price'' can affect the availability of value based purchasing arrangements. Because the statute was drafted more than 30 years ago, when such arrangements were not prevalent in the market, it is understandable that such interpretations by CMS to date regarding ''best price'' have been limited to one ''best price'' per drug.

The Medicaid statute defines best price in relevant part to mean, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, non-profit entity, or governmental entity within the United States, with certain exclusions enumerated at sections 1927(c)(1)(C)(i)(I) through (VI) of the Act. Historically, we have interpreted this language to result in only one best price per drug. The current Medicaid ''best price'' regulation at § 447.505 generally tracks the statutory language, but reads in relevant part that ''best price'' means, for a single source drug or innovator multiple source drug, the lowest price available from the manufacturer during the rebate period *in any pricing structure* (including capitated payments), in the same quarter for which the AMP is computed (emphasis added).

The current regulation is interpreted further in the preamble language to the COD final rule and MDRP releases where we have indicated that the lowest price available means ''actually realized'' by the manufacturer or the lowest price at which a manufacturer sells a [covered outpatient drug]—that is, one lowest price available per dosage form and strength of a drug. This interpretation results in setting a best price that is either at a greatly reduced price or possibly zero if a single dosage form or strength dispensed to one patient is subject to a full or very large rebate under a VBP arrangement. Thus, we need to reconcile the interpretation of the statute in regulation, which currently contemplates that for any quarter, the ''best price'' is a single price for each dosage form and strength of a drug that represents the actual revenue realized by the manufacturer for that drug—in any pricing structure offered by the manufacturer (such as capitated payments)—with the realities of the current evolving marketplace which contemplate that multiple prices could be made available by the manufacturer for a particular drug based on the drug's performance (such as the case with VBP arrangements that use evidence or outcomes-based measures) in a quarter.

In that regard, because VBP and other innovative payment arrangements sometimes result in various price points for a dosage form and strength of a single drug or therapy being available in a quarter, we are proposing to reflect this possibility in this proposed rule. Specifically, we are proposing that a single drug may be available at multiple price points, each of which may establish a ''best price'' based on the relevant or applicable VBP arrangement and patient evidence-based or outcome-based measures.

We believe we can do this because we previously interpreted the statutory definition of best price at § 447.505(a) to reference the best price ''in any pricing structure,'' contemplating the possibility of various pricing structures, such as capitated payments. With the new VBP pricing structures that are available in the marketplace, we believe it is appropriate and reasonable to propose to further interpret what pricing structures are available, and account for the new VBP pricing structures, which may introduce the offering of a drug at multiple price points. That is, we are proposing to expand our interpretation of ''in any pricing structure'' and also the term ''price available'' by proposing that the price realized in a VBP arrangement by the manufacturer when a measure is not met for a single patient would not reset the best price for the drug in the quarter. Rather, we propose that multiple prices could be realized by the manufacturer and when a price is realized as a result of a VBP pricing structure, multiple price points (price points as a result of a VBP and price points absent a VBP) may be reported for one dosage form and strength.

As an example, under VBP, the manufacturer would report a single best price for the drug for the quarter for sales of the drug in that quarter. In addition, the manufacturer would also report a distinct set of ''best prices'' that would be available based on the range of evidence-based or outcomes measures for that drug that are possible under the VBP arrangement. As an example, the manufacturer could offer varying rebates based on a patient's response after the drug is administered. The calculated MDRP rebate due to the state using the VBP best price would be a function of whether or not the Medicaid rebate is being paid on a unit of a drug dispensed to a Medicaid patient that participated in a VBP, and the level of rebate associated with that patient's outcome. The rebate paid for that patient would only represent the amount of rebate due to the state from the manufacturer for that patient, not all patients. That is, the rebate would be specific to that patient's outcome, as that price is the lowest price available from the manufacturer based on that patient's outcomes. Otherwise, the best price used in the Medicaid rebate formula would mirror the lowest price available absent a VBP arrangement.

Therefore, we are proposing to further interpret the regulatory language ''in any pricing structure'' to include VBP arrangements. Then, we are proposing to interpret the statutory and regulatory phrase ''lowest price available'' as used in the definition of best price, to permit, in the context of a VBP arrangement, to include a set of prices at which a manufacturer makes a product available based on that pricing structure. This being the case, we are proposing that the definition of best price be expanded at § 447.505(a) to provide that a lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of a VBP (as defined at § 447.502). We understand the operational challenges this may bring to MDRP systems and that it will take us time to make such system changes. We welcome comments on this proposal, its impact on the MDRP, the commercial market, and its operational implications. Specifically, we request comments regarding the potential impact of these changes on supporting payment innovation and health care quality. We also seek comments on steps which would be needed by manufacturers and states to implement these Best Price changes, including how states would track health outcomes for Medicaid beneficiaries to align with the outcomes developed in a private market VBP.

Also, to provide consistency between AMP and best price, as we did under the Medicaid Program; Covered Outpatient Drugs final rule with comment (81 FR 5170), we are proposing to revise § 447.505(d)(3) to make it consistent with § 447.504(f)(3). That is, § 447.504(f)(3) provides that the manufacturer must adjust the AMP for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices actually realized to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the

determination of AMP by statute or regulation. We propose to add a similar qualifying phrase at the end of § 447.505(d)(3) to state that the manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates, or other arrangements are not excluded from the determination of best price by statute or regulation. We believe this is consistent with the requirement at section 1927(c)(1)(C)(ii)(I) of the Act, which provides that best price shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates, and therefore, best price must account for these to the extent they are not excluded by statute or regulation.

C. Changes To Update Definitions To Reflect Recent Statutory Changes Made by Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, Enacted April 18, 2019), BBA 2018 and the Affordable Care Act

1. Definitions (§ 447.502)

a. Innovator Multiple Source Drug

The Medicaid Services Investment and Accountability Act of 2019 clarified the definition of innovator multiple source drug at section 1927(k) of the Act by removing the phrase ''an original new drug application'' and inserting ''a new drug application,'' removing ''was originally marketed'' and inserting ''is marketed,'' and inserting, '', unless the Secretary determines that a narrow exception applies (as described in § 447.502 of title 42, Code of Federal Regulations (or any successor regulation))'' before the period. Section 1927(k)(7)(A)(ii) of the Act now defines innovator multiple source drug to mean a multiple source drug that is marketed under a new drug application approved by the Food and Drug Administration (FDA), unless the Secretary determines that a narrow exception applies (as described in § 447.502 (or any successor regulation)). To align the regulatory definition with the definition in the statute, as clarified by the Medicaid Services Investment and Accountability Act of 2019, we are proposing to define innovator multiple source drug in § 447.502 as a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section or any successor regulation). It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

b. Line Extension and New Formulation

Section 1927(c)(2)(C) of the Act defines line extension to mean, for a drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse deterrent formulation is an extended release formulation. As discussed earlier in section I.E. of this proposed rule, we proposed to define line extension in the February 2, 2012 proposed rule, but did not finalize a definition in the COD final rule or the April 1, 2019 final rule. We reiterated in the April 1, 2019 final rule that manufacturers are to rely on the statutory definition of line extension at section 1927(c)(2)(C) of the Act, and where appropriate are permitted to use reasonable assumptions in their determination of whether their drug qualifies as a line extension (81 FR 5265).

After several years of experience with manufacturers self-reporting their line extensions, and numerous inquiries from manufacturers regarding the identification of drugs as line extensions, we have noted inconsistency among manufacturers in their identification of drugs as line extensions. In addition, we are concerned that manufacturers may have a financial incentive to be underinclusive in their identification of drugs as line extensions because a drug identified as a line extension may be subject to a higher rebate. We note that if manufacturers underreport their line extensions, rebates may be calculated incorrectly and underpaid.

We believe the line extension provision was codified in statute to assure that manufacturers are not circumventing rebate liability by creating a line extension drug and avoiding inflation-based additional rebates. In order to ensure that section 1927(c)(2)(C) of the Act is fully implemented and the universe of line extensions is identified consistent with our understanding of Congressional intent, we are proposing to provide further interpretation of the statute in this proposed rule.

As an initial matter, we are proposing that only the initial single source drug or innovator multiple source drug (the initial brand name listed drug) must be an oral solid dosage form. In the 2012 proposed rule (77 FR 5338, 5339), we proposed that both the initial brand name drug and the line extension drug had to be an oral solid dosage form. However, as noted above, we did not finalize a regulatory definition of line extension, and instructed manufacturers to make ''reasonable assumptions'' regarding whether a drug is a line extension (81 FR 5265). The statute states that the alternative calculation must be performed in the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form. Upon further evaluation of this statutory language, we believe that the statutory text can be reasonably construed to provide that only the initial single source drug or innovator multiple source drug must be an oral solid dosage form. We believe this interpretation is appropriate because the alternative construction (requiring both the line extension and the initial single source drug or innovator multiple source drug to be an oral solid dosage form) may inappropriately limit the universe of line extension drugs in a manner which would allow a manufacturer to circumvent rebate liability when creating a line extension and to potentially avoid inflation-based additional rebates, in cases where such rebates should apply. Therefore, we are proposing that when determining whether a drug is a line extension, only the initial single source drug or innovator multiple source drug must be an oral solid dosage form. That is, we are proposing that the line extension of the initial brand name listed drug does not need to be an oral solid dosage form. We believe this is consistent with the statutory language and will assist in appropriately identifying drugs that may be line extension drugs. Therefore, we are proposing to amend § 447.509(a)(4)(i) and (ii) to refer to ''a drug that is a line extension of a single source drug or an innovator multiple source drug provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form,'' and §§ 447.509(a)(4)(i)(A) and (a)(4)(ii)(A) to refer to ''a single source drug or an innovator multiple source drug'' in the regulatory text that describes the alternative rebate calculation.

In response to requests to provide more specific guidance on how to identify a line extension drug, we are proposing to define ''line extension'' and ''new formulation'' at § 447.502. Specifically, we are proposing that as provided in section 1927(c)(2)(C) of the

Act, the term ''line extension'' means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

Additionally, we are proposing to define ''new formulation'' to mean, for a drug, any change to the drug, provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug. New formulations, (for the purpose of determining if a drug is a line extension) would not include abuse deterrent formulations but would include, but would not be limited to: Extended release formulations); changes in dosage form, strength, route of administration, ingredients, pharmacodynamics, or pharmacokinetic properties; changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC); and combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device. We are requesting comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in DDR for purposes of calculating the alternative URA.

We note that under § 447.509(a)(4)(iii), manufacturers are required to calculate the alternative URA if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. Although a drug may satisfy the definition of line extension, and should therefore be identified in DDR as a line extension, a manufacturer is not required to calculate the alternative URA unless the manufacturer of the line extension also manufactures, or has a corporate relationship with the manufacturer of the initial brand name listed drug.

Based on the definition of line extension that was included in the Affordable Care Act, we believe that the statute gives us discretion and authority to interpret the term ''line extension'' broadly. We are expressly soliciting comments on our proposed definitions of ''line extension'' and ''new formulation,'' specifically on whether these terms should be interpreted more narrowly. Moreover, if stakeholders believe that a narrower interpretation is appropriate, we are soliciting comments on how to identify those drugs that constitute a line extension and a new formulation to apply the alternative URA calculation when required by statute.

i. Combination Drugs

The statutory definition of line extension does not expressly exclude combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device, and, as noted previously in this rule, our proposed definition of new formulation includes combination drugs provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug.

As noted in the COD final rule (81 FR 5197, 5265 through 5267), we received numerous comments regarding our proposal in the February 2, 2012 proposed rule to include combination drugs in the definition of line extension. In particular, commenters were concerned that our proposal required sharing of proprietary pricing information with competitors. We believe that the commenters' concerns have been mitigated by § 447.509(a)(4)(iii), which requires the additional rebate to be calculated only if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug. Therefore, we are clarifying that while our proposed definition of new formulation includes combination drugs, the alternative URA calculation is only required under § 447.509(a)(4)(iii) for a rebate period if the manufacturer of the line extension also manufactures the initial brand name listed drug or has a corporate relationship with the manufacturer of the initial brand name listed drug.

Furthermore, we note that in the event that the initial brand name listed drug is a combination drug, neither the statutory definition of line extension nor our proposed definitions of line extension or new formulation exclude new formulations of combination drugs. For example, if an initial brand name listed drug is a combination drug consisting of a previously approved drug plus a new molecular entity, and FDA subsequently approves a new drug consisting only of the new molecular entity, then we would consider the new drug to be a new formulation of the initial brand name listed drug because it would constitute a change to the initial brand name listed drug and contains at least one active ingredient in common with the initial brand name listed drug.

As stated previously, we believe we have the discretion and authority to include a broad range of drugs as a line extension, including combination drugs. However, we are also aware that some combination drugs appear to be slightly different than an existing drug while other combination drugs are very different drugs than the initial brand name listed drug. For example, if a new combination drug contains a new molecular entity in combination with a previously approved drug, the resultant new combination may appear to be very different from the initial brand name listed drug, however, we believe that it is a new formulation of an initial brand name listed drug. Conversely, we believe that a new combination of two previously approved drugs, or a combination of a previously approved drug and a non-drug product (for example, a dietary supplement or a device), may not be a significant alteration even though it also is a new formulation of an initial brand name listed drug. Given that different stakeholders have differing thoughts on what constitutes a new formulation of an initial brand name listed drug, and CMS is attempting to provide a reasonable interpretation of the statute to define or describe what constitutes a change that should be considered a new formulation, we are soliciting comments that may provide a way to define and identify those combination drugs that should be identified as line extensions while excluding those combination drugs that should not be so identified.

ii. New Strengths

In the COD final rule (81 FR 5267), we indicated that we do not consider new strengths of the same formulation of the initial brand name listed drug to be a line extension because section 1927(c)(2)(C) of the Act does not expressly contemplate that a new strength is a line extension. As noted previously in this proposed rule though, we did not finalize a regulatory definition of line extension, and instructed manufacturers to make ''reasonable assumptions'' regarding whether a drug is a line extension. As noted in section I.E. of this proposed rule, we are proposing to interpret the definition of line extension more broadly, which includes proposing a much broader definition of new formulation. The statutory definition of line extension does not expressly exclude a new strength of a drug, and we believe a change in strength is a relatively simple modification to a currently marketed product. Furthermore, changing the strength of an initial brand name listed drug allows a manufacturer to establish a new base date AMP, thereby avoiding inflation

based rebate liability, which may incentivize a manufacturer to change the strength of a drug that is losing its exclusivity or patent protection to prolong the lifecycle of the drug, preventing money saving generic substitution. Therefore, consistent with the intent of the statute, we believe that a new strength of a drug, produced or distributed at a later time than the initial strength(s), should be identified as a line extension and made subject to the line extension alternative URA calculation. Therefore, as noted in section I.E. of this proposed rule, our proposed definition of new formulation includes changes in strength.

iii. New Indication

In the February 2, 2012 proposed rule, we proposed that a drug approved with a new indication for an already approved drug would be a line extension (77 FR 5323). We received several comments stating that the proposal was not feasible because the approval of a new indication for an already approved drug may not result in a different drug product and it would not be logical that a drug is a line extension of itself. Additional comments noted that it is not possible to apply the alternative line extension calculation to rebate invoices for an NDC only for those claims that were prescribed the newly approved indication. We agree that if following the approval of a new indication a manufacturer markets its drug in such a way that it is not a separately identifiable drug product the alternative URA calculation would not apply. However, if following the approval of a new indication the manufacturer markets the drug in such a way that it is a separately identifiable drug product, we are proposing that the alternative URA calculation would apply. Thus, as discussed previously in this proposed rule, our proposed definition of new formulation includes changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC).[12] We are requesting comments about whether a drug approved with a new indication that is not separately identifiable should be considered a new formulation and, if so, how such a drug could be identified in DDR for purposes of calculating the alternative URA.

We believe that Congress included the alternative URA calculation for a line extension in order to address changes to a drug that allow a manufacturer to avoid inflation-based additional rebates by establishing a new market date and base date AMP for the drug. We agree with the comments suggesting that if there is a change to a drug but that drug is not separately identifiable, then it is not feasible for the manufacturer to identify the drug as a line extension and perform an alternative URA calculation.

c. Oral Solid Dosage Form

Oral solid dosage form is defined at § 447.502 to mean capsules, tablets, or similar drugs products intended for oral use as defined in accordance with FDA regulation at 21 CFR 206.3 that defines solid oral dosage form. As we now have more experience reviewing and dealing with the line extension provisions from the Affordable Care Act, we believe that manufacturers may not be interpreting the term oral solid dosage form consistently. To mitigate any potential confusion, we believe that manufacturers and other stakeholders would benefit from a more detailed definition. In this proposed rule, we are proposing to modify the definition of oral solid dosage form.

In the COD final rule (81 FR 5198), CMS interpreted an oral route of administration as any drug that is intended to be taken by mouth. Because there is potential confusion about whether a dosage form must be swallowed, or otherwise enter the gastrointestinal tract in order to be considered an orally administered dosage form, we are proposing to interpret that an oral form of a drug is one that enters the oral cavity. This includes, but is not limited to, a tablet or film administered sublingually and a drug that is orally inhaled. We believe that this interpretation provides greater clarity to stakeholders regarding what constitutes an oral form of a drug.

Additionally, we believe that manufacturers may not be interpreting the term solid dosage form consistently. To mitigate any potential confusion, we are proposing to interpret that a solid dosage form is a dosage form that is neither a gas nor a liquid.

The FDA regulation at 21 CFR 206.3 defines the term ''solid oral dosage form'' for the purpose of identifying drugs for which a code imprint is required to permit identification of the product. The phrase ''capsules, tablets or similar drugs products'' may not encompass the range of dosage forms that we believe should be considered for the application of the line extension provision in the Affordable Care Act. For example, a sublingual film is an oral solid dosage form; however, because of the physical attributes of the dosage form, there may not be a requirement to imprint an identifying code on the dosage form. Another example of an oral solid dosage form is a powdered drug administered by oral inhalation. Therefore, we are proposing to modify the definition of oral solid dosage form at § 447.502 to read that it is an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity. Additionally, an oral solid dosage form that incorporates a medical device would not be exempt from this definition solely due to the addition of a device to the oral solid dosage form. For example, if a manufacturer adds a device to a tablet, the new drug would not be exempt from being a line extension solely due to the addition of a device to the tablet.

d. Multiple Source Drug

The Medicaid Services Investment and Accountability Act of 2019 clarified the definition of multiple source drug in section 1927(k) of the Act by removing ''(not including any drug described in paragraph (5))'' and inserting '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),''. Section 1927(k)(7)(A)(i) of the Act now provides that the term multiple source drug means, with respect to a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act for which there is at least 1 other drug product which: Is rated as therapeutically equivalent (under FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations''), except as provided in section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined in section 1927(k)(7)(C) of the Act and as determined by FDA, and is sold or marketed in the United States during the period.

We are proposing to revise the definition of multiple source drug at § 447.502 to align with the statutory definition. Specifically, we are proposing to revise the definition of multiple source drug to mean, for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient

[12] An NDC comprises three segments. The first segment is a labeler code, associated with the labeler, the second segment is a product code, which in association with a specific labeler code identifies the product, and the third segment is a package code, which, in association with the preceding segments, identifies the package size and type. For purposes of reporting to the MDRP, FDA's 10-digit NDC must be converted to an 11-digit NDC. The 9-digit NDC cited here is a combination of the labeler code plus the product code. FDA requirements for an NDC are at 21 CFR 207.33.

drug under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all the following criteria:

- Is rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/*).
- Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by the FDA.
- Is sold or marketed in the United States during the period.

e. Single Source Drug

The Medicaid Services Investment and Accountability Act of 2019 clarified the definition of single source drug in section 1927(k) of the Act by removing the phrase ''an original new drug application'' and inserting ''a new drug application'', inserting '', including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under paragraph (4),'' after ''covered outpatient drug'', inserting ''unless the Secretary determines that a narrow exception applies (as described in § 447.502 of title 42, Code of Federal Regulations or any successor regulation))'' after ''under the new drug application'' and adding language to specify that such term also includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA. Section 1927(k)(7)(A)(iv) of the Act now defines a single source drug to mean a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in § 447.502 or any successor regulation) and the term includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA. To align the regulatory definition with the definition in the statute at section 1927(k)(7)(A)(iv) of the Act, as clarified by the Medicaid Services Investment and Accountability Act of 2019, we are proposing to revise the regulatory definition of single source drug at § 447.502. We are proposing to define single source drug in § 447.502 to mean a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in § 447.502 or any successor regulation) and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

e. CMS-Authorized Supplemental Rebate Agreements

States may enter into separate or supplemental drug rebate agreements as long as such agreements achieve drug rebates equal to or greater than the drug rebates set forth under the national drug rebate agreement. See section 1927(a)(1) of the Act. CMS approval to enter directly into such agreements with manufacturers is required under section 1927(a)(1) of the Act, and thus, states are required to use the state plan amendments process as a means to seek CMS authorization. Supplemental rebates must be considered a reduction in the amount expended under the State plan in the quarter for medical assistance as provided at section 1927(b)(1)(B) of the Act. See program guidance at *https://www.medicaid.gov/federal-policy-guidance/downloads/smd091802.pdf.*

The Affordable Care Act revised section 1927(b)(1)(A) of the Act to require that manufacturers provide rebates for covered outpatient drugs dispensed to individuals enrolled with a Medicaid MCO when the organization is responsible for coverage of such drugs. At that time, states had to re-assess whether or not to directly collect supplemental rebates related to covered outpatient drugs dispensed to Medicaid managed care enrollees if the MCO was responsible for such drug coverage. Some states required their MCOs to collect and share supplemental rebates under the CMS-authorized supplemental rebate agreement, while other states permitted their MCOs to negotiate their own rebates with manufacturers outside of the CMS-authorized supplemental rebate agreement, allowing the MCO to keep the savings generated by the supplemental rebates.

The Affordable Care Act amendment to section 1927(b)(1)(A) of the Act also prompted some manufacturers to make assumptions with regard to AMP and best price calculations. Specifically, manufacturers made assumptions that all supplemental rebates paid by manufacturers for prescriptions dispensed to Medicaid managed care enrollees should be excluded from the manufacturer's determination of AMP and best price. That included those rebates paid directly to Medicaid MCOs, even if those rebates were not a result of a CMS-authorized supplemental rebate agreement, and therefore, not shared with the state or eventually used to offset state drug expenditures prior to claiming Federal financial participation (FFP) from the federal government. Since CMS-authorized supplemental rebate agreement is not defined as it is used at §§ 447.504(c)(19) and (e)(9) and 447.505(c)(7), manufacturers assumed that any supplemental rebates paid based on dispensing to Medicaid managed care enrollees are always a part of a CMS-authorized supplemental rebate agreement with the states. However, rebates paid to Medicaid MCOs may be paid by manufacturers that are not part of a CMS-authorized rebate agreement and are not shared with the state to offset drug expenditures prior to claiming FFP. Therefore, in order to clarify that such rebates paid by manufacturers are not part of a state's CMS-authorized supplemental rebate agreement, we propose to define CMS-authorized supplemental rebate agreement to mean an agreement that is approved through a state plan amendment (SPA) by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers.

Furthermore, and consistent with section 1927(b)(1)(B) of the Act which provides that the amounts received by a State under subsection (a)(1) (Federal rebates) or an agreement under (a)(4) (the existing state rebates) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1) of the Act. The proposed definition further states that the revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal government.

D. Exclusion of Certain Manufacturer Sponsored Patient Assistance Programs (''PBM Accumulator Programs'') From Determination of Best Price (§ 447.505) and Average Manufacturer Price (AMP) (§ 447.504)

Manufacturers participating in the MDRP are required to report certain pricing information to the Secretary, including a covered outpatient drug's best price and AMP. Best price is defined at section 1927(c)(1)(C) of the Act to mean, with respect to a single source or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal, Food, Drug and Cosmetic Act), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or government entity within the United States, subject to certain exclusions. Section 1927(c)(1)(C)(ii) of the Act further defines the term best price to be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section). The definition of best price is further defined at § 447.505(a) and includes the lowest price available from the manufacturer during the rebate period to any provider, which is defined to mean a hospital, HMO, MCO, or entity that provides coverage or services to individuals for illnesses or injuries or providers services or items in the provision of healthcare. Paragraph (b) further indicates that best price includes all prices, including applicable discounts, rebates, or other transactions that adjust prices either directly or indirectly to the best price eligible entities in paragraph (a).

We have learned that some health plans (which meet the definition of provider when determining best price) are being instructed or encouraged by their pharmacy benefit managers (PBMs) to apply manufacturer sponsored patient assistance programs, such as patient copay assistance programs, to the benefit of the plan, instead of entirely to the patient. (Note that Medicaid patients are not eligible for these manufacturer patient assistance programs, but the administration of these programs by commercial health plans and PBMs can affect the rebates that the Medicaid program receives from the manufacturer-sponsor of these programs.)

For example, certain PBMs have instructed health plans to not allow the manufacturer copay assistance to be applied towards a patient's plan deductible for a brand name drug not on a plan's formulary. PBMs contend that such programs steer consumers towards more expensive medications when there may be more cost saving options, such as generic substitution. Therefore, PBMs offer health plans that are commonly referred to as PBM accumulator programs and tout them as cost saving measures. For instance, using a copayment assistance card program as an example, instead of applying the manufacturer sponsored patient assistance program in a manner that bestows the entire benefit of the program to the patient or consumer, and ensures no contingency on a purchase requirement, as applicable, the PBM (on behalf of the plan) identifies when a copayment card is used by a patient and adjusts the beneficiary's deductible only in instances when the out-of-pocket contribution is made by the beneficiary. As a result, the manufacturer assistance does not accrue towards a patient's deductible and the patient sometimes does not realize this until the manufacturer copayment assistance runs out and the patient receives a significantly larger bill for the drug. This results in the health plan delaying the application of its plan benefit to the patient to the detriment of the patient or consumer, thus generating savings for the plan. We provide an illustration below:

Example:

Assume:

$2500—Drug cost
$2500—Patient Deductible
$10,000—Copayment Assistance Program Maximum

Copay Assistance Program With No PBM Accumulator Program

In this scenario, the manufacturer's copayment assistance accrues to the benefit of the patient because the patient has a high deductible, which is what we believe the manufacturer intended. In such cases, it is clear that the manufacturer's program is directly assisting the patient's copayment/deductible costs.

TABLE 1—COPAY ASSISTANCE PROGRAM WITH NO PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$2000	$2000	$2000	$2000	$2000
Patient Pays	25	25	25	25	25	25
Manufacturer Pays	2475	475 deductible reached. Manufacturer only pays $475.	475	475	475	475

Copay Assistance Program With PBM Accumulator Program

In the PBM accumulator scenario, the PBM does not apply the manufacturer's copayment assistance to the deductible of the patient thus delaying the patient satisfying his/her deductible, which benefits the health plan. The patient usually is not aware of the change until he/she is subject to a larger cost share of the drug when the manufacturer's support copay benefit maximum is reached (see May column). At that time, the patient receives a significantly a larger bill.

TABLE 2—COPAY ASSISTANCE PROGRAM WITH PBM ACCUMULATOR PROGRAM

	Jan	Feb	Mar	Apr	May	June
Plan Pays	$0	$0	$0	$0	$0	$2000
Patient Pays	25	25	25	25	2400	500
Manufacturer Pays	2475	2475	2475	2475	100 manufacturer copay benefit max. reached.	0

As demonstrated by the example above, the health plan is benefiting from the manufacturer sponsored copay assistance program instead of the patient (consumer). However, manufacturers, in these instances, claim they are not aware of when these practices by the health plans take place, and therefore, make reasonable assumptions that their discount programs meet the criteria at § 447.505(c) that exclude such programs from best price.

Specifically, manufacturers make reasonable assumptions that their programs meet the best price exclusions listed in § 447.505(c)(8) through (12) which provide:

- Manufacturer-sponsored drug discount card programs, *but only to the extent that the full value of the discount is passed on to the consumer and the pharmacy, agent, or other entity does not receive any price concession.* § 447.505(c)(8).
- Manufacturer coupons to a customer redeemed by a consumer, agent, pharmacy, or another entity acting on behalf of the manufacturer; *but only to the extent that the full value of the coupon is passed on to the consumer, and the pharmacy, agent, or other entity does not receive any price concession.* § 447.505(c)(9).
- Manufacturer copayment assistance programs, *to the extent that the program benefits are provided entirely to the patient and the pharmacy, agent, or other entity does not receive any price concession.* § 447.505(c)(10).
- Manufacturer-sponsored patient refund or rebate programs, *to the extent that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent or other entity does not receive any price concession.* § 447.505(c)(11).
- Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the voucher or benefit of such program is not contingent on any other purchase requirement; *the full value of the voucher or benefit of such program is passed on to the consumer; and the pharmacy, agent or other entity does not receive any price concession.* § 447.505(c)(12).

However, we understand from some manufacturers that they do not monitor or place parameters around how the benefits of their manufacturer sponsored assistance programs are applied when an individual has health plan coverage. Therefore, we are proposing to revise these paragraphs to provide expressly that the exclusions discussed above apply only to the extent the manufacturer ensures the full value of the assistance or benefit is passed on to the consumer or patient. We believe manufacturers have the ability to establish coverage criteria around their manufacturer assistance programs to ensure the benefit goes exclusively to the consumer or patient. We note that nothing in this proposed change should be construed to contradict any OIG guidance. We welcome comments on this proposal.

The current list of prices excluded from best price as noted above also apply to AMP as specified in § 447.504(c) and (e). As stated in the COD final rule, in order to provide consistency between the AMP and best price sections, where applicable, and to help with streamlining and clarifying a manufacturer's price reporting responsibilities, the same methodology is applied to AMP (81 FR 5253), and for the same reasons already discussed above, we are making a corresponding proposal with respect to these exclusions in the context of AMP.

Accordingly, we are proposing to revise the determination of best price § 447.505 to add a requirement that manufacturers ensure that the benefits of their assistance programs as provided at § 447.505(c)(8) through (12) are provided entirely to the consumer and are proposing corresponding changes to the AMP regulations at § 447.504(c)(25) through (29) and (e)(13) through (17).

E. Authorized Generic Drugs (§§ 447.502, 447.504, 447.506)

The Continuing Appropriations Act of 2020, and Health Extenders Act of 2019 (Health Extenders Act) made changes to section 1927(k) of the Act, revising how manufacturers calculate the AMP for a covered outpatient drug for which the manufacturer permits an authorized generic to be sold. Manufacturers that approve, allow, or otherwise permit any drug to be sold under the manufacturer's own new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act shall no longer include those sales of these authorized generics in the calculation of AMP.

Specifically, section 1603 of Health Extenders Act, which is titled—*Excluding Authorized Generic Drugs from Calculation of Average Manufacturer Price for Purposes of the Medicaid Drug Rebate Program; Excluding Manufacturers from Definition of Wholesaler,* amended:

- Section 1927(k)(1)(C) of the Act to replace the term ''inclusion'' with ''exclusion'' in the title and further amended subparagraph (C) to read (emphasis added)—In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under *the manufacturer's* new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.
- The definition of wholesaler at section 1927(k)(11) of the Act to remove references to manufacturers from the definition of wholesaler.

The amendments to section 1927 of the Act authorized under section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers must reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). Furthermore, in accordance with 42 CFR 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

Therefore, in accordance with the statutory amendments to section 1927(k)(1)(C) and (k)(11) of the Act described above, we are proposing to revise §§ 447.502, 447.504, and 447.506 as they apply to AMP and authorized generic sales as follows:

- We are proposing to revise § 447.502 to change the definition of wholesaler to reflect the revised statutory definition of wholesaler at section 1927(k)(11) of the Act. Wholesaler has been revised to remove any reference to ''manufacturer(s)'' consistent with the changes to the definition of wholesaler made by section 1603(b) of the Health Extenders Act. We are proposing the term ''Wholesaler'' to mean a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.
- Since the definition of wholesaler at section 1927(k)(11) of the Act no longer includes manufacturers, we further propose to remove from the list of sales, nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP, sales to other manufacturers who act as wholesalers for drugs distributed to

retail community pharmacies at § 447.504(b)(2). The nominal price sales, and associated discounts, rebates, payments or other financial transactions included in AMP in accordance with § 447.504(d) (AMP for 5i drugs that are not generally dispensed through retail community pharmacies) do not change because the statute at 1927(k)(1)(C) only speaks to authorized generic sales from the manufacturer to wholesalers that distribute to retail community pharmacies.

• We propose to revise § 447.506, which provides specific requirements to manufacturers regarding the treatment of authorized generic drug sales when determining AMP and best price. For purposes of those calculations, the current regulation defines primary manufacturer as the manufacturer that holds the NDA of the authorized generic drug and the secondary manufacturer as the manufacturer that is authorized by the primary manufacturer to sell the drug, but does not hold the NDA. The regulation further requires that the primary manufacturer must include in its calculation of AMP its sales of authorized generic drugs that have been sold or licensed to a secondary manufacturer, acting as a wholesaler for drugs distributed to retail community pharmacies, or when the primary manufacturer holding the NDA sells directly to a wholesaler. The Health Extenders Act revised the definition of wholesaler at 1927(k)(11) of the Act by removing ''manufacturer'' and revised the determination of AMP at section 1927(k)(1)(C) of the Act by replacing the term ''inclusion'' with ''exclusion'' in the title and further amended paragraph (C) to state, in the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under *the manufacturer's* new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies. Therefore, we are proposing to revise § 447.506(b) to replace the word ''Inclusion'' with ''Exclusion'' in the first sentence and replace the second sentence in its entirety to state that the primary manufacturer (as defined at § 447.506(a)) must exclude from its calculation of AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies when reporting the AMP of the brand name drug.

More specifically, we are proposing that a separate AMP is determined for the brand drug, which shall be exclusive of any authorized generic sale, and a separate AMP shall be generated for the authorized generic. As discussed previously in this proposed rule, typically, an authorized generic is a product that a manufacturer (primary manufacturer) allows another manufacturer (secondary manufacturer) to sell under the primary manufacturer's FDA approved New Drug Application (NDA) but under a different National Drug Code (NDC) number. The authorized generic is typically the primary manufacturer's brand product offered at a lower price point. Primary manufacturers may sell the authorized generic product to the secondary manufacturer they are allowing to sell an authorized generic of their brand product, and such sales are commonly referred to as transfer sales. Primary manufacturers have included those transfer sales in the determination of the brand product's AMP. Under the amendments made to section 1927 of the Act, a primary manufacturer that sells the authorized generic version of the brand drug to the secondary manufacturer can no longer include the price of the transfer sale of the authorized generic to the secondary manufacturer in its calculation of AMP for the brand product. The exclusion of these transfer sales from the primary manufacturer's brand drug AMP will likely result in higher AMPs for the brand drugs and a potential increase to a manufacturer's Medicaid drug rebates to states. To assist manufacturers, we provided guidance in *Manufacturer Release #111* and Manufacturer Release #112. In turn, we received inquiries as to what is meant by ''In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under *the manufacturer's* new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be *exclusive* of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.'' Specifically, we received questions regarding when a primary manufacturer itself, or an affiliate of the manufacturer is also producing the authorized generic, and whether, such a case, constitutes ''a case of a manufacturer that approves, allows, or otherwise permits'' the drug to be sold under the manufacturer's NDA, such that the exclusion applies. And if not, whether the primary manufacturer may include the average price paid for the authorized generic when calculating AMP for the brand drug. We believe that irrespective of the relationship between the manufacturer of the brand drug, and the manufacturer of the authorized generic, if the primary manufacturer ''approves, allows, or otherwise permits'' is the drug to be sold under the primary manufacturer's NDA, then the AMP for the brand should be calculated separately from (not include) the sales of the authorized generic. That is, it would not matter whether the manufacturer being approved, allowed, or otherwise permitted to sell the drug under the primary manufacturer's NDA was the same, affiliated or non-affiliated.

Therefore, we are interpreting section 1927(k)(1)(C) of the Act, which provides that in the case of a manufacturer approves, allows, or otherwise permits any of its drugs to be sold under the same NDA, the AMP for that brand drug shall be exclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies, to mean a separate AMP should be calculated for each drug product—that is, one AMP for the brand drug, and one AMP for the authorized generic product, and the AMP for the brand drug should always exclude sales of the authorized generic product. This includes a situation when it is the same manufacturer making both the brand name drug and authorized generic, or if the drugs are being manufactured by different, but affiliated manufacturers or even non-affiliated manufacturers. We are proposing a policy that applies irrespsective of a specific brand manufacturer's sales arrangement.

The amendments made by section 1603 of the Health Extenders Act are effective October 1, 2019. Therefore, manufacturers are required to reflect the changes to the calculation of their AMPs for rebate periods beginning October 1, 2019 (reported to CMS no later than 30 days after the end of the rebate period). Furthermore, in accordance with § 447.510(b), manufacturers have 12 quarters from the quarter in which the data were due to revise AMP, if necessary.

F. Medicaid Drug Rebates (MDR) (§ 447.509)

Manufacturers that participate in the MDRP are required to pay rebates for covered outpatient drugs that are dispensed to Medicaid patients. The rebates are calculated based on formulas described in section 1927(c) of the Act. As described in section I. of this proposed rule, the BBA 2015 made revisions to the statutory rebate formula for covered outpatient drugs other than single source or innovator multiple source drugs. That is, section 602 of BBA 2015, amended section 1927(c)(3)

of the Act to require that manufacturers pay additional rebates on their covered outpatient drugs other than single source or innovator multiple source drugs (non-innovator multiple source (N) drugs) when the AMP of the N drug increases at a rate that exceeds the rate of inflation. The amendments made by section 602 of BBA 2015, were effective beginning with the January 1, 2017 quarter (that is, first quarter of 2017). The implementation of these amendments was discussed in Manufacturer Release 97 and Manufacturer Release 101.

Prior to the enactment of BBA 2015, the basic quarterly URA calculation for N drugs was equal to 13 percent of a drug's quarterly AMP. However, section 602(a) of BBA 2015 amended section 1927(c)(3) of the Act by adding an inflation-based additional rebate requirement to the URA for N drugs, which is similar to the additional rebate applied to single source (S) and innovator multiple source (I) drugs.

To calculate the additional rebate portion of the URA calculation for N drugs, section 602(a) of BBA 2015 amended section 1927 of the Act to establish a base AMP or base date AMP value for N drugs based, in part, upon each N drug's market date. In general, for N drugs marketed on or before April 1, 2013, the base date AMP is equal to the third quarter of 2014 and the Base CPI–U is the CPI–U for September 2014. For N drugs marketed after April 1, 2013, the base date AMP is equal to the AMP for the fifth full calendar quarter after which the drug is marketed as a drug other than a single source or innovator multiple source drug and the base CPI–U is equal to the CPI–U for the last month of the base AMP quarter.

We are proposing to revise § 447.509 to codify the rebate formulas in regulation. Specifically, we are proposing to revise paragraph (a)(6) to distinguish the basic rebate for N drugs from this additional rebate. In addition, we are proposing to add paragraph (a)(7) to expressly include the additional rebate calculation for N drugs. We are proposing that in addition to the basic rebate under paragraph (a)(6), for each dosage form and strength of a N drug, the rebate amount will increase by an amount equal to the product of the following: The total number of units of such dosage form and strength paid for under the State plan in the rebate period, and the amount, if any, by which the AMP for the dosage form and strength of the drug for the period exceeds the base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug. We also are proposing to add paragraph (a)(8) to capture the that the total rebate amount for noninnovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

In addition to the proposed regulatory changes related to section 602 of BBA 2015 amendments noted above, we also propose to amend § 447.509 at:

- Paragraph (a)(5) to specify that in no case will the total rebate amount exceed 100 percent of the AMP of the single source or innovator multiple source drug; and
- By adding paragraph (a)(9) to specify that in no case will the total rebate amount exceed 100 percent of the AMP of the noninnovator multiple source drug.
- We also added to paragraph (a)(7)(B) to state that the base date AMP has the meaning of AMP set forth in sections 1927(c)(2)(A)(ii)(II), 1927(c)(2)(B) and 1927(c)(3)(C) of the Act as the regulation did not provide a specific definition of base date AMP for calculating the additional rebate. We believe it is reasonable to include this in regulation in order to provide further clarity for manufacturers and states with regard to the calculation of the additional rebate, and to ensure the appropriate product data and pricing information is submitted to CMS.

G. Requirements for Manufacturers (§ 447.510)

In accordance with section 1927(b)(3) of the Act and the terms of the NDRA, manufacturers are required to report pricing information to CMS on a timely basis or face a penalty. Current regulations at § 447.510 implement the manufacturer price reporting requirements including the timing of revisions to pricing data. The current regulation at 42 CFR 447.510(b)(1) requires that the revision to pricing data be made within the 12 quarters from which the data were due, unless it meets one of the exceptions in paragraphs (i) through (v).

As previously discussed in section II.B. of this proposed rule, VBP has evolved into a possible option for states and manufacturers to help manage drug expenditures. Many VBP arrangements or pay-over-time models may be better suited for periods longer than 12 quarters, and manufacturers entering into such arrangements may need to adjust AMPs and best prices beyond the 12 quarters because the evidence-based or outcomes-based measures are being measured beyond a period of 12 quarters or a final installment payment is being made outside of the 12 quarters. With this evolution it has become apparent that certain manufacturer reporting requirements could be viewed as an impediment to adopting VBP arrangements. For instance, under current regulations, a manufacturer would not be able to account for any adjustments to prices that may occur outside of the 12 quarters because of VBP arrangements (or even pay-over-time models), as required.

The definition of AMP at section 1927(k)(1)(B)(ii) of the Act, indicates that any other discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to retail community pharmacies shall be included in AMP for a covered outpatient drug. The special rules in section 1927(c)(1)(C)(ii) of the Act define best price to be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates. Since manufacturers are required to report AMP and best price that capture these statutory required financial transactions, including such financial transactions (for example, rebates, incremental payments) that are a result of VBP arrangements or pay-over-time models, and such pricing structures may be designed to result in transactions taking place outside of the 3-year window, we are proposing to add § 447.510(b)(1)(vi) to specify an additional exception to the 12-quarter rule to account for the unique nature of VBP arrangements and pay-over-time models. Specifically, we are proposing that the manufacturer may make changes outside of the 12-quarter rule as a result of a VBP arrangement when the outcome must be evaluated outside of this 12-quarter period.

G. Requirements for States (§ 447.511)

Section 1927(b)(2)(A) of the Act requires that states be held responsible to report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each Medicaid managed care organization, and shall promptly transmit a copy of such report to the Secretary. The accuracy and timeliness of this SDUD report is important for the MDRP, other programs, and legislative efforts including, but not limited to:

• Actuarial and cost impact projections of legislative or regulatory changes to the MDRP;

• The calculation of Medicaid's portion of the branded prescription drug fee specified at section 9008 of the ACA); and

• Ongoing audits that demonstrate that some states still fail to bill rebates for physician-administered drugs (PADs), although it has been 13 years since the requirement began.

States are required to send invoices (CMS–R–144 Medicaid Drug Rebate Invoice) to each manufacturer in the MDRP for which payment was made on behalf of the state and federal government for the manufacturers' drugs, or in the case of MCOs, drugs dispensed to a beneficiary in a rebate period. States are required to send a copy of their SDUD (a summary report of their invoice utilization data) to CMS each quarter. If a state makes an adjustment to a rebate invoice, the state is required to send an updated SDUD to us in the same reporting period in which the manufacturer received the adjustment.

We have found that some states do not have sufficient edits in place to detect, reject and investigate SDUD outliers, which may distort the rebate amounts due by manufacturers. This results in states overbilling manufacturers and generating disputes on rebate invoices; imposing resource burdens on manufacturers, states, CMS, and other MDRP partners, as well as interrupting the payment of rebates to states and CMS. Many states seemingly fail to implement needed system edits to identify such disputes prior to billing manufacturers. Although both overbilling and underbilling must be disputed, manufacturers often neglect to dispute instances of rebate underbilling.

We have also found that many states do not send the same SDUD to CMS as they transmit to manufacturers. In fact, some states send us ''pre-edited'' SDUD, while the manufacturer's rebate invoice contains edited data. These practices do not comply with § 447.511(b), which requires that states submit the same SDUD to us on a quarterly basis that they transmit to the manufacturers. As we move to implement new systems, we expect to put in place data error screening to better reject or alert identified potential inaccuracies to SDUD. States should also be improving current systems and planning updates to future systems to better identify and correct inaccurate SDUD before reporting to manufacturers and CMS.

To better hold states accountable for their data integrity and to mitigate the effects of inaccurate and untimely SDUD, we are proposing to revise § 447.511. Specifically, we are proposing to revise paragraph (a) to specify that any subsequent updates or changes in the data on the CMS–R–144 must be included in the state's utilization data submitted to CMS. We are also proposing to revise paragraph (b) to state that, on a quarterly basis, the state must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers on the CMS–R–144, as specified in § 447.511(a). In addition, to conform to the statutory requirement at section 1927(b)(2)(A) of the Act, we are proposing to add in regulatory text that the state data submission will be due no later than 60 days after the end of each rebate period. In the event that a due date falls on a weekend or federal holiday, the submission will be due on the first business day following that weekend or federal holiday. We also propose that any adjustments to previously submitted data would be transmitted to the manufacturer and CMS in the same reporting period.

We are also proposing to add § 447.511(d) to specify that the state data must be certified by the state Medicaid director (SMD), the deputy state Medicaid director (DSMD), or an individual other than the SMD or DSMD, who has authority equivalent to an SMD or DSMD or an individual with the directly delegated authority to perform the certification on behalf of the individuals noted above.

We are also proposing to add § 447.511(e) to specify the state data certification language that must be included in the submission. That is, each data submission by a state must include the following certification language: I hereby certify, to the best of my knowledge, that the state's data submission is complete and accurate at the time of this submission, and was prepared in accordance with the state's good faith, reasonable efforts based on existing guidance from CMS, section 1927 of the Act and applicable federal regulations. I further certify that the state has transmitted data to CMS, including any adjustments to previous rebate periods, in the same reporting period as provided to the manufacturer. Further, the state certifies that it has applied any necessary edits to the data for both CMS and the labeler to avoid inaccuracies at both the NDC/line item and file/aggregate level. Such edits are to be applied in the same manner and in the same reporting period to both CMS and the manufacturer.

H. State Plan Requirements, Findings and Assurances (§ 447.518)

Traditionally, states have utilized the supplemental rebate agreement (SRA) pathway to secure additional rebates over and above the federal rebate required of manufacturers participating in the MDRP. In order to do so, the Secretary must authorize a state to enter directly into these agreements with a manufacturer in accordance with section 1927(a)(1) of the Act. In accordance with section 1927(a)(1) of the Act, we require states to submit a state plan amendment for a SRA which includes a template of the SRA providing the framework for the agreement the state has with the manufacturer. A CMS-authorized SRA provides the parameters the state and manufacturer agree upon regarding the supplemental rebates, most importantly, that such rebates are at least as large as the rebates required by the federal government in accordance with 1927(a)(4) of the Act.

To make new and expensive innovative drugs more available to Medicaid patients, states are permitted to use a SRA pathway to negotiate VBP agreements with manufacturers that are intended to be financially beneficial for Medicaid. As with a traditional SRAs, these VBP SRAs must be financially advantageous for states, but must also include an evidence or outcomes-based measure. As with any other SRA, states are required to seek a SPA approval for a VBP SRA in accordance with section 1927(a)(1) of the Act. Through the SRA SPA process, a state, when approved by CMS, can enter into VBP SRAs directly with manufacturer(s) for both FFS and MCO covered outpatient drug claims. Under the SRA VBP arrangement, the state may need set up processes to report the results of the evidence or outcomes-based measures of the patient back to the manufacturer. This could require the state to take on additional responsibilities and expense in order to eventually collect a rebate, such as tracking the patient, collecting data on the patient (such as the results of evidence or outcomes-based measures) or providing services to the patient.

We understand that more states want to develop their own VBP arrangements, but states want to better understand the challenges, resources and costs to structure these programs and make them successful. In addition, given that we have a significant interest in the success of these innovative VBP programs, as well as the nature of the drugs that are subject to these agreements, we have an interest in helping evaluate these programs' effectiveness. To accomplish

this, we want to create a mechanism to exchange information about state VBP programs. This approach is consistent with section 1902(a)(30)(A) of the Act which requires that methods and procedures be established relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care.

Therefore, in accordance with section 1902(a) of the Act, we propose that states provide to us specific data elements associated with these VBP SRAs to ensure that payments associated with Medicaid patients receiving a drug under a VBP structure are consistent with efficiency, economy, and quality of care. To that end, we propose adding § 447.511(d)(1) and (2) to specify that a state participating in a VBP arrangement report data as specified on a yearly basis, and within 60 days of the end of each year, including the following data elements:

- State.
- National Drug Code(s) (for the drugs covered under the VBP).
- Product FDA list name.
- Number of prescriptions.
- Cost to the state to administer VBP (for example, systems changes, tracking outcomes, etc.).
- Total savings generated by the supplemental rebate due to VBP.

We invite comments on this approach and are particularly interested in understanding from states the burden with such a proposal and from all commenters whether the data elements are appropriate and useful with the goals of the proposal that we have laid out above.

I. Drug Utilization Review (DUR) Program and Electronic Claims Management System for Outpatient Drug Claims (§§ 456.700 Through 456.725), Managed Care Standard Contract Requirements and Requirements for MCOs, PIHPs, or PAHPs That Provide Covered Outpatient Drugs (§ 438.3(s))

Section 1004 of the SUPPORT for Patients and Communities Act requires states to implement certain opioid-specific drug use review (DUR) standards within their fee-for-service (FFS) and managed care programs. These requirements supplement prior DUR standards under section 1927(g) of the Act. In Medicaid, DUR involves the structured, ongoing review of healthcare provider prescribing, pharmacist dispensing, and patient use of medication. DUR involves a comprehensive review of patients' prescription and medication data and dispensing to help ensure appropriate medication decision making and positive patient outcomes. Potentially inappropriate prescriptions, unexpected and potentially troublesome patterns, data outliers, and other issues can be identified when reviewing prescriptions through prospective DUR or retrospective DUR activities. In Prospective DUR, the screening of prescription drug claims occurs to identify problems such as therapeutic duplication, drug-disease contraindications, incorrect dosage or duration of treatment, drug allergy and clinical misuse or abuse prior to dispensing of the prescription to the patient. Retrospective DUR involves ongoing and periodic examination and reviews of claims data to identify patterns of inappropriate use, fraud, abuse, or medically unnecessary care and facilitates corrective action when needed. Often times, these activities are synergistic; information gleaned through retrospective DUR claim reviews can be used to shape effective safety edits that can be implemented through prospective DUR, better enabling prescribers and dispensers to investigate prescription concerns prior to dispensing the medication to the patient. From prospective alerts (which can incorporate information from the beneficiary's claims data), potential issues can be identified to help promote the appropriate prescription and dispensing of outpatient drugs to beneficiaries. DUR programs play a key role in helping health care systems understand, interpret, and improve the prescribing, administration, and use of medications.

Section 1902 of the Act, as amended by section 1004 of the SUPPORT for Patients and Communities Act, requires states to implement safety edits and claims review automated processes for opioids as DUR requirements. We interpret ''safety edits'' to refer to the prospective DUR review specified in section 1927(g)(2)(A) of the Act. These prospective safety edits provide for identifying potential problems at point of sale (POS) to engage both patients and prescribers about identifying and mitigating possible opioid misuse, abuse, and overdose risk at the time of dispensing. The POS safety edits provide real-time information to the pharmacist prior to the prescription being dispensed to a patient, but do not necessarily prevent the prescription from being dispensed. When a safety edit is prompted, the pharmacist receives an alert and may be required, as dictated by good clinical practice and predetermined standards determined by the state, to take further action to resolve the alert before the prescription can be dispensed.[13] A claims review automated process, which we interpret to refer to as a retrospective DUR review) as defined in section 1927(g)(2)(B) of the Act, provides for additional examination of claims data to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care. Retrospective reviews often involve reviews of patient drug and disease history generated from claims data after prescriptions have been dispensed to the beneficiary. For many retrospective reviews, in an effort to promote appropriate prescribing and utilization of medications, claims data is evaluated against state determined criteria on a regular basis to identify recipients with drug therapy issues, enabling appropriate action to be taken based on any issues identified. After these reviews, prescribers often have the opportunity to review prescriptions and diagnosis history and make changes to therapies based on the retrospective review intervention. Retrospective claims reviews provide access to more comprehensive information relevant to the prescriptions and services that are being furnished to beneficiaries and better enable and encourage prescribers and dispensers to minimize opioid risk in their patients, and assure appropriate pain care.

Many of the proposed safety edits and reviews described in this proposed rule are designed to implement requirements outlined in the SUPPORT for Patients and Communities Act. The purpose of these safety edits and claims reviews is to prompt prescribers and pharmacists to conduct additional safety reviews to determine if the patient's opioid use is appropriate and medically necessary. Provisions to address antipsychotic utilization in children and fraud and abuse requirements are also included in the SUPPORT for Patient and Communities Act and are measures designed to enhance appropriate utilization of medication. We recognize that the SUPPORT for Patients and Communities Act provides considerable flexibility for states to specify particular parameters of the safety edits, claims review automated processes, program for monitoring use of antipsychotic

[13] Prada, Sergio. (2019). Comparing the Medicaid Prospective Drug Utilization Review Program Cost-Savings Methods Used by State Agencies in 2015 and 2016. American Health and Drug Benefits. 12. 7–12.

medications in children, and process for identifying fraud and abuse. Additionally, we acknowledge that many states already have effective DUR processes and other controls in place, and that section 1902(oo)(1)(E) of the Act (as added by section 1004 of the SUPPORT for Patients and Communities Act) clarifies that states may meet new opioid-related requirements with such safety edits, claims review automated processes, programs, or processes as were in place before October 1, 2019. However, to ensure a consistent baseline of minimum national standards for these DUR activities, while preserving appropriate flexibility for the states to determine their particular parameters and implementation, we believe it is necessary under our authority to implement section 1927(g) of the Act, to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, to codify in regulation the proposed safety edits, claims review automated processes, program for monitoring antipsychotic medications in children, and fraud and abuse process requirements as described in this proposed rule. Accordingly, the provisions of this proposed rule would implement opioid-related requirements established in the SUPPORT for Patients and Communities Act and further implement requirements under section 1927(g) of the Act, in an effort to reduce prescription-related fraud, misuse and abuse.

In addition to codifying the SUPPORT for Patients and Communities Act requirements, we are proposing additional minimum DUR standards in this proposed rule that states would be required to implement as part of their DUR programs. Specifically, section 1927 of the Act provides for drug use review programs for covered outpatient drugs to assure that prescriptions (1) are appropriate, (2) are medically necessary, and (3) are not likely to result in adverse medical results. Accordingly, under our authority to implement section 1927(g) of the Act and consistent with the goals of the SUPPORT for Patients and Communities Act to assure the appropriate use of prescription opioids, we are proposing minimum standards for DUR reviews related to medication assisted treatment (MAT) and identification of beneficiaries who could be at high risk of opioid overdose for consideration of naloxone prescribing or dispensing.

We also are seeking comments on potential additional standards that we might implement through future rulemaking, to ensure minimally adequate DUR programs that help ensure prescribed drugs are: Appropriate, medically necessary, and not likely to result in adverse medical results. We are interpreting adverse medical results to include medication errors or medical adverse events, reactions and side effects. We anticipate that any such additional standards would be clinically based and scientifically valid and developed with state collaboration, standards development organizations, and entities that support Medicaid DUR programs, and would help ensure all states have established a reasonable and appropriate DUR program. Such proposed standards would align with current clinical guidelines and could address the following: Maintaining policies and systems to assist in preventing over-utilization and under-utilization of prescribed medications, establishing quality assurance measures and systems to reduce medication errors and adverse drug interactions, and improving medication compliance and overall well-being of beneficiaries. We are considering other mechanisms to encourage states to adopt additional DUR standards in a timely manner to respond to new and emerging issues in drug use, as the rulemaking process can be a lengthy process. For example, we are considering issuing possible future suggested ''best practices'' or guidance for states in advance of and in anticipation of rulemaking. We are seeking comments on the best processes for collaboratively developing future minimum DUR standards and are seeking comments from states and other stakeholders on potential approaches.

The early signs of the opioid crisis emerged years ago, with groundwork for the crisis being laid in the late 1990s, when providers began to prescribe opioid analgesics at greater rates, which led to widespread misuse and abuse of both prescription and illegal opioids. After what the CDC characterizes as a ''first wave'' of opioid deaths, a second wave followed in 2010, involving heroin, with a third wave beginning in 2013 involving overdoses from synthetic opioids.[14] CDC data indicate that from 1999 through 2017, almost 400,000 people died from an overdose involving any opioid, including prescription and illicit opioids.[15] In 2018, there was an additional 67,367 drug overdose deaths occurred in the United States. The age-adjusted rate of overdose deaths decreased by 4.6 percent from 2017 (21.7 per 100,000) to 2018 (20.7 per 100,000). Opioids—mainly synthetic opioids (other than methadone)—are currently the main driver of drug overdose deaths. Opioids were involved in 46,802 overdose deaths in 2018 (69.5 percent of all drug overdose deaths)[16] and two out of three (67.0 percent) opioid-involved overdose deaths involved synthetic opioids.[17]

In a 2016 informational bulletin titled, ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction'' CMS issued guidance to states to outline both how to help curb the opioid crisis,[18] and in 2019 guidance was issued on how states can use statutory authority to expand the treatment of pain through complementary and integrative approaches.[19] Another section of the SUPPORT for Patients and Communities Act, section 6032, has directed HHS to collaborate with the Pain Management Best Practices Inter-Agency Task Force (PMTF), to develop an Action Plan on payment and coverage in Medicare and Medicaid for acute and chronic pain, and substance use disorders, informed by a Request for Information and a public meeting held at CMS in September, 2019.[20] The Action Plan is related to CMS's Fighting the Opioid Crisis Roadmap, which describes our three-pronged approach to managing pain using a safe and effective range of treatment options that rely less on prescription opioids, expanding treatment for OUD, and using data to target prevention efforts and identify fraud and abuse.[21]

In 2018, the SUPPORT for Patients and Communities Act was passed as

[14] ''Understanding the Epidemic.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 19 Dec. 2018, *https://www.cdc.gov/drugoverdose/epidemic/index.html.*

[15] ''Understanding the Epidemic.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 19 Dec. 2018, *www.cdc.gov/drugoverdose/epidemic/index.html.*

[16] Hedegaard H, Miniño AM, Warner M. Drug Overdose Deaths in the United States, 1999–2018.pdf icon NCHS Data Brief, No 356. Hyattsville, MD: National Center for Health Statistics. 2020.

[17] Wilson N, Kariisa M, Seth P, et al. Drug and Opioid-Involved Overdose Deaths—United States, 2017–2018. MMWR Morb Mortal Wkly Rep 2020;69:290–297.

[18] ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.'' CMCS Informational Bulletin available at *www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.*

[19] ''Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management.'' CMCS Informational Bulletin at *https://www.medicaid.gov/sites/default/files/federal-policy-guidance/downloads/cib022219.pdf.*

[20] ''Request for Information for the Development of a CMS Action Plan to Prevent Opioid Addiction and Enhance Access to Medication-Assisted Treatment.'' CMCS request for information available at *https://www.cms.gov/About-CMS/Story-Page/Opioid-SUPPORT-Act-RFI.pdf.*

[21] ''CMS Roadmap: Fighting the Opioid Crisis.'' Available at *https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/Opioid-epidemic-roadmap.pdf.*

part of a bipartisan effort to address the opioid crisis, as well as the treatment of pain. The practice of chronic pain management and the opioid crisis have influenced one another as each has evolved in response to different influences and pressures. At the same time CMS seeks to implement these requirements, we want to ensure Medicaid beneficiaries with chronic pain can work with their health care providers to optimize function, quality of life, and productivity while minimizing risks for opioid misuse and harm such as addiction and overdose.[22] Therefore, we are considering appropriate approaches through which we could collaboratively develop future minimum DUR standards with involvement from states and other stakeholders, taking into account the need for administrative flexibility and adequate time for operational implementation, which could be implemented more quickly to respond to public health crises that may arise in the future on a more rapid timeframe. We are also considering posting DUR recommendations on our website or through guidance to States to allow quick dissemination of the information.

1. Minimum Standards for DUR Programs Under the SUPPORT for Patients and Communities Act and Section 1927 of the Act

In § 456.703, we are proposing to redesignate paragraph (h) as paragraph (i) and to add a new paragraph (h), specifying minimum standards for DUR programs. The proposed minimum standards in § 456.703(h)(1), discussed in greater detail below, would implement the amendments made by section 1004 of the SUPPORT for Patients and Communities Act and section 1927(g) of the Act and are intended to help ensure DUR programs continue to adapt and improve the quality of pharmaceutical care provided to beneficiaries in the face of evolving healthcare guidelines and technology practices.

We are proposing the provisions below for implementation of requirements in the SUPPORT for Patients and Communities Act[23] consistent with section 1927(g) of the Act. The proposed safety edits and claim reviews are intended to help protect beneficiaries from serious potential consequences of overutilization, including misuse, abuse, overdose, and increased side effects. In addition to the risk of abuse, misuse, and diversion, opioids can have side effects including respiratory depression, confusion, tolerance, and physical dependence.[24]

The Centers for Disease Control and Prevention has recommended, in 2016 guidance,[25] that primary care providers prescribing to adults in outpatient settings consider non-pharmacologic therapy and non-opioid pharmacologic therapy as the first-line treatment for chronic pain.[26] The CDC guideline defines chronic pain as ''pain continuing or expected to continue for greater than 3 months or past the time of normal tissue healing.'' Regarding chronic pain, CDC states clinicians should use caution when initiating prescribing opioids at any dosage, and should carefully reassess evidence of individual benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.[27] Caution is also recommended in prescribing opioids for acute pain, noting that long-term opioid use often begins with treatment of acute pain; when opioids are prescribed for non-traumatic, non-surgical acute pain, primary care clinicians should prescribe the lowest effective dose for the shortest duration possible—usually 3 days or less is sufficient and more than 7 days will rarely be needed.[28] Non-pharmacologic therapies pose minimal risks, and many of these treatments, when available and accessible—such as exercise therapy, physical therapy, and cognitive behavioral therapy (CBT) have been shown to effectively treat chronic pain associated with some conditions.[29] For example, exercise therapy can be effective in treating moderate pain associated with lower back pain, osteoarthritis, and fibromyalgia in some patients.[30]

In 2019 the Department of Health and Human Services' PMTF issued its report to HHS and Congress, *the Pain Management Best Practices Inter-Agency Task Force Report,* on best practices for the treatment of acute and chronic pain. The CDC has identified 50 million adults in the United States with chronic daily pain,[31] and the NIH states that chronic daily pain cost the nation between $560 billion and $635 billion annually.[32] [33] The PMTF final report emphasizes a person-centered approach to pain care that includes the use of individualized, multimodal treatment based on an effective pain treatment plan, and the PMTF identified and described five broad treatment categories: Medications, restorative therapies, interventional approaches, behavioral approaches, and complementary and integrative health that can be used through multidisciplinary care. In its report, the PMTF recognized that there have been ''unintended consequences that have resulted following the release of the CDC Guideline in 2016, which are due in part to misapplication or misinterpretation of the Guideline, including forced tapers and patient abandonment'' [34] and noted the ''CDC has also published a pivotal article in the New England Journal of Medicine on April 24, 2019, specifically reiterating that the CDC Guideline has

[22] Pain Management Best Practices Inter-Agency Task Force. ''Pain Management Best Practices.'' Available at *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

[23] *https://www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf.*

[24] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[25] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' *Centers for Disease Control and Prevention,* Centers for Disease Control and Prevention, 18 Mar. 2016, *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1er.html.*

[26] Dowell, D., Haegerich, T.M., Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States 2016, *Morbidity and Mortality Weekly Report* March 18, 2016: 65)1 [Accessed February 11, 2019 at *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm.*

[27] ''CDC Guidelines for Prescribing Opioids for Chronic pain. '' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[28] Dowell, D., Haegerich, T.M., Chou, R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States 2016, *Morbidity and Mortality Weekly Report* March 18, 2016: 65)1 [Accessed February 11, 2019 at *https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm*].

[29] For a review of the evidence base for CBT, see Ehde D.M., Dillworth, T.M. and Turner, J.A. Cognitive-Behavioral Therapy for Individuals with Chronic Pain: Efficacy, Innovations, and Directions for Research. *American Psychologist,* 69(2); 153–166.

[30] Additional information on non-opioid treatments for chronic pain are available at *https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf.*

[31] ''Managing Chronic Pain.'' *Centers for Disease Control and Prevention,* Centers for Disease Control and Prevention, 18 Dec. 2019, *www.cdc.gov/learnmorefeelbetter/programs/chronic-pain.htm.*

[32] Gaskin, Darrell J. ''The Economic Costs of Pain in the United States.'' *Relieving Pain in America: A Blueprint for Transforming Prevention, Care, Education, and Research.,* U.S. National Library of Medicine, 1 Jan. 1970, *www.ncbi.nlm.nih.gov/books/NBK92521/.*

[33] ''Prevalence of Chronic Pain and High-Impact Chronic Pain Among Adults—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 16 Sept. 2019, *www.cdc.gov/mmwr/volumes/67/wr/mm6736a2.htm.*

[34] Additional information on non-opioid treatments for chronic pain are available at *https://www.cdc.gov/drugoverdose/pdf/nonopioid_treatments-a.pdf.*

been, in some instances, misinterpreted or misapplied.'' [35] HHS recently issued the *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics,* to assure proper tapering and discontinuation of long-term opioids, in part to avoid harms and encourage person-centered care that is tailored to the specific needs and unique circumstances of each pain patient,[36] in addition to the CMS-issued guidance to states in 2016 and 2019 to both outline how to help curb the opioid crisis and provide guidance to states that want to expand care for the treatment of pain.[37] [38]

Accordingly, we are proposing to add § 456.703(h)(1)(i) to include minimum standard requirements as described in this proposed rule, with the detailed design and implementation specifications left to the state's discretion to meet state-specific needs. The purpose of these proposed safety edits (specifically, safety edits to implement state-defined limits on initial prescription fill days' supply for patients not currently receiving opioid therapy, quantity, duplicate fills, and early refills) and reviews is to further implement section 1927(g) of the Act to prevent and reduce the inappropriate use of opioids and potentially associated adverse medical events to sufficiently address the nation's opioid overdose epidemic, consistent with the provisions under section 1004 of the SUPPORT for Patients and Communities Act.

When implementing the SUPPORT for Patients and Communities Act, we propose the following safety edits in § 456.703(h)(1)(i) in addition to a comprehensive opioid claims review automated retrospective review process where trends witnessed in safety edits can be reviewed and investigated. These reviews will allow subsequent appropriate actions to be taken as designed by the states.

a. Opioid Safety Edits Including Initial Fill Days' Supply for Opioid-Naïve Beneficiaries, Quantity, Therapeutically Duplicative Fills, and Early Refill Limits

The SUPPORT for Patients and Communities Act requires states to have in place prospective safety edits (as specified by the state) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the state.[39] As discussed in detail below, consistent with the SUPPORT for Patients and Communities Act and DUR requirements under section 1927(g)(2)(A) of the Act, we are proposing that state-identified limitations must include state-specified restrictions on initial prescription fill days' supply for patients not currently receiving opioid therapy; quantity limits for initial and subsequent fills, therapeutically duplicative fills, and early fills on opioids prescriptions; and a claims review automated process that indicates prescription fills of opioids in excess of these limitations to provide for the ongoing periodic reviews of opioids claim data and other records in order to identify patterns of fraud, abuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization among physicians, pharmacists and individuals receiving Medicaid benefits. To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require these safety edits to reinforce efforts to combat the nation's opioid crisis and ensure DUR opioid reviews are consistent with current clinical practice. These proposed safety edits are intended to protect Medicaid patients from serious consequences of overutilization, including overdose, dangerous interactions, increased side effects and additive toxicity (additive side effects). In addition, overutilization of opioids may serve as an indication of uncontrolled disease and the need of increased monitoring and coordination of care.

(i) Limit on Days' Supply for Opioid Naïve Beneficiaries

To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states to establish safety edit limitations on the days' supply for an initial prescription opioid fill for beneficiaries who have not filled an opioid prescription within a defined time period to be specified by the state. In most cases, ''Days Supply'' is calculated by dividing the dispensed quantity of medication by the amount of the medication taken by the patient in one day per the prescriber's instructions. ''Days' Supply'' means how many days the supply of dispensed medication will last. This limit would not apply to patients currently receiving opioids and is meant for beneficiaries who have not received opioids within this specified time period (as defined and implemented by the state). The patients who have not received opioids within a specified timeframe are referred to as opioid naïve and would be subjected to the days' supply limit on the opioid prescription. While the SUPPORT for Patients and Communities Act mentions limits on subsequent fills of opioids, consistent with section 1927(g) of the Act, we are proposing this edit on initial fills of opioids to help avoid excessive utilization by opioid naïve beneficiaries, with its attendant risk of adverse effects.

The CDC Guideline recommends that opioids prescribed for acute pain in outpatient primary care settings to adults generally should be limited to 3 days or fewer, and more than a 7 days' supply is rarely necessary.[40] Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred [for chronic pain] and should be considered by practitioners and patients prior to treatment with opioids.[41] Clinical evidence cited by the CDC review found that opioid use for acute pain is associated with long-term opioid use, and that a greater amount of early opioid exposure is associated with greater risk for long-term use. An expected physiologic response in patients exposed to opioids for more than a few days is physical dependence and the chances of long-term opioid use begin to increase after just 3 days of use and rise rapidly thereafter.[42] The CDC

[35] Dowell D., Haegerich T.M., Chou R. No shortcuts to safer opioid prescribing. N Engl J Med 2019; 380: 2285–2287.

[36] HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics. Oct. 2019, *www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf.*

[37] ''Best Practices for Addressing Prescription Opioid Overdoses, Misuse and Addiction.'' CMCS Informational Bulletin available at *www.medicaid.gov/federal-policy-guidance/downloads/CIB-02-02-16.pdf.*

[38] ''Medicaid Strategies for Non-Opioid Pharmacologic and Non-Pharmacologic Chronic Pain Management.'' CMCS Informational Bulletin at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib022219.pdf*).

[39] Section 1902(oo)(1)(A)(i)(I) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[40] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[41] Ibid.

[42] Shah A., Hayes C.J., Martin B.C. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use—United States, 2006–2015. Morbidity and Mortality Weekly Report 2017; 66:265–269 [Accessed February 11, 2019 at *http://dx.doi.org/10.15585/mmwr.mm6610a1*].

Guideline mentions that more than a few days of exposure to opioids significantly increases hazards, that each day of unnecessary opioid use increases likelihood of physical dependence without adding benefit, and that prescriptions with fewer days' supply would minimize the number of pills available for unintentional or intentional diversion.[43]

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids.[44] Limiting days for which opioids are prescribed for opioid naïve patients could minimize the need to taper opioids to prevent distressing or unpleasant withdrawal symptoms and help prevent opioid dependence, the risk of which is associated with the amount of opioid initially prescribed.[45]

On state DUR surveys many states indicated they already have initial fill limitations in place describing the limitations of 100 dosage units or a 34 days supply. Initial opioid analgesic prescriptions of less than or equal to 7 days' duration appear sufficient for many pain patients seen in primary care settings.[46] We note that in its 2019 clarification of the Guideline, the CDC noted that it was ''intended for primary care clinicians treating chronic pain for patients 18 and older, and examples of misapplication include applying the Guideline to patients in active cancer treatment, patients experiencing acute sickle cell crises, or patients experiencing post-surgical pain.'' States can consider the current CDC Guideline and other clinical guidelines when implementing initial fill limitations, being mindful of the context in which such guidelines are written (for example, acute pain, chronic pain, treatment setting, population, etc.).

The CDC Guideline states primary care clinicians should assess benefits and harms of opioids with patients early on when starting opioid therapy for chronic pain and regularly when escalating doses and continue to evaluate therapy with patients on an ongoing basis. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioid therapy. Consistent with the foregoing clinical recommendations, we are proposing to require states to implement safety edits aligned with clinical guidelines alerting the dispenser at the POS when an opioid prescription is dispensed to an opioid naïve patient that exceeds a state-specified days' supply limitation. In consideration of clinical recommendations to limit opioid use to the shortest possible duration and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing in § 456.703(h)(1)(i)(A) to require states to implement a days' supply limit when an initial opioid prescription is dispensed to a patient not currently receiving ongoing therapy with opioids.

(ii) Opioid Quantity Limits

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states establish safety edits to implement quantity limits on the number of opioid units to be used per day, as identified by the state. We propose that states take clinical indications and dosing schedules into account when establishing quantity limits to restrict the quantity of opioids per day to ensure dose optimization and to minimize potential for waste and diversion. While the SUPPORT for Patients and Communities Act mentions quantity limits on subsequent fills of opioids, consistent with section 1927(g) of the Act, we are proposing this edit to apply with respect to initial and subsequent fills of opioids to avoid excessive utilization, with its attendant risk of adverse effects.

We propose that the quantity limits would be required to take into account both dosage and frequency, to allow for dose optimization of pills, capsules, tablets, etc. (pills) and limit the supply of opioids being dispensed. Dose optimization is a method to consolidate the quantity of medication dispensed to the smallest amount required to achieve the desired daily dose and/regimen. Dosage optimization seeks to prospectively identify patients who have been prescribed multiple pills, capsules and/or tablets (''pills'') per day of a lower strength medication meant to be taken together to achieve higher dose, when a higher strength of medication already is available, and provides clinicians a tool to switch these patients to a regimen that is an equivalent daily dose given as a single pill (or a smaller quantity of pills). Performing this intervention with medications that are available in multiple strengths, with comparable pricing among these strengths, can yield significant drug cost savings. In addition, dose-optimization yields simplifies dosing schedules, decreases pill burdens, improves treatment compliance and limits the number of excess units available for diversion.[47] This proposed safety edit would allow most patients to achieve pain relief while minimizing patient pill burdens and unnecessary unused opioids.[48] When implementing this edit we expect states to also consider current opioid guidelines, clinical indications, and dosing schedules of opioids to ensure prescriptions are appropriate, medically necessary, and not likely to result in adverse events.

Decreasing the initial amount prescribed will lower the risk that patients develop an addiction to these drugs and transition to chronic use or misuse.[49] A survey of adults in Utah estimated that in the previous 12 months, 1 in 5 state residents were prescribed an opioid medication and 72 percent had leftover pills and nearly three-quarters of those with leftover pills kept them.[50] Leftover medications are an important source of opioids that are misused or diverted.[51] We believe that decreasing the initial amount prescribed will lower the risk that patients develop opioid use disorder.[52]

[43] Ibid.

[44] ''CDC Guideline for Prescribing Opioids for Chronic Pain.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[45] Shah A, Hayes CJ, Martin BC. Characteristics of initial prescription episodes and likelihood of long-term opioid use—United States, 2006–2015. *MMWR Morb Mortal Wkly Rep.* 2017;66(10):265–269. doi:10.15585/mmwr.mm6610a1.

[46] ''Days' Supply of Initial Opioid Analgesic Prescriptions and Additional Fills for Acute Pain Conditions Treated in the Primary Care Setting—United States, 2014 | MMWR.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, *https://www.cdc.gov/mmwr/volumes/68/wr/mm6806a3.htm.*

[47] Calabrese D., Baldinger S., Dose Optimization Intervention Yields Significant Drug Cost Savings. *https://www.jmcp.org/doi/pdf/10.18553/jmcp.2002.8.2.146.*

[48] Daoust R. Limiting Opioid Prescribing. *JAMA.* 2019; 322(2):170–171. doi:10.1001/jama.2019.5844.

[49] Ibid.

[50] Ibid.

[51] ''FDA Patient Education Campaign Targets Opioid Diversion, Disposal.'' Available at *https://patientengagementhit.com/news/fda-patient-education-campaign-targets-opioid-diversion-disposal.*

[52] Opioid Use During the Six Months After an Emergency Department Visit for Acute Pain: A Prospective Cohort Study. Friedman, Benjamin W. et al. Annals of Emergency Medicine, Volume 0, Issue 0.

Prescribing opioids using lowest dosage at fewest possible units dispensed based on product labeling, and matching duration to scheduled reassessment, helps reduce the quantity of unused, leftover opioid pills. Additionally, clinicians should continue to evaluate benefits and harms of continued ongoing therapy with opioid patients every 3 months or more frequently.[53] If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids.[54] In consideration of clinical recommendations to limit opioid units to the fewest number possible and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse events, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(i)(B) that states be required to implement quantity limits on opioids prescriptions (both initial and subsequent fills) to help identify abuse, misuse, excessive utilization, or inappropriate or medically unnecessary care.

iii. Therapeutic Duplication Limitations

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states to establish safety edits to alert the dispenser to potential therapeutic duplication before a prescription is filled for an opioid product that is in the same therapeutic class as an opioid product currently being prescribed for the beneficiary. Prescriptions for multiple opioids and multiple strengths of opioids increase the supply of opioids available for diversion and abuse, as well as the opportunity for self-medication and dose escalation.[55] Some patients, especially those living with multiple chronic conditions, may consult multiple physicians, which can put them at risk of receiving multiple medications in the same therapeutic class for the same diagnosis.[56] In some instances, the side-effects produced by overmedication, due to the duplication of prescriptions within the same therapeutic class, are more serious than the original condition.[57] We propose to require this opioid safety edit to help avoid inappropriate or unnecessary therapeutic duplication when simultaneous use of multiple opioids is detected.

In consideration of clinical recommendations to use caution in combining opioids and to limit opioid use to only when necessary while assessing clinical benefits and harms of opioid treatment on an ongoing basis, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(i)(C) that states must implement safety edits for therapeutically duplicative fills for initial and subsequent prescription fills on opioids prescriptions and identify suspected abuse, misuse, excessive utilization, or inappropriate, or medically unnecessary care.

iv. Early Fill Limitations

To further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require that states establish safety edits to alert the dispenser before a prescription is filled early for an opioid product, based on the days' supply provided at the most recent fill or as specified by the state. These early fill edits on opioids are intended to protect beneficiaries from adverse events associated with using an opioid medication beyond the prescribed dose schedule and to help minimize the opioid supply available for diversion.

In consideration of clinical recommendations to limit opioid use to only when necessary and as prescribed, we believe this safety edit is necessary to assure that opioid prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(i)(D) that states must implement early fill safety alerts on opioids prescriptions to identify abuse, misuse, excessive utilization, or inappropriate, or medically unnecessary care.

b. Maximum Daily Morphine Milligram Equivalent (MME) Limits

Section 1004 of the SUPPORT for Patients and Communities Act requires state DUR programs to include safety edit limits (as specified by the state) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the state plan (or under a waiver of the state plan) for treatment of chronic pain (as designed and implemented by the state) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any threshold identified by the state.[58] Accordingly, to further implement section 1927(g)(1) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we are proposing that states must include in their DUR programs safety edit limitations identified by the State on the maximum daily morphine milligram equivalent (MME) for treatment of pain and a claims review automated process, discussed below in connection with paragraph (h)(1)(iii), that indicates when an individual is prescribed a morphine milligram equivalent in excess of these limitations.

Section 1004 of the SUPPORT for Patients and Communities Act specifically addresses MME limitations in the context of chronic pain. According to the CDC, acute pain (as distinct from chronic pain) usually occurs suddenly and usually has a known cause, like an injury, surgery, or infection. For example, acute pain can be caused from a wisdom tooth extraction, a surgery, or a broken bone after an automobile accident. Acute pain normally resolves as your body heals. Chronic pain, on the other hand, can last weeks, months or years—past the normal time of healing.[59] Regarding chronic pain, CDC states clinicians should use caution when prescribing opioids at any dosage, and should carefully reassess evidence of individual

[53] Dowell, Deborah, et al. ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' JAMA, U.S. National Library of Medicine, 19 Apr. 2016, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6390846/.*

[54] Frieden TR, Houry D. Reducing the Risks of Relief—The CDC Opioid-Prescribing Guideline. *N Engl J Med.* 2016; 374(16):1501–1504. doi:10.1056/NEJMp1515917.

[55] Manchikanti, Laxmaiah, et al. ''Opioid Epidemic in the United States.'' Pain Physician, U.S. National Library of Medicine, July 2012, *www.ncbi.nlm.nih.gov/pubmed/22786464.*

[56] Ibid.

[57] ''Therapeutic Duplication.'' Journal of the American Medical Association, vol. 160, no. 9, 1956, p. 780, doi:10.1001/jama.1956.02960440052016.

[58] Section 1902(oo)(1)(A)(i)(II) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[59] ''Opioids for Acute Pain.'' Centers for Disease Control and Prevention, available at *https://www.cdc.gov/drugoverdose/pdf/patients/Opioids-for-Acute-Pain-a.pdf.*

benefits and risks when considering increasing dosage to ≥50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥90 MME/day or carefully justify a decision to titrate dosage to ≥90 MME/day.[60] With this proposal to require maximum daily MME limits, we do not mean to suggest rapid discontinuation of opioids already prescribed at higher dosages. The MME/day metric is often used as a gauge of the overdose potential of the amount of opioid that is being given at a particular time.[61]

Calculating the total daily dosage of opioids helps identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose. The opioid MME levels mentioned previously in this proposed rule typically would not be clinically appropriate for acute, short term pain; moreover, if the prescription were for acute pain, given the risks associated with high acute doses (in particular, respiratory risks), we believe that this limitation also would be appropriate to ensure appropriateness, medical necessity, and avoidance of adverse events. Accordingly, we are proposing to require states to establish MME threshold amounts for implementation regardless of whether the prescription is for treatment of chronic or acute pain.

The proposed prospective safety edit must include a MME threshold amount to meet statutory requirements, to assist in identifying patients at potentially high clinical risk who may benefit from closer monitoring and care coordination. Calculation of MMEs is used to assess the total daily dose of opioids, taking into account the comparative potency of different opioids and frequency of use. The calculation to determine MMEs includes drug strength, quantity, days' supply and a defined conversion factor unique to each drug.[62] Patients prescribed higher opioid dosages are at higher risk of overdose death.[63] Calculating the total MME daily dose of opioids can help identify patients who may benefit from closer monitoring, reduction or tapering of opioids, prescribing of naloxone, or other measures to reduce risk of overdose.[64] HHS's *Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics,*[65] is also a valuable resource for considering how best to taper and/or discontinue usage in a thoughtful manner consistent with best clinical practices. We note that HHS does not recommend opioids be tapered rapidly or discontinued suddenly due to the significant risks of opioid withdrawal, unless there is a life-threatening issue confronting the individual patient. The FDA issued a safety announcement on tapering in April 2019 noting concerns about safely decreasing or discontinuing doses of opioids in patients who are physically dependent after hearing reports about serious harm.[66]

When determining MME threshold amounts, states are reminded that clinical resources, including, for example, the CDC Guideline,[67] recommend caution when prescribing opioids for chronic pain in certain circumstances, and recommend that primary care practitioners reassess evidence of individual benefits and risks when increasing doses and subsequently, justifying decisions by thoroughly documenting the clinical basis for prescribing in the patient's medical record.[68] It is important to be cognizant that the CDC Guideline states the dosage thresholds referenced therein pertain solely to opioids used to treat chronic pain in primary care settings and that these thresholds, as recommended by the CDC, do not represent hard limits for opioid prescriptions.[69]

In consideration of clinical recommendations and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe this proposed safety edit is necessary to assure at risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(ii) that states be required to implement safety edits that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of the MME dose limitation identified by the state.

c. Automated Claims Reviews for Opioids

To further implement section 1927(g) of the Act and section 1004 of the SUPPORT for Patients and Communities Act, we propose that states must have in place a claims automated review process (as designed and implemented by the state) that indicates when an individual enrolled under the state plan (or under a waiver of the state plan) is prescribed opioids in excess of above-proposed limitations identified by the state. In these ongoing, comprehensive reviews of opioid claim data, states should continuously monitor opioid prescriptions, including overrides of safety edits by the prescriber or dispenser on initial fill days' supply for opioid naïve patients, quantity limits, therapeutically duplicative fills, early refills and maximum daily MME limitations on opioids prescriptions.

These opioid claim reviews are necessary to allow states to continually monitor opioid prescriptions beneficiaries are receiving and determine and refine future potential prospective DUR safety edits, based on the findings of the claims reviews. Information obtained through retrospective DUR claim reviews can be used to shape effective safety edits that can be implemented through prospective DUR, better enabling prescribers and dispensers to investigate prescription concerns prior to dispensing the medication to the patient. Through ongoing monitoring and observation of trends over time, these reviews will allow for regular updates to safety edits in an evolving pain treatment landscape.

Accordingly, we are proposing at § 456.703(h)(1)(iii) that states must conduct retrospective claims review automated processes that indicate prescription fills in excess of the

[60] ''CDC Guidelines for Prescribing Opioids for Chronic pain.'' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[61] Ibid.

[62] Calculating Total Daily Dose of Opioids For Safer Dosage. Centers for Disease Control and Prevention, available at *https://www.cdc.gov/drugoverdose/pdf/calculating_total_daily_dose-a.pdf.*

[63] Guideline for Prescribing Opioids for Chronic Pain. *www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[64] Ibid.

[65] *https://www.hhs.gov/opioids/sites/default/files/2019-10/Dosage_Reduction_Discontinuation.pdf*).

[66] ''FDA identifies harm reported from sudden discontinuation of opioid pain medicines and requires label changes to guide prescribers on gradual, individualized tapering.'' Food and Drug Administration. Available at *https://www.fda.gov/drugs/drug-safety-and-availability/fda-identifies-harm-reported-sudden-discontinuation-opioid-pain-medicines-and-requires-label-changes.*

[67] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. MMWR Recomm Rep 2016;65(No. RR–1):1–49. DOI: *http://dx.doi.org/10.15585/mmwr.rr6501el. https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fmmwr%2Fvolumes%2F65%2Frr%2Frr6501e1er.htm.*

[68] Dowell, Deborah, et al. ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' JAMA, U.S. National Library of Medicine, 19 Apr. 2016, *https://www.ncbi.nlm.nih.gov/pubmed/26977696.*

[69] Staff, News. ''CDC Clarifies Opioid Guideline Dosage Thresholds.'' AAFP Home, 12 Jan. 2018, *www.aafp.org/news/health-of-the-public/20180112cdcopioidclarify.html.*

prospective safety edit limitations specified by the state under paragraphs § 456.703(h)(1)(i) or (h)(1)(ii) to provide for the ongoing review of opioid claims data to identify patterns of fraud, misuse, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits above-proposed limitations. In addition to opioid claims data, we also intend for states to consider incorporating other available records to provide for the ongoing periodic reviews of opioids claim data and other records (including but not limited to prescription histories, diagnoses, medical records, and prescription drug monitoring program (PDMP) files, when available), in their retrospective claims review automated processes order to identify patterns of fraud, misuse, abuse, excessive utilization, or inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization among physicians, pharmacists and individuals receiving Medicaid benefits.

d. Concurrent Utilization Reviews

Section 1902 of the Act, as amended by the SUPPORT for Patients and Communities Act, requires states to have an automated process for claims review (as designed and implemented by the state) that monitors when an individual enrolled under the state plan (or under a waiver of the state plan) is concurrently prescribed opioids and benzodiazepines or opioids and antipsychotics.[70] This requirement is consistent with the requirement in section 1927(g)(1)(A) of the Act that state DUR programs must assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results.

Clinically, through the use of retrospective automated claim reviews, concurrent use of opioids and benzodiazepines and opioids and antipsychotics, as well as potential complications resulting from other medications concurrently being prescribed with opioids, can be reduced. States are reminded that the requirement for a retrospective automated claims review added by section 1004 of the SUPPORT for Patients and Communities Act does not preclude the state from also establishing a prospective safety edit system to provide additional information to patients and providers at the POS about concurrent utilization alerts.[71] In addition, the state could use the authorities under section 1927 to subject these patients to appropriate utilization management techniques. We also would like to remind states that section 1927(g)(1) of the Act also currently supports including other potentially harmful opioid interactions as additional prospective or retrospective reviews in state DUR programs, such as opioids and central nervous system (CNS) depressants, including alcohol or sedatives. We fully support states including such additional opioid interactions or contraindications in prospective or retrospective reviews as part of a comprehensive DUR program.

In consideration of clinical recommendations to limit opioids interactions with certain other drugs, including benzodiazepines and antipsychotics, and to assess the clinical benefits and harms of opioid treatment on an ongoing basis, we believe the retrospective reviews we are proposing to require are necessary to assure at-risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing in § 456.703(h)(1)(iv)(A) and (B) that states be required to implement a claims review automated process that monitors when an individual is concurrently prescribed opioids and benzodiazepines; or opioids and antipsychotics.

i. Opioid and Benzodiazepines Concurrent Fill Reviews

In 2016, FDA added a boxed warning to prescription opioid analgesics, opioid-containing cough products, and benzodiazepines with information about the serious risks associated with using these medications concurrently.[72] The CDC Guideline recommends that clinicians avoid prescribing benzodiazepines concurrently with opioids whenever possible. Benzodiazepines may be abused for recreational purposes by some individuals, with some opioid overdoses also involving opioids and benzodiazepines or other substances, such as alcohol.[73]

Studies show that people concurrently using both drugs are at higher risk of visiting the emergency department or being admitted to a hospital for a drug-related emergency.[74] Due to the heightened risk of adverse events associated with the concurrent use of opioids and benzodiazepines, physicians should avoid the initial combination of opioids and benzodiazepines by offering alternative approaches.[75] This review would alert providers when these drugs have been prescribed concurrently to assist in avoiding and mitigating associated risks.

ii. Opioid and Antipsychotic Concurrent Fill Reviews

This alert is supported by FDA's boxed warning of increased risk of respiratory and central nervous system (CNS) depression with concurrent use of opioid and CNS depressants such as antipsychotics or sedatives, including extreme sleepiness, slowed or difficult breathing, unresponsiveness or the possibility that death can occur.[76] Patients concurrently prescribed opioid and antipsychotic drugs can benefit from increased coordination of care. Additionally, improving treatment of comorbid mental disorders is an important consideration when trying to reduce the overall negative impacts of pain. As the PMTF report noted, ''the occurrence of pain and behavioral health comorbidities, including depression, post-traumatic stress disorder, and substance use disorders, is well documented, and it is established that psychosocial distress can contribute to pain intensity, pain-related disability, and poor response to chronic pain treatment.'' [77] Evidence indicates that

[70] Section 1902(oo)(1)(A)(i)(III) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[71] *See* section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[72] Office of the Commissioner. ''Drug Safety Communications—FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning.'' *U.S. Food and Drug Administration Home Page,* Office of the Commissioner, *https://www.fda.gov/media/99761/download.*

[73] Jones, Jermaine D, et al. ''Polydrug Abuse: a Review of Opioid and Benzodiazepine Combination Use.'' Drug and Alcohol Dependence, U.S. National Library of Medicine, 1 Sept. 2012, *www.ncbi.nlm.nih.gov/pmc/articles/PMC3454351/.*

[74] Forum, Addiction Policy. ''Sedative Use Disorder.'' Addiction Policy Forum, *https://www.addictionpolicy.org/sedative-use-disorder.*

[75] ''Reduce Risk of Opioid Overdose Deaths by Avoiding and Reducing Co-Prescribing Benzodiazepines.'' MLN Matters Number: SE19011. Available at *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE19011.pdf.*

[76] Office of the Commissioner. ''Drug Safety Communications—FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning.'' *U.S. Food and Drug Administration Home Page,* Office of the Commissioner, *https://www.fda.gov/media/99761/download.*

[77] Pain Management Best Practices Inter-Agency Task Force. ''Pain Management Best Practices.'' Available at *https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf.*

optimizing mental health and pain treatment can improve outcomes in both areas for patients seen in primary and specialty care settings. Untreated psychiatric conditions may increase the risk of both unintentional and intentional medication mismanagement, OUD, and overdose.[78] Given the intersection between psychiatric/psychological symptoms and chronic pain, it is important that the behavioral health needs of patients with pain are appropriately and carefully evaluated and treated with the concurrent physical pain problem.[79] As such, beneficiaries who are concurrently prescribed both opioids and antipsychotics should be considered from a health system or policy perspective when addressing their treatment.[80] A patient's unique presentation and circumstances should be considered when prescribing opioids and antipsychotics. This review would encourage coordination of care for patients taking antipsychotic and opioid medications concurrently.

e. Other Considerations

Consistent with section 1902(oo)(1)(A)(iii) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act, the provisions proposed to be implemented in § 456.703(h)(1) would not prohibit states from designing and implementing an automated claims review process that provides for other processes for the prospective or retrospective review of claims. Furthermore, none of these proposed provisions would prohibit the exercise of clinical judgment by a provider regarding the best or most appropriate care and treatment for any patient.

We encourage states to develop prospective and retrospective drug reviews that are consistent with medical practice patterns in the state to help meet the health care needs of the Medicaid patient population. In doing so, we encourage states to utilize, for example, the 2016 CDC Guideline[81] for primary care practitioners on prescribing opioids in outpatient settings for chronic pain.

In order to avoid abrupt opioid withdrawal, prior authorization may be necessary for patients who will need clinical intervention to taper off high doses of opioids to minimize potential symptoms of withdrawal and manage their treatment regimen, while encouraging pain treatment using non-pharmacologic therapies and non-opioid medications, where available, and appropriate.

When implementing these requirements, we encourage states to offer education and training and to provide consistent messaging across all healthcare providers. Education and training of all providers on new opioid-related provisions and on the treatment of acute and chronic pain, and on behavioral health issues related to pain, would help minimize workflow disruption and ensure beneficiaries have access to their medications in a timely manner.

f. Program To Monitor Antipsychotic Medications in Children

Under section 1004 of the SUPPORT for Patients and Communities Act, states must have a program (as designed and implemented by the state) to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the state plan (or under a waiver of the state plan), including any Medicaid expansion group for Children's Health Insurance Program (CHIP).[82] Additionally, states must annually submit information on activities carried out under this program for individuals not more than the age of 18 years old generally, and children in foster care specifically, as part of the annual report submitted to the Secretary under section 1927(g)(3)(D) of the Act, as provided in section 1902(oo)(1)(D) of the Act.

Antipsychotic medications are increasingly used for a wide range of clinical indications in diverse populations, including privately and publicly insured youth.[83] Antipsychotics' adverse metabolic effects have heightened concern over growth in prescribing to youth, including off-label prescribing and polytherapy of multiple antipsychotics.[84] Studies have raised concerns regarding the long-term safety and effectiveness of antipsychotics in this broadened population. Studies in adults have found that antipsychotics can cause serious side effects and long-term safety and efficacy for off-label utilization is a particular concern in children.[85] Some of the most concerning effects include uncontrollable movements and tremors, an increased risk of diabetes, substantial weight gain, elevated cholesterol, triglycerides and prolactin, changes in sexual function, and abnormal lactation.[86] Children appear to be at higher risk than adults for a number of adverse effects, such as extrapyramidal symptoms and metabolic and endocrine abnormalities. Some studies suggests that antipsychotic treatment may be associated with increased mortality among children and youths and the distal benefit/risk ratio for long-term off-label treatment remains to be determined.[87] [88]

In consideration of clinical recommendations to monitor and manage the appropriate use of antipsychotic medications by children and to assess the clinical benefits and harms of treatment on an ongoing basis, we believe this program is necessary to assure children are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(v) that states be required to implement programs to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP). We understand states need considerable flexibility when implementing this program. These proposed provisions are not meant to prohibit the exercise of clinical judgment by a provider regarding the best or most appropriate care and treatment for any patient. States are expected to consult national guidelines and are encouraged to work with their pharmacy and therapeutics (P&T) and DUR committees to identify clinically appropriate safety edits and reviews. We recommend states consider expanding DUR programs to include reviews on children for polytherapy (therapy that

[78] Ibid.

[79] Ibid.

[80] Davis, Matthew A., et al. ''Prescription Opioid Use among Adults with Mental Health Disorders in the United States.'' The Journal of the American Board of Family Medicine, vol. 30, no. 4, 2017, pp. 407–417, doi:10.3122/jabfm.2017.04.170112.

[81] ''CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016.'' Centers for Disease Control and Prevention, Centers for Disease Control and Prevention, 29 Aug. 2017, *https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6501e1er.pdf.*

[82] Section 1902(oo)(1)(B) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[83] Crystal, Stephen et al. ''Broadened use of atypical antipsychotics: safety, effectiveness, and policy challenges.'' *Health affairs (Project Hope)* vol. 28,5 (2009): w770–81. doi:10.1377/hlthaff.28.5.w770.

[84] Ibid.

[85] Ibid.

[86] Marder SR, et al. Physical health monitoring of patients with schizophrenia. Am J Psychiatry. 2004;161(8):1334.

[87] *https://jamanetwork.com/journals/jamapsychiatry/article-abstract/2717966.*

[88] *https://www.healthline.com/health/consumer-reports-antipsychotics-children#1.*

uses more than one medication), inappropriate utilization or off label utilization.

g. Fraud and Abuse Identification

Section 1902(oo)(1)(C) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act, provides that States must have a process (as designed and implemented by the state) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the state plan (or under a waiver of the state plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled. We propose to implement this requirement at § 456.703(h)(1)(vi); specifically, we propose that the state's DUR program must include a process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

We intend that this proposed process would operate in a coordinated fashion with other state program integrity efforts. States would have flexibility to define specific parameters for reviews for fraud and abuse, as well as protocols for recommendation, referral, or escalation of reviews to the relevant Program Integrity/Surveillance Utilization Review (SURS) unit, law enforcement, or state professional board, based on patterns discovered through the proposed DUR process. Additionally, state policy should specify the documentation required when suspected fraud and/or abuse results in a recommendation, referral, or escalation for further review, including the findings of any subsequent investigation into the potential deviation from the standard of care. States would be expected to ensure that DUR reviews conducted pursuant to this proposed requirement are aligned with all applicable federal requirements, including those specified in 42 CFR 455.12, 455.13 through 455.21 and 455.23 and section 1902(a)(64) of the Act.

We acknowledge that other initiatives, which many states are already undertaking, could work synergistically with the proposed requirement to help reduce fraud, misuse, and abuse related to opioids. For example, patient review and restriction programs (lock-in programs)[89] and prescription drug monitoring programs[90] also play an important role in detecting and preventing opioid-related fraud, misuse and abuse. Lock-in programs, also called patient review and restriction or drug management programs, are meant to cut down on ''doctor shopping''—the practice of going to several doctors or pharmacies to fill multiple prescriptions for opioids or other controlled substances for illicit sale or misuse or to support an addiction. Such programs are used primarily to restrict overutilization of medications. Additionally, programs may require beneficiaries to receive all prescriptions through one pharmacy, have all prescriptions written by one prescriber, receive health care services from one clinical professional, or all three depending on how the program is designed.[91]

Section 5042 of the SUPPORT for Patients and Communities Act requires covered providers who are permitted to prescribe controlled substances and who participate in Medicaid to query qualified Prescription Drug Monitoring Programs (PDMPs) before prescribing controlled substances to most Medicaid beneficiaries, beginning October 1, 2021. PDMPs are database tools sometimes utilized by government officials and law enforcement for reducing prescription drug fraud, abuse and diversion, but which more frequently can be used to monitor controlled substance use by healthcare providers including prescribers and pharmacists. PDMPs collect electronically transmitted prescribing and some dispensing data submitted by pharmacies and dispensing practitioners. The data are monitored and analyzed to support states' efforts in education, research, enforcement and abuse prevention.[92] Data analytics can help to determine the extent to which beneficiaries are prescribed high amounts of opioids, identify beneficiaries who may be at serious risk of opioid misuse or overdose, and identify prescribers with questionable opioid prescribing patterns for these beneficiaries.[93] [94] The process required under the SUPPORT for Patients and Communities Act and this proposed rule to identify potential fraud or abuse, can help ensure that state officials and staff implementing the state's program integrity, PDMP, and DUR functions work collaboratively to identify opportunities for DUR activities to assist in the identification of potential fraud and abuse.

2. Other CMS Proposed Standards

In addition to codifying the SUPPORT for Patients and Communities Act requirements, we are proposing additional minimum DUR standards in this proposed rule that states would be required to implement as part of their DUR programs at § 456.703(h)(1)(vii). Specifically, under our authority to implement section 1927(g) of the Act and consistent with the goals of the SUPPORT for Patients and Communities Act to help combat the nation's opioid overdose epidemic, we are proposing minimum standards related to MAT and identification of beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. These additional standards are being included to ensure prescribed drugs are: (1) Appropriate; (2) medically necessary; and (3) not likely to result in adverse medical results.

State DUR programs would be required to include prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT, and prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state to expand appropriate utilization of naloxone for dispensing to individuals at risk of overdose. As further discussed below, we are proposing these minimum requirements to further implement section 1927(g) of the Act to prevent and reduce the inappropriate use of opioids and potentially associated adverse medical results, consistent with the

[89] ''Pharmacy Lock-In Programs Slated For Expanded Use.'' OPEN MINDS, *www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/.*

[90] Office of National Drug Control Policy. Prescription Drug Monitoring Program. Prescription Drug Monitoring Program, April 2011. *https://www.ncjrs.gov/pdffiles1/ondcp/pdmp.pdf.*

[91] ''Pharmacy Lock-In Programs Slated For Expanded Use.'' OPEN MINDS, *www.openminds.com/market-intelligence/executive-briefings/pharmacy-lock-programs-slated-expanded-use/.*

[92] ''Prescription Drug Monitoring Frequently Asked Questions (FAQ)| The PDMP Training and Technical Assistance Center.'' *Prescription Drug Monitoring Frequently Asked Questions (FAQ) | The PDMP Training and Technical Assistance Center, www.pdmpassist.org/content/prescription-drug-monitoring-frequently-asked-questions-faq.*

[93] Beaton, Thomas. ''Preventing Provider Fraud through Health IT, Data Analytics.'' *HealthPayerIntelligence,* 5 Oct. 2018, *https://healthpayerintelligence.com/news/preventing-provider-fraud-through-health-it-data-analytics.*

[94] OIG, *Opioids in Medicare Part D: Concerns about Extreme Use and Questionable Prescribing,* OEI–02–17–00250, July 2017. *https://oig.hhs.gov/oei/reports/oei-02-17-00250.pdf.*

provisions under section 1004 of the SUPPORT for Patients and Communities Act.

a. Medication Assisted Treatment (MAT)

To further implement section 1927(g)(1) of the Act and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing to require states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or had an OUD diagnosis within a specified number of days (as determined by the state), without having a new indication to support utilization of opioids (such as a new cancer diagnosis, new palliative care treatment or entry into hospice).

MAT is treatment for opioid use disorder (OUD) that includes addiction treatment and services plus a medication approved by FDA for opioid addiction, detoxification, or maintenance treatment or relapse prevention for opioid use disorder.[95] The SUPPORT for Patient and Communities Act defines MAT to include all FDA approved drugs and licensed biological products to treat opioid disorders, as well as counseling services and behavioral therapies with respect to the provision of such drugs and biological products.[96] MAT has proven to be clinically effective in treating opioid use disorder and significantly reduces the need for inpatient detoxification services.[97] Medications such as buprenorphine and methadone, in combination with counseling and behavioral therapies, provide a whole-patient approach to the treatment of opioid use disorders.

Using opioid medications during the course of MAT is dangerous from a clinical perspective. A safety edit designed to notify healthcare providers about the co-administration of MAT drugs and opioids would be useful to alert the providers regarding a possible need for increased coordination of care. We believe states could take effective action to help prevent adverse medical results, possible OUD relapse, and increase coordination of care in patients with a history of OUD. We understand states need considerable flexibility when implementing these reviews to address complicated patient populations. The proposed prospective safety edits, automatic retrospective claims reviews, or a combination of these approaches, would help identify cases where a beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for MAT or has received an OUD diagnosis. Accordingly, we are proposing that states would have flexibility to determine which of these DUR approaches the state would implement, including the flexibility to incorporate both into an effective DUR program. State flexibility also would extend to specifying the time period between the prior episode of MAT or OUD diagnosis (or most recent prior episode of MAT or OUD diagnosis) and the subject opioid prescription that, if not met, would trigger the alert (for example, an opioid prescription within 24 months of the end of the most recent episode of MAT would trigger a prospective safety edit). Flexibility could also extend to diagnoses where opioid use after MAT is appropriate without compromising OUD treatment (for example in end of life care or in cancer patients with severe pain resulting from their disease or that does not respond to alternative pain management options).

In consideration of clinical recommendations to ensure appropriate MAT treatment, and to prevent opioid related abuse and misuse, we believe the proposed prospective safety edits and/or retrospective claim reviews are necessary to assure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. This proposed requirement is authorized by and expected to advance the purposes of section 1927(g) of the Act and is consistent with the purposes of section 1004 of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(vii)(A) that states be required to implement reviews to alert when the beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for Medication Assisted Treatment (MAT) for an opioid use disorder or has been diagnosed with an opioid use disorder, within a timeframe specified by the state, in the absence of a new indication to support utilization of opioids (such as new cancer related pain diagnosis or entry into hospice care). In addition to helping ensure appropriate utilization of medications, these edits would assist in coordination of care, and potentially in improved treatment of pain.

b. Naloxone

To further implement section 1927(g)(1) of the Act, and consistent with section 1004 of the SUPPORT for Patients and Communities Act, we are proposing and seeking comment on requiring states to establish prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state, to identify beneficiaries who could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone with the goal of expanding appropriate utilization of naloxone to individuals at risk of opioid overdose. Naloxone is a medication designed to rapidly reverse opioid overdose by binding to opioid receptors and reversing the effects of opioids. Naloxone works quickly to restore normal respiration to a person whose breathing has slowed or stopped as a result of an opioid overdose, including both illicit and prescription opioids. However, naloxone only works if a person has opioids in their system; the medication has no effect if opioids are absent.[98]

The prescribing or coprescribing of naloxone in patients at elevated risk for opioid overdose or for those who have overdosed on opioids can save lives.[99] We recommend states consider ways for expanded use, distribution and access to naloxone when clinically appropriate.

When implementing this review, states should determine standards for identifying individuals at high risk for opioid overdose, such as individuals who have been discharged from emergency medical care following opioid overdose, individuals who use heroin or misuse prescription pain relievers as well as those who use high dose opioids for long-term management of chronic pain.[100] Before starting and

[95] There are four drugs or drug combinations currently used in MAT: Buprenorphine; naltrexone; buprenorphine in combination with naloxone; and methadone.

[96] Support for Patients and Communities Act, Section 1006(b). Requirement For State Medicaid Plans To Provide Coverage For Medication-Assisted Treatment.

[97] ''Medication and Counseling Treatment''. September 28, 2015. Available at *https://www.samhsa.gov/medication-assisted-treatment/treatment.*

[98] ''Understanding Naloxone.'' Harm Reduction Coalition. Available at *https://harmreduction.org/issues/overdose-prevention/overview/overdose-basics/understanding-naloxone/.*

[99] NEJM Journal Watch: Summaries of and Commentary on Original Medical and Scientific Articles from Key Medical Journals, HHS-recommends-coprescribing-naloxone-with-opioids-high. *https://www.jwatch.org/fw114907/2018/12/20/hhs-recommends-coprescribing-naloxone-with-opioids-high.*

[100] Ibid.

periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. When prescribing opioids, the CDC Guideline recommends clinicians should incorporate strategies to mitigate opioid risks, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥50 MME/day), or concurrent benzodiazepine use, are present.[101] We understand states need considerable flexibility when implementing this review to address a complex problem and are proposing that states would have flexibility to determine which DUR approach the state would implement into an effective DUR program: Either or both of prospective safety edits and/or retrospective claims reviews. Further, we propose that states would have flexibility to determine the particular criteria they would use to identify which beneficiaries may be at high risk of opioid overdose such that they should be considered for co-prescription or co-dispensing of naloxone.

In consideration of clinical recommendations to expand naloxone use to prevent adverse medical events among those who are prescribed opioids or those who may be at high risk of opioid overdose or have previously overdosed, we believe this review is necessary to assure at risk individuals are receiving appropriate treatment that is not likely to result in adverse medical results, and to accomplish other purposes of the DUR program under section 1927(g) of the Act and of the SUPPORT for Patients and Communities Act. Accordingly, we are proposing at § 456.703(h)(1)(vii)(B) that states be required to implement prospective safety edit alerts, automatic retrospective claims review, or a combination of these approaches as determined by the state to identify when a beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone. We anticipate that this proposal may help expand appropriate utilization of naloxone, including by facilitating dispensing to individuals at risk of overdose.

3. Exclusions

The above described DUR requirements added to section 1902(oo) of the Act by section 1004 of the SUPPORT for Patients and Communities Act, which we propose to implement along with additional related proposals under section 1927(g) of the Act at § 456.703(h)(1)(i) through (vii)(B), do not and would not apply for individuals who are receiving hospice or palliative care or those in treatment for cancer; residents of a long-term care facility, a facility described in section 1905(d) of the Act (that is, an intermediate care facility for the intellectually disabled), or of another facility for which frequently abused drugs are dispensed for residents through a contact with a single pharmacy; or other individuals the state elects to treat as exempted from such requirements.

States are expected to consult national guidelines and are encouraged to work with their pharmacy and therapeutics (P&T) and DUR committees to identify other clinically appropriate patient populations for possible exclusion from the safety reviews specified in § 456.703(h)(1)(i) through (vii) to avoid impeding critical access to needed medication when managing specific complex disease states.

We understand states need considerable flexibility when implementing these reviews to address complicated patient populations. We propose to implement this statutory exclusion at § 456.703(h)(2), such that states would not be required to implement the specified DUR requirements with respect to these populations. However, while states are not required to comply with these requirements with respect to these individuals, we clarify, and propose to codify in the regulation, that states voluntarily may apply to them the prospective safety edits and claims review automated processes otherwise required under the SUPPORT for Patients and Communities Act and this proposed rule.[102] We also recognize that it is important for patients who are taking opioid-based MAT drugs to continue their therapy without disruption. In this regard, states may at their discretion include these drugs in their DUR reviews under section 1927(g) of the Act.

4. Managed Care Requirements

Consistent with section 1902(oo)(1)(A)(ii) of the Act, as added by the SUPPORT for Patients and Communities Act, states also must ensure that their contracts with MCOs under section 1903(m) of the Act and managed care entities (MCEs) under section 1905(t)(3) of the Act require that the MCOs or MCEs have safety edits, an automated review processes, a program to monitor antipsychotic medications in children, and fraud and abuse identification requirements as described in this proposed rule for individuals eligible for medical assistance under the state plan (or waiver of the state plan) who are enrolled with the entity, subject to the exclusions of individuals as proposed in section 1902(oo)(1)(C) of the Act.[103] States must include these DUR provisions in managed care contracts by October 1, 2019. Although the foregoing provisions added by the SUPPORT for Patients and Communities Act address only MCOs and MCEs in the managed care context, we propose also to extend these requirements to contracts with prepaid ambulatory health plans (PAHPs) and prepaid inpatient health plans (PIHPs) under our authority in section 1902(a)(4) under which existing PIHP and PAHP requirements are based. Thus, under this proposed rule, states would be required to include prepaid ambulatory health plans (PAHPs) and prepaid inpatient health plans (PIHPs) when uniformly implementing the updates and requirements specified in the SUPPORT for Patients and Communities Act for all Medicaid managed care plans. Furthermore, as required by section 1004 of the SUPPORT for Patients and Communities Act, each Medicaid MCO and MCE within a state must also operate a DUR program that complies with the above specified requirements. We are proposing to define MCEs in § 438.2 to have the meaning given to the term under section 1932(a)(1)(B) of the Act, which defines the term to mean a Medicaid managed care organization, as defined in section 1903(m)(1)(A), that provides or arranges for services for enrollees under a contract pursuant to section 1903(m) of the Act, or a primary care case manager, as defined in section 1905(t)(2) of the Act. Managed care regulations at § 438.3(s)(4) require Medicaid managed care DUR programs in which an MCO, PIHP, or PAHP contracts to provide coverage for covered outpatient drugs to operate consistently with section 1927(g) of the Act and part 456, subpart K, and that state contracts must be updated to include these requirements. We are proposing to amend the regulation at § 438.3(s) and (s)(4) and (5) to require that MCEs comply with the requirements in section 1902(oo)(1)(A) of the Act as implemented in these proposed regulations, similar to MCOs, PIHPs, and PAHPs.

[101] ''CDC Guidelines for Prescribing Opioids for Chronic pain.'' Available at *https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.*

[102] Section 1902(oo)(3) of the Act, as added by section 1004 of the SUPPORT for Patients and Communities Act.

[103] *H.R. 6. 24 Oct. 2018, www.congress.gov/115/bills/hr6/BILLS-115hr6enr.pdf. Page 17.*

5. Reporting Requirements

Consistent with section 1927(g)(3)(D) of the Act, we require each State Medicaid agency to submit to us an annual report on the operation of its Medicaid DUR program. Under § 456.712(a), the state must require the DUR Board to prepare and submit, on an annual basis, a report to the State Medicaid agency. Under § 456.712(b), each State Medicaid agency must in turn submit this report to us, as well as specified additional information, including but not limited to descriptions of the nature and scope of the state's prospective and retrospective DUR programs, detailed information on the specific DUR criteria and standards in use, a description of the actions taken to ensure compliance with predetermined standards requirements in § 465.703, a summary of the educational interventions used and an assessment of their effect on quality of care, and an estimate of the cost savings generated as a result of the DUR program. We have compiled state FFS Medicaid DUR annual reports since 1995 and has published them on *Medicaid.gov* since 2010. Since 2016, § 438.3(s)(4) requires any MCO, PIHP or PAHP that covers covered outpatient drugs to operate a DUR program that complies with section 1927(g) of the Act and 42 CFR part 456, subpart K, as though these requirements applied to the MCO, PIHP, or PAHP instead of the state, including requirements related to annual DUR reporting. Given the commercial nature of many managed care entities, incorporation of information posted to *Medicaid.gov* provides new considerations with regards to public disclosure of information received by CMS.

In an effort to share and encourage innovative and collaborative practices, we also are proposing to publish all information received in annual DUR reports from managed care programs and FFS programs on a CMS website. Accordingly, we are proposing to add new paragraph (c) to § 456.712 to provide that all FFS and managed care DUR reports received by CMS under § 456.712(b) and, as applicable, pursuant to § 438.3(s), will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs.

6. State Plan Amendment (SPA) Requirements

The SUPPORT for Patients and Communities Act amended the state plan requirements in section 1902(a) of the Act to include a new paragraph (85), which requires the state plan to provide that the state is in compliance with the new drug review and utilization requirements set forth in section 1902(oo) of the Act, as also added by the SUPPORT for Patients and Communities Act. The SUPPORT for Patients and Communities Act also requires all states to implement these requirements by October 1, 2019, and to submit an amendment to their state plan no later than December 31, 2019, consistent with the state plan amendment requirements in 42 CFR part 430, subpart B, to describe how the state addresses these provisions in the state plan. States are also expected to give appropriate tribal notification, as required, if applicable. Guidance regarding requirements was issued to states in a CMS informational bulletin *https://www.medicaid.gov/federal-policy-guidance/downloads/cib080519-1004.pdf.* If provisions in this proposed rule that would implement the amendments made by section 1004 of the SUPPORT for Patients and Communities Act are finalized, an additional state plan amendment potentially could be needed to ensure that state plans are in compliance with applicable final regulations. We would expect to provide related guidance in connection with any final rule.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a ''collection of information'' requirement is submitted to the Office of Management and Budget (OMB) for review and approval. For the purposes of the PRA and this section of the preamble, collection of information is defined under 5 CFR 1320.3(c) of the PRA's implementing regulations.

To fairly evaluate whether an information collection must be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this proposed rule that contain information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates (*http://www.bls.gov/oes/current/oes_nat.htm*). Table 3 presents the mean hourly wage, the cost of fringe benefits and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 3—NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefits and overhead ($/hr)	Adjusted hourly wage ($/hr)
Chief Executives	11–1011	96.22	96.22	192.44
Data Entry and Information Processing Workers	43–9020	17.05	17.05	34.10
General Operations Mgr	11–1021	59.56	59.56	119.12

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding State Plan Requirements, Findings, and Assurances (§ 447.518(d)(1) and (2))

The following proposed changes will be submitted to OMB for approval under control number 0938–TBD (CMS–10722). The control number is currently to be determined (TBD) but will be issued by OMB upon their clearance of this proposed rule's information collection request (a.k.a., ''PRA package''). The subsequent final rule will set out the assigned control number.

Under section 1902(a)(30)(A) the Act, we are granted the authority to require that methods and procedures be established by states relating to the utilization of, and the payment for, care and services available under the state plan process (including but not limited to utilization review plans) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that state payments to providers of Medicaid services are consistent with efficiency, economy, and quality of care.

To that end, as part of the state plan approval process relative to the VBP program, this rule proposes new reporting requirements that would affect the 51 state Medicaid programs (the 50 states and the District of Columbia). Specifically, a State participating in value-based purchasing arrangements must report data described in § 447.518(d)(1) and (2) on an annual basis and no later than 60 days after the end of each year. The reported data would include: The State name, National drug code(s) (for drugs covered under the VBP), product FDA list name, number of prescriptions, cost to the State to administer VBP (for example: Systems changes, tracking evidence or outcomes-based measures, etc.), and the total savings generated by the supplemental rebate due to the VBP. The reporting requirements would be applicable to both FFS and MCO COD claims. Following our evaluation of the response to this proposed rule, we may decide to issue a form to help ensure that the proper information is reported at the proper address.

We estimate it would take an additional 4 hours at $119.12/hr for a general operations manager to collect the supplemental rebate agreement VBP drug utilization information, add this data to the state's quarterly report when due annually (we will choose the quarter in which the annual data will be due), and submit the report to CMS. In aggregate we estimate an ongoing annual burden of 306 hours (6 hr/report × 1/year × 51 respondents) at a cost of $36,444.60 (816 hr × $119.12/hr).

2. ICRs Regarding Requirements for States (§ 447.511(b), (d) and (e))

The following proposed changes will be submitted to OMB for approval under control number 0938–0582 (CMS–R–144). Subject to renewal, the control number is currently set to expire on July 31, 2020. It was last approved on March 14, 2019, and remains active.

Under proposed § 447.511(b) states, territories, and the District of Columbia would be required to ensure by certification that the quarterly rebate invoices sent to manufacturers that participate in the MDRP no later than 60 days after the end of each rebate period via CMS–R–144 (Quarterly Medicaid Drug Rebate Invoice), mirrors the data sent to us. This rule would not impose any changes to the CMS–R–144 form.

Under proposed § 447.511(d) states would now be required to certify that their SDUD meets the requirements specified under proposed § 447.511(e) via a certification statement. We believe the certification would not impose a significant burden as we will provide systems access to state certifiers to log in once per quarter to certify their SDUD report. Certifiers would have to apply for a CMS user ID and password, and keep current with required annual computer-based training, as current state staff with access to our systems must do. To comply with the proposed certification requirements, States must already have system edits in place to find and correct SDUD outliers prior to reporting to manufacturers and CMS.

We estimate it would take 5 hours at $192.44/hr for the State Medicaid Director, Deputy State Medicaid Director, another individual with equivalent authority, or an individual with directly delegated authority from one of the above to obtain current CMS systems access. In aggregate we estimate a one-time system ID/password access burden of 280 hours (5 hr × 56 respondents) at a cost of $53,883 (280 hr × $192.44/hr).

We also estimate an additional annual burden of 2 hours (or 30 minutes/quarter) at $192.44/hr for a chief executive to certify such data and to add the state data certification language in their submission. In aggregate we estimate a burden of 112 hours (2 hr × 56 respondents) at a cost of $21,553 (112 hr × $192.44/hr).

3. ICRs Regarding the Payment of Claims 18 (§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B))

The following proposed changes will be submitted to OMB for approval under control number 0938–1265 (CMS–10529). Subject to renewal, the control number is currently set to expire on April 30, 2021. It was last approved on June 10, 2019, and remains active.

This proposed rule would implement provisions of Bipartisan Budget Act of 2018 (BBA 2018) (Pub. L. 115–123, enacted February 9, 2018), which includes several provisions that modify COB and TPL in both statute and regulation related to special treatment of certain types of care and payment in Medicaid and Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) (Pub. L. 111–3, enacted February 4, 2009). Section 53102 of BBA 2018 amended the TPL provision at section 1902(a)(25) of the Act. Effective February 9, 2018, section 53102(a)(1) of the BBA 2018 amended section 1902(a)(25)(E) of the Act to require states to cost avoid claims for prenatal care for pregnant women including labor and delivery and postpartum care, and to allow the state Medicaid agency 90 days instead of 30 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments. Effective April 18, 2019, section 7 of the Medicaid Services Investment and Accountability Act of 2019 (the MSIAA) amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement services, as well as requiring states to collect information on TPL before making payments.

On April 18, 2019, section 7 of the MSIAA amended section 1902(a)(25)(E) of the Act to allow 100 days instead of 90 days to pay claims related to medical support enforcement and preventive pediatric services, as well as requiring all states, the District of Columbia, and the territories (56 respondents) to collect information on third party TPL before making payments (§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B)). Under the authority in section 1902(a)(25)(A) of the Act, our regulations at 42 CFR part 433, subpart D establishes

requirements for state Medicaid agencies to support the coordination of benefits (COB) effort by identifying TPL. Sections 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B) detail the exception to standard COB cost avoidance by allowing pay and chase for certain types of care, as well as the timeframe allowed prior to Medicaid paying claims for certain types of care. Title XIX of the Act requires state Medicaid programs to identify and seek payment from liable third parties, before billing Medicaid.

We estimate it would take 1 hour at $34.10/hr for a data entry/information processing worker to collect information on TPL and report that information to CMS on CMS–64 (approved by OMB under the aforementioned OMB control number and CMS ID number) on a quarterly basis. In aggregate we estimate an annual burden of 224 hours (1 hr/response × 4 responses/year × 56 respondents) at a cost of $7,638 (224 hr × $34.10/hr).

C. Summary of Proposed Requirements and Annual Burden Estimates

Table 4 sets out our proposed annual burden estimates.

TABLE 4—SUMMARY OF ANNUAL REQUIREMENT AND BURDEN

Section under Title 42 of the CFR	Number of respondents	Responses (per year)	Time per response (hours)	Total time (hours)	Labor rate ($/hr)	Total cost ($)	OMB Control No. (CMS ID No.)
§ 447.511	56	1	5	280	192.44	53,883	0938–0582 (CMS–R–144).
§ 447.511	56	4	0.5	112	192.44	21,553	0938–0582 (CMS–R–144).
§ 447.518(d)(1) and (2)	51	1	6	306	119.12	36,440	0938–TBD (CMS–10722).
§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B).	56	4	1	224	34.10	7,638	0938–1265 (CMS–10529).
Total	56	13	Varies	1,432	Varies	180,276	n/a.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB and a final rule is issued.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at *www.cms.hhs.gov/PaperworkReductionActof1995,* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** Section of this proposed rule and identify the rule (CMS–2482–P) the ICR's CFR citation, and OMB control number.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

A. Statement of Need

This proposed rule would implement changes to:

- Section 1927 of the Act
- Statutory changes from the Medicaid Services Investment and Accountability Act of 2019 (Pub. L. 116–16, enacted April 18, 2019), BBA 2018 and the Affordable Care Act;
- Section 602 of BBA 2015, which amended section 1927(c)(3) of the Act;
- Section 2501(d) of the Affordable Care Act, which added section 1927(c)(2)(C) of the Act;
- Section 1927(b)(2)(A) of the Act requiring states to report to each manufacturer not later than 60 days after the end of each rebate period;
- Changes and additions to section 1927(g)(1) of the Act as set forth by section 1004 of the SUPPORT for Patients and Communities Act; and
- Title XIX of the Act and section 7 of the Medicaid Services Investment and Accountability Act of 2019 amending section 1902(a)(25)(E) of the Act ((§ 433.139(b)(2), (b)(3)(i) and (b)(3)(ii)(B)).
- Changes made by Public Law 116–59, the Continuing Appropriations Act, 2020, and Health Extenders Act of 2019 (Health Extenders Act), which made changes to section 1927(k)(1) and 1927(k)(11) of the Act.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, small pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We are not preparing an analysis for the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603

of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule with comment period would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. This rule would have no consequential effect on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on state and local governments, preempts state law, or otherwise has federalism implications. Since this regulation does not impose any substantial direct compliance costs on state or local governments, preempt state law, or otherwise have federalism implications, the requirements of Executive Order 13132 are not applicable.

Executive Order 13771 (January 30, 2017) requires that the costs associated with significant new regulations ''to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.'' This proposed rule is not subject to the requirements of E.O. 13771 because it is expected to result in no more than de minimis costs.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 433

Administrative practice and procedure, Child support, Claims, Grant programs-health, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 438

Grant programs-health, Medicaid, Reporting and Recordkeeping requirements.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

42 CFR Part 456

Administrative practice and procedure, Drugs, Grant programs-health, Health facilities, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 433—STATE FISCAL ADMINISTRATION

■ 1. The authority citation for part 433 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 2. Section 433.139 is amended by—
■ a. Removing and reserving paragraph (b)(2); and
■ b. Revising paragraphs (b)(3)(i) and (b)(3)(ii)(B).

The revisions read as follows:

§ 433.139 Payment of claims.

* * * * *

(b) * * *

(2) [Reserved]

(3) * * *

(i) The claim is for preventive pediatric services, including early and periodic screening, diagnosis and treatment services provided for under part 441, subpart B of this chapter, that are covered under the State plan; or

(ii) * * *

(B) For child support enforcement services beginning February 9, 2018, the provider certifies that before billing Medicaid, if the provider has billed a third party, the provider has waited 100 days from the date of the service and has not received payment from the third party.

* * * * *

PART 438—MANAGED CARE

■ 3. The authority citation for part 438 continues to read as follows:

Authority: 42 U.S.C. 1302.

■ 4. Section 438.2 is amended by adding the definition of ''Managed care entities (MCEs) in alphabetical order to read as follows:

§ 438.2 Definitions.

* * * * *

Managed care entity (MCE) means a Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act, that provides or arranges for services for enrollees under a contract pursuant to section 1903(m) of the Act or a primary care case manager, as defined in section 1905(t)(2) of the Act.

* * * * *

■ 5. Section 438.3 is amended by revising paragraphs (s) introductory text, (s)(4) and (5) to read as follows:

§ 438.3 Standard contract requirements.

* * * * *

(s) *Requirements for MCOs, MCEs, PIHPs, or PAHPs that provide covered outpatient drugs.* Contracts that obligate MCOs, MCEs, PIHPs or PAHPs to provide coverage of covered outpatient drugs must include the following requirements:

* * * * *

(4) The MCO, MCE, PIHP or PAHP must operate a drug utilization review program that complies with the requirements described in section 1927(g) of the Act and part 456, subpart K of this chapter, as if such requirement applied to the MCO, MCE, PIHP, or PAHP instead of the State.

(5) The MCO, MCE, PIHP or PAHP must provide a detailed description of its drug utilization review program activities to the State on an annual basis.

* * * * *

PART 447—PAYMENTS FOR SERVICES

■ 6. The authority citation for part 447 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1396r–8.

■ 7. Section 447.502 is amended—
■ a. In the definition of ''Bundled sale'' by adding paragraph (3);
■ b. By adding the definition of ''CMS-authorized supplemental rebate agreement'' in alphabetical order;
■ c. By revising the definition of ''Innovator multiple source drug'';
■ d. By adding the definition of ''Line extension'' in alphabetical order;
■ e. By revising the definition of ''Multiple source drug'';
■ f. By adding the definition of ''New formulation'' in alphabetical order;
■ g. By revising the definitions of ''Oral solid dosage form'' and ''Single source drug'';
■ h. By adding the definitions of ''Value-based purchasing (VBP) arrangement'' in alphabetical order; and
■ i. By revising the definition of ''Wholesaler''.

The additions and revisions read as follows:

§ 447.502 Definitions.

* * * * *

Bundled sale * * *

(3) Value-based purchasing (VBP) arrangements may qualify as a bundled sale, if the arrangement contains a performance requirement such as an outcome(s) measurement metric.

* * * * *

CMS-authorized supplemental rebate agreement means an agreement that is approved through a state plan amendment (SPA) by CMS, which allows a state to enter into single and/or multi-state supplemental drug rebate arrangements that generate rebates that are at least as large as the rebates set forth in the Secretary's national rebate agreement with drug manufacturers. Revenue from these rebates must be paid directly to the state and be used by the state to offset a state's drug expenditures resulting in shared savings with the Federal government.

* * * * *

Innovator multiple source drug means a multiple source drug, including an authorized generic drug, that is marketed under a new drug application (NDA) approved by FDA, unless the Secretary determines that a narrow exception applies (as described in this section or any successor regulation). It also includes a drug product marketed by any cross-licensed producers, labelers, or distributors operating under the NDA and a covered outpatient drug approved under a biologics license application (BLA), product license application (PLA), establishment license application (ELA) or antibiotic drug application (ADA).

* * * * *

Line extension means, for a drug, a new formulation of the drug, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary).

* * * * *

Multiple source drug means, for a rebate period, a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, for which there is at least 1 other drug product which meets all of the following criteria:

(1) Is rated as therapeutically equivalent (under the FDA's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'' which is available at *http://www.accessdata.fda.gov/scripts/cder/ob/*).

(2) Except as provided at section 1927(k)(7)(B) of the Act, is pharmaceutically equivalent and bioequivalent, as defined at section 1927(k)(7)(C) of the Act and as determined by FDA.

(3) Is sold or marketed in the United States during the period.

* * * * *

New formulation means, for a drug, any change to the drug, provided that the new formulation contains at least one active ingredient in common with the initial brand name listed drug. New formulations include, but are not limited to: Extended release formulations; changes in dosage form, strength, route of administration, ingredients, pharmacodynamics, or pharmacokinetic properties; changes in indication accompanied by marketing as a separately identifiable drug (for example, a different NDC); and combination drugs, such as a drug that is a combination of two or more drugs or a drug that is a combination of a drug and a device.

* * * * *

Oral solid dosage form means an orally administered dosage form that is not a liquid or gas at the time the drug enters the oral cavity.

* * * * *

Single source drug means a covered outpatient drug, including a drug product approved for marketing as a non-prescription drug that is regarded as a covered outpatient drug under section 1927(k)(4) of the Act, which is produced or distributed under a new drug application approved by the FDA, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application unless the Secretary determines that a narrow exception applies (as described in this section or any successor regulation), and includes a covered outpatient drug that is a biological product licensed, produced, or distributed under a biologics license application approved by the FDA.

* * * * *

Value-based purchasing (VBP) arrangement means an arrangement or agreement intended to align pricing and/or payments to an observed or expected therapeutic or clinical value in a population (that is, outcomes relative to costs) and includes, but is not limited to:

(1) Evidence-based measures, which substantially link the cost of a drug to existing evidence of effectiveness and potential value for specific uses of that product.

(2) Outcomes-based measures, which substantially link payment for the drug to that of the drug's actual performance in patient or a population, or a reduction in other medical expenses.

Wholesaler means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including but not limited to repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

■ 8. Section 447.504 is amended by—

■ a. Removing paragraph (b)(2);

■ b. Redesignating paragraph (b)(3) as paragraph (b)(2);

■ c. Revising paragraphs (c)(25) through (29); and

■ d. Revising paragraphs (e)(13) through (17).

The revisions read as follows:

§ 447.504 Determination of average manufacturer price.

* * * * *

(c) * * *

(25) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(26) Manufacturer-sponsored programs that provide free goods, including but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: The voucher or benefit of such a program is not contingent on any other purchase requirement; The full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(27) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP eligible entity does not receive any price concession.

(28) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer ensures that the manufacturer provides a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(29) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the

patient and the pharmacy, agent, or other AMP eligible entity does not receive any price concession

* * * * *

(e) * * *

(13) Manufacturer coupons to a consumer redeemed by the manufacturer, agent, pharmacy or another entity acting on behalf of the manufacturer, but only to the extent that the manufacturer ensures the full value of the coupon is passed on to the consumer and the pharmacy, agent, or other AMP-eligible entity does not receive any price concession.

(14) Manufacturer-sponsored programs that provide free goods, including, but not limited to vouchers and patient assistance programs, but only to the extent that the manufacturer ensures: The voucher or benefit of such a program is not contingent on any other purchase requirement; The full value of the voucher or benefit of such a program is passed on to the consumer; and the pharmacy, agent, or other AMP eligible entity does not receive any price concession.

(15) Manufacturer-sponsored drug discount card programs, but only to the extent that the manufacturer ensures the full value of the discount is passed on to the consumer and the pharmacy, agent, or the other AMP-eligible entity does not receive any price concession.

(16) Manufacturer-sponsored patient refund/rebate programs, to the extent that the manufacturer ensures the manufacturer provided a full or partial refund or rebate to the patient for out-of-pocket costs and the pharmacy agent, or other AMP eligible entity does not receive any price concession.

(17) Manufacturer copayment assistance programs, to the extent that the manufacturer ensures the program benefits are provided entirely to the patient and the pharmacy agent, or other AMP eligible entity does not receive any price concession

* * * * *

■ 9. Section 447.505 is amended—

■ a. In paragraph (a), by revising the definition of ''Best price'';

■ b. In paragraphs (c)(8) and (9), by removing the phrase ''extent that'' and adding in its place the phrase ''extent the manufacturer ensures that'';

■ c. In paragraphs (c)(10), (11) and (12), by removing the phrase ''that the'' and adding in its place the phrase ''that the manufacturer ensures the''; and

■ d. By revising paragraphs (d)(3).

The revisions reads as follows:

§ 447.505 Determination of best price.

(a) * * *

Best price means, for a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for an authorized generic drug), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity in the United States in any pricing structure (including capitated payments) in the same quarter for which the AMP is computed. The lowest price available from a manufacturer may include varying best price points for a single dosage form and strength as a result of a value based purchasing arrangement (as defined at § 447.502).

* * * * *

(d) * * *

(3) The manufacturer must adjust the best price for a rebate period if cumulative discounts, rebates, or other arrangements subsequently adjust the prices available, to the extent that such cumulative discounts, rebates or other arrangements are not excluded from the determination of best price by statute or regulation.

■ 10. Section 447.506 is amended by revising paragraph (b) to read as follows:

§ 447.506 Authorized generic drugs.

* * * * *

(b) *Exclusion of authorized generic drugs from AMP by a primary manufacturer.* The primary manufacturer must exclude from its calculation of AMP any sales of authorized generic drugs to wholesalers for drugs distributed to retail community pharmacies when reporting the AMP of the brand name drug of that authorized generic drug.

* * * * *

■ 11. Section 447.509 is amended—

■ a. By revising paragraphs (a)(4)(i) introductory text, (a)(4)(i)(A), (a)(4)(ii) introductory text, (a)(4)(ii)(A), and (a)(5);

■ b. In paragraph (a)(6) introductory text, by removing word ''rebate'' and adding in its place the phrase ''basic rebate''; and

■ c. By adding paragraphs (a)(7), (8) and (9).

The revisions and additions read as follows:

§ 447.509 Medicaid drug rebates (MDR).

(a) * * *

(4) * * *

(i) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug, provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form, the rebate obligation for the rebate periods beginning January 1, 2010 through September 30, 2018 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug.

* * * * *

(ii) In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug, provided that the initial single source drug or innovator multiple source drug is an oral solid dosage form, the rebate obligation for the rebate periods beginning on or after October 1, 2018 is the amount computed under paragraphs (a)(1) through (3) of this section for such new drug or, if greater, the amount computed under paragraph (a)(1) of this section plus the product of all of the following:

(A) The AMP of the line extension of a single source drug or an innovator multiple source drug.

* * * * *

(5) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP of the single source or multiple source innovator drug.

* * * * *

(7) *Additional rebate for noninnovator multiple source drugs.* In addition to the basic rebate described in paragraph (a)(6) of this section, for each dosage form and strength of a noninnovator multiple source drug, the rebate amount will be increased by an amount equal to the product of the following:

(i) The total number of units of such dosage form and strength paid for under the State plan in the rebate period.

(ii) The amount, if any, by which:

(A) The AMP for the dosage form and strength of the drug for the period exceeds: (B) The base date AMP for such dosage form and strength, increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index associated with the base date AMP of the drug. The base date AMP has the meaning of AMP set forth in sections 1927(c)(2)(A)(ii)(II), 1927(c)(2)(B) and 1927(c)(3)(C) of the Act.

(8) *Total rebate.* The total rebate amount for noninnovator multiple source drugs is equal to the basic rebate amount plus the additional rebate amount, if any.

(9) *Limit on rebate.* In no case will the total rebate amount exceed 100 percent of the AMP for the noninnovator multiple source drug.

* * * * *

■ 12. Section 447.510 is amended by adding paragraph (b)(1)(vi) to read as follows:

§ 447.510 Requirement for manufacturers.

* * * * *

(b) * * *

(1) * * *

(vi) The change is a result of a VBP arrangement, as defined in § 447.502, requiring the manufacturer to make changes outside of the 12-quarter rule, when the outcome must be evaluated outside of the 12-quarter period.

* * * * *

■ 13. Section 447.511 is amended—

■ a. In paragraph (a) introductory text, by removing the phrase ''following data:'' and adding in its place the phrase ''following data and any subsequent changes to the data fields on the CMS–R–144 Medicaid Drug Rebate Invoice form:'';

■ b. By revising paragraph (b); and

■ c. By adding paragraphs (d) and (e).

The revision and additions read as follows:

§ 447.511 Requirements for States.

* * * * *

(b) *Data submitted to CMS.* On a quarterly basis, the State must submit drug utilization data to CMS, which will be the same information as submitted to the manufacturers on the CMS–R–144, as specified in paragraph (a) of this section. The state data submission will be due no later than 60 days after the end of each rebate period. In the event that a due date falls on a weekend or Federal holiday, the submission will be due on the first business day following that weekend or Federal holiday. Any adjustments to previously submitted data will be transmitted to the manufacturer and CMS in the same reporting period.

* * * * *

(d) *State data certification.* Each data submission in this section must be certified by one of the following:

(1) The State Medicaid Director (SMD);

(2) The Deputy State Medicaid Director (DSMD);

(3) An individual other than the SMD or DSMD, who has authority equivalent to an SMD or DSMD; or

(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in paragraphs (d)(1) through (3) of this section.

(e) *State data certification language.* Each data submission by a state must include the following certification language: ''I hereby certify, to the best of my knowledge, that the state's data submission is complete and accurate at the time of this submission, and was prepared in accordance with the state's good faith, reasonable efforts based on existing guidance from CMS, section 1927 of the Act and applicable federal regulations. I further certify that the state has transmitted data to CMS, including any adjustments to previous rebate periods, in the same reporting period as provided to the manufacturer. Further, the state certifies that it has applied any necessary edits to the data for both CMS and the labeler to avoid inaccuracies at both the NDC/line item and file/aggregate level. Such edits are to be applied in the same manner and in the same reporting period to both CMS and the manufacturer.''

■ 14. Section 447.518 is amended by adding paragraphs (d)(1) and (2) to read as follows:

§ 447.518 State plan requirements, findings, and assurances.

* * * * *

(d) * * *

(1) A State participating in value-based purchasing arrangements must report data described in paragraph (d)(2) of this section on an annual basis.

(2) Within 60 days of the end of each year, the State must submit all of the following data:

(i) State.

(ii) National drug code(s) (for drugs covered under the VBP).

(iii) Product FDA list name.

(iv) Number of prescriptions.

(v) Cost to the State to administer VBP (for example, systems changes, tracking outcomes, etc.).

(vi) Total savings generated by the supplemental rebate due to VBP.

PART 456—UTILIZATION CONTROL

■ 15. The authority citation for part 456 is revised to read as follows:

Authority: 42 U.S.C. 1302.

■ 16. Section 456.703 is amended by—

■ a. Redesignating paragraph (h) as (i); and

■ b. Adding a new paragraph (h).

The addition reads as follows:

§ 456.703 Drug use review programs.

* * * * *

(h) *Minimum standards for DUR programs.* (1) *Minimum standards.* In operating their DUR programs, states must include the following minimum standards:

(i) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on:

(A) Days' supply for patients not currently receiving opioid therapy for initial prescription fills;

(B) Quantity of prescription dispensed for initial and subsequent prescription fills;

(C) Therapeutically-duplicative initial and subsequent opioid prescription fills; and

(D) Early refills, for subsequent prescription fills.

(ii) Prospective safety edit limitations for opioid prescriptions, as specified by the State, on the maximum daily morphine milligram equivalent for treatment of chronic pain, for initial and subsequent prescription fills.

(iii) A retrospective claims review automated process that indicates prescription fills of opioids in excess of the prospective safety edit limitations specified by the state under paragraphs (h)(1)(i) or (ii) of this section to provide for the ongoing review of opioid claims data to identify patterns of fraud, abuse, excessive utilization, inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or provision of inappropriate or medically unnecessary care among prescribers, pharmacists and individuals receiving Medicaid benefits.

(iv) A retrospective claims review automated process and, at the option of the state, prospective safety edits that monitor when an individual is concurrently prescribed opioids and:

(A) Benzodiazepines; or

(B) Antipsychotics.

(v) A program to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan, including any Medicaid expansion groups for the Children's Health Insurance Program (CHIP).

(vi) A process to identify potential fraud or abuse of controlled substances by individuals enrolled under the State plan, health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

(vii) Prospective safety edits, retrospective claims review automated processes, or a combination of these approaches as determined by the state, to identify when:

(A) A beneficiary is prescribed an opioid after the beneficiary has been prescribed one or more drugs used for Medication Assisted Treatment (MAT) of an opioid use disorder or has been diagnosed with an opioid use disorder, within a timeframe specified by the state, in the absence of a new indication to support utilization of opioids (such as new cancer diagnosis or entry into hospice care); and

(B) A beneficiary could be at high risk of opioid overdose and should be considered for co-prescription or co-dispensing of naloxone.

(2) *Exclusion.* The requirements in paragraphs (h)(1)(i) through (vii) of this section do not apply with respect to individuals receiving hospice or palliative care or treatment for cancer; individuals who are residents of long-term care facilities, intermediate care facilities for the intellectually disabled, or facilities that dispense frequently abused drugs through a contract with a single pharmacy; or other individuals the state elects to exempt. While States are not required to apply these requirements with respect to these individuals, States may elect to do so.

* * * * *

■ 17. Section 456.712 is amended by adding paragraph (c) to read as follows:

§ 456.712 Annual report.

* * * * *

(c) *Public availability.* All FFS and managed care DUR reports received by CMS under paragraph (b) of this section and, as applicable, pursuant to § 438.3(s) of this chapter, will be publicly posted on a website maintained by CMS for the sharing of reports and other information concerning Medicaid DUR programs.

Dated: February 6, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: June 11, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–12970 Filed 6–16–20; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 85 Friday,

No. 119 June 19, 2020

Part V

The President

Executive Order 13929—Safe Policing for Safe Communities

Notice of June 17, 2020—Continuation of the National Emergency With Respect to North Korea

Federal Register
Vol. 85, No. 119
Friday, June 19, 2020

Presidential Documents

Title 3—

The President

Executive Order 13929 of June 16, 2020

Safe Policing for Safe Communities

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose.* As Americans, we believe that all persons are created equal and endowed with the inalienable rights to life and liberty. A fundamental purpose of government is to secure these inalienable rights. Federal, State, local, tribal, and territorial law enforcement officers place their lives at risk every day to ensure that these rights are preserved.

Law enforcement officers provide the essential protection that all Americans require to raise their families and lead productive lives. The relationship between our fellow citizens and law enforcement officers is an important element in their ability to provide that protection. By working directly with their communities, law enforcement officers can help foster a safe environment where we all can prosper.

Unfortunately, there have been instances in which some officers have misused their authority, challenging the trust of the American people, with tragic consequences for individual victims, their communities, and our Nation. All Americans are entitled to live with the confidence that the law enforcement officers and agencies in their communities will live up to our Nation's founding ideals and will protect the rights of all persons. Particularly in African-American communities, we must redouble our efforts as a Nation to swiftly address instances of misconduct.

The Constitution declares in its preamble that one of its primary purposes was to establish Justice. Generations of Americans have marched, fought, bled, and died to safeguard the promise of our founding document and protect our shared inalienable rights. Federal, State, local, tribal, and territorial leaders must act in furtherance of that legacy.

Sec. 2. *Certification and Credentialing.* (a) State and local law enforcement agencies must constantly assess and improve their practices and policies to ensure transparent, safe, and accountable delivery of law enforcement services to their communities. Independent credentialing bodies can accelerate these assessments, enhance citizen confidence in law enforcement practices, and allow for the identification and correction of internal deficiencies before those deficiencies result in injury to the public or to law enforcement officers.

(b) The Attorney General shall, as appropriate and consistent with applicable law, allocate Department of Justice discretionary grant funding only to those State and local law enforcement agencies that have sought or are in the process of seeking appropriate credentials from a reputable independent credentialing body certified by the Attorney General.

(c) The Attorney General shall certify independent credentialing bodies that meet standards to be set by the Attorney General. Reputable, independent credentialing bodies, eligible for certification by the Attorney General, should address certain topics in their reviews, such as policies and training regarding use-of-force and de-escalation techniques; performance management tools, such as early warning systems that help to identify officers who may require intervention; and best practices regarding community engagement. The Attorney General's standards for certification shall require independent credentialing bodies to, at a minimum, confirm that:

(i) the State or local law enforcement agency's use-of-force policies adhere to all applicable Federal, State, and local laws; and

(ii) the State or local law enforcement agency's use-of-force policies prohibit the use of chokeholds—a physical maneuver that restricts an individual's ability to breathe for the purposes of incapacitation—except in those situations where the use of deadly force is allowed by law.

(d) The Attorney General shall engage with existing and prospective independent credentialing bodies to encourage them to offer a cost-effective, targeted credentialing process regarding appropriate use-of-force policies that law enforcement agencies of all sizes in urban and rural jurisdictions may access.

Sec. 3. *Information Sharing.* (a) The Attorney General shall create a database to coordinate the sharing of information between and among Federal, State, local, tribal, and territorial law enforcement agencies concerning instances of excessive use of force related to law enforcement matters, accounting for applicable privacy and due process rights.

(b) The database described in subsection (a) of this section shall include a mechanism to track, as permissible, terminations or de-certifications of law enforcement officers, criminal convictions of law enforcement officers for on-duty conduct, and civil judgments against law enforcement officers for improper use of force. The database described in subsection (a) of this section shall account for instances where a law enforcement officer resigns or retires while under active investigation related to the use of force. The Attorney General shall take appropriate steps to ensure that the information in the database consists only of instances in which law enforcement officers were afforded fair process.

(c) The Attorney General shall regularly and periodically make available to the public aggregated and anonymized data from the database described in subsection (a) of this section, as consistent with applicable law.

(d) The Attorney General shall, as appropriate and consistent with applicable law, allocate Department of Justice discretionary grant funding only to those law enforcement agencies that submit the information described in subsection (b) of this section.

Sec. 4. *Mental Health, Homelessness, and Addiction.* (a) Since the mid-twentieth century, America has witnessed a reduction in targeted mental health treatment. Ineffective policies have left more individuals with mental health needs on our Nation's streets, which has expanded the responsibilities of law enforcement officers. As a society, we must take steps to safely and humanely care for those who suffer from mental illness and substance abuse in a manner that addresses such individuals' needs and the needs of their communities. It is the policy of the United States to promote the use of appropriate social services as the primary response to individuals who suffer from impaired mental health, homelessness, and addiction, recognizing that, because law enforcement officers often encounter such individuals suffering from these conditions in the course of their duties, all officers should be properly trained for such encounters.

(b) The Attorney General shall, in consultation with the Secretary of Health and Human Services as appropriate, identify and develop opportunities to train law enforcement officers with respect to encounters with individuals suffering from impaired mental health, homelessness, and addiction; to increase the capacity of social workers working directly with law enforcement agencies; and to provide guidance regarding the development and implementation of co-responder programs, which involve social workers or other mental health professionals working alongside law enforcement officers so that they arrive and address situations together. The Attorney General and the Secretary of Health and Human Services shall prioritize resources, as appropriate and consistent with applicable law, to support such opportunities.

(c) The Secretary of Health and Human Services shall survey community-support models addressing mental health, homelessness, and addiction. Within 90 days of the date of this order, the Secretary of Health and Human Services shall summarize the results of this survey in a report to the President, through the Assistant to the President for Domestic Policy and the Director of the Office of Management and Budget, which shall include specific recommendations regarding how appropriated funds can be reallocated to support widespread adoption of successful models and recommendations for additional funding, if needed.

(d) The Secretary of Health and Human Services shall, in coordination with the Attorney General and the Director of the Office of Management and Budget, prioritize resources, as appropriate and consistent with applicable law, to implement community-support models as recommended in the report described in subsection (c) of this section.

Sec. 5. *Legislation and Grant Programs.* (a) The Attorney General, in consultation with the Assistant to the President for Domestic Policy and the Director of the Office of Management and Budget, shall develop and propose new legislation to the Congress that could be enacted to enhance the tools and resources available to improve law enforcement practices and build community engagement.

(b) The legislation described in subsection (a) of this section shall include recommendations to enhance current grant programs to improve law enforcement practices and build community engagement, including through:

(i) assisting State and local law enforcement agencies with implementing the credentialing process described in section 2 of this order, the reporting described in section 3 of this order, and the co-responder and community-support models described in section 4 of this order;

(ii) training and technical assistance required to adopt and implement improved use–of-force policies and procedures, including scenario-driven de-escalation techniques;

(iii) retention of high-performing law enforcement officers and recruitment of law enforcement officers who are likely to be high-performing;

(iv) confidential access to mental health services for law enforcement officers; and

(v) programs aimed at developing or improving relationships between law enforcement and the communities they serve, including through community outreach and listening sessions, and supporting non-profit organizations that focus on improving stressed relationships between law enforcement officers and the communities they serve.

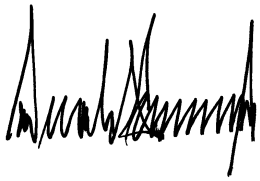
Sec. 6. *General Provisions.* (a) Nothing in this order shall be construed to impair or otherwise affect:

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

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

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

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



THE WHITE HOUSE,
June 16, 2020.

[FR Doc. 2020–13449
Filed 6–18–20; 11:15 am]
Billing code 3295–F0–P

Presidential Documents

Notice of June 17, 2020

Continuation of the National Emergency With Respect to North Korea

On June 26, 2008, by Executive Order 13466, the President declared a national emergency with respect to North Korea pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security and foreign policy of the United States constituted by the existence and risk of proliferation of weapons-usable fissile material on the Korean Peninsula. The President also found that it was necessary to maintain certain restrictions with respect to North Korea that would otherwise have been lifted pursuant to Proclamation 8271 of June 26, 2008, which terminated the exercise of authorities under the Trading With the Enemy Act (50 U.S.C. App. 1–44) with respect to North Korea.

On August 30, 2010, the President signed Executive Order 13551, which expanded the scope of the national emergency declared in Executive Order 13466 to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by the continued actions and policies of the Government of North Korea, manifested by its unprovoked attack that resulted in the sinking of the Republic of Korea Navy ship *Cheonan* and the deaths of 46 sailors in March 2010; its announced test of a nuclear device and its missile launches in 2009; its actions in violation of United Nations Security Council Resolutions 1718 and 1874, including the procurement of luxury goods; and its illicit and deceptive activities in international markets through which it obtains financial and other support, including money laundering, the counterfeiting of goods and currency, bulk cash smuggling, and narcotics trafficking, which destabilize the Korean Peninsula and imperil United States Armed Forces, allies, and trading partners in the region.

On April 18, 2011, the President signed Executive Order 13570 to take additional steps to address the national emergency declared in Executive Order 13466 and expanded in Executive Order 13551 that would ensure the implementation of the import restrictions contained in United Nations Security Council Resolutions 1718 and 1874 and complement the import restrictions provided for in the Arms Export Control Act (22 U.S.C. 2751 *et seq.*).

On January 2, 2015, the President signed Executive Order 13687 to take further steps with respect to the national emergency declared in Executive Order 13466, as expanded in Executive Order 13551, and addressed further in Executive Order 13570, to address the threat to the national security, foreign policy, and economy of the United States constituted by the provocative, destabilizing, and repressive actions and policies of the Government of North Korea, including its destructive, coercive cyber-related actions during November and December 2014, actions in violation of United Nations Security Council Resolutions 1718, 1874, 2087, and 2094, and commission of serious human rights abuses.

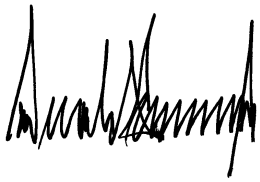
On March 15, 2016, the President signed Executive Order 13722 to take additional steps with respect to the national emergency declared in Executive Order 13466, as modified in scope and relied upon for additional steps in subsequent Executive Orders, to address the Government of North Korea's continuing pursuit of its nuclear and missile programs, as evidenced by

its February 7, 2016 launch using ballistic missile technology and its January 6, 2016 nuclear test in violation of its obligations pursuant to numerous United Nations Security Council resolutions and in contravention of its commitments under the September 19, 2005 Joint Statement of the Six-Party Talks, that increasingly imperils the United States and its allies.

On September 20, 2017, the President signed Executive Order 13810 to take further steps with respect to the national emergency declared in Executive Order 13466, as modified in scope and relied upon for additional steps in subsequent Executive Orders, to address the provocative, destabilizing, and repressive actions and policies of the Government of North Korea, including its intercontinental ballistic missile launches of July 3 and July 28, 2017, and its nuclear test of September 2, 2017; its commission of serious human rights abuses; and its use of funds generated through international trade to support its nuclear and missile programs and weapons proliferation.

The existence and risk of proliferation of weapons-usable fissile material on the Korean Peninsula and the actions and policies of the Government of North Korea continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared in Executive Order 13466, expanded in scope in Executive Order 13551, addressed further in Executive Order 13570, further expanded in scope in Executive Order 13687, and under which additional steps were taken in Executive Order 13722, and Executive Order 13810, and the measures taken to deal with that national emergency, must continue in effect beyond June 26, 2020. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to North Korea declared in Executive Order 13466.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
June 17, 2020.

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21 34578
36 35628
218 33914

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

S. 3744/P.L. 116–145
Uyghur Human Rights Policy Act of 2020 (June 17, 2020; 134 Stat. 648)
Last List June 18, 2020

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