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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 932

[Doc. No. AMS–SC–20–0012; SC20–932–2 FR]

Olives Grown in California; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This rule implements a recommendation from the California Olive Committee (Committee) to decrease the assessment rate established for the 2020 fiscal year and subsequent fiscal years. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective June 15, 2020.

FOR FURTHER INFORMATION CONTACT: Kathie Notoro, Marketing Specialist, or Terry Vawter, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 538–1672, Fax: (559) 487–5906, or Email: *Kathie.Notoro@usda.gov* or *Terry.Vawter@usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@usda.gov.*

SUPPLEMENTARY INFORMATION: This action, pursuant to 5 U.S.C. 553, amends regulations issued to carry out a marketing order as defined in 7 CFR 900.2(j). This rule is issued under Marketing Agreement and Order No. 932, as amended (7 CFR part 932), regulating the handling of olives grown in California. Part 932 (referred to as the ''Order'') is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.'' The Committee locally administers the Order and is comprised of producers and handlers of olives operating within the area of production, and a public member.

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 13563 and 13175. This action falls within a category of regulatory actions that the Office of Management and Budget (OMB) exempted from Executive Order 12866 review. Additionally, because this rule does not meet the definition of a significant regulatory action, it does not trigger the requirements contained in Executive Order 13771. See OMB's Memorandum titled ''Interim Guidance Implementing Section 2 of the Executive Order of January 30, 2017, titled 'Reducing Regulation and Controlling Regulatory Costs' '' (February 2, 2017).

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the Order now in effect, California olive handlers are subject to assessments. Funds to administer the Order are derived from such assessments. It is intended that the assessment rate will be applicable to all assessable olives beginning on January 1, 2020, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This action decreases the assessment rate from $44.00 per ton of assessed olives, the rate that was established for the 2018–19 and subsequent fiscal years, to $15.00 per ton of assessed olives for the 2020 and subsequent fiscal years. The lower rate is the result of a significantly higher crop size, and the need to cover Committee expenses.

The Order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. Industry members serving on the Committee are familiar with its needs and with the costs of goods and services in their local area and are thus able to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. All directly affected persons have an opportunity to participate and provide input.

The Committee met on December 5, 2019, and unanimously recommended 2020 expenditures of $1,035,406, and an assessment rate of $24.00 per ton of assessed olives. In comparison, last year's budgeted expenditures were $1,628,923. However, on December 6, 2019, the Committee staff received an email requesting that the assessment rate be lower than the unanimously agreed to rate of $24.00. The Committee met again by conference call on January 22, 2020, to discuss the possibility of a lower assessment rate. During the conference call, a handler and some producers stated they would be willing to pay up to $100.00 per ton during the next alternate, low-bearing year, if the crop volume tonnage drops below what is necessary to fund the Committee's activities. After further Committee discussions, an assessment rate of $15.00 per ton of assessed olives was agreed to and recommended. The assessment rate of $15.00 is $29.00 lower than the rate currently in effect. Handlers received 81,689 tons of assessable olives from the 2019 crop year. This is substantially more than the 2018 crop year, which was 17,953 tons of assessable olives. The 2020 fiscal year assessment rate decrease will ensure the Committee has enough revenue to fund the recommended 2020 budgeted expenditures while ensuring the funds in the financial reserve will be kept within the maximum permitted by § 932.40.

The Order has a fiscal year and a crop year that are independent of each other. The crop year is a 12-month period that begins on August 1 of each year and ends on July 31 of the following year. The fiscal year is the 12-month period that begins on January 1 and ends on December 31 of each year. Olives are an alternate-bearing crop, with a small crop followed by a large crop. For assessment rate rules under the Order, the actual, rather than estimated, 2019 crop year receipts are used to determine the assessment rate for the 2020 fiscal year.

The major expenditures recommended by the Committee for the 2020 fiscal year includes $631,300 for program administration, $123,500 for marketing activities, $225,606 for research, and $55,000 for inspection equipment. Budgeted expenses for these items during the 2019 fiscal year were $713,900 for program administration, $513,500 for marketing activities, $343,523 for research, and $58,000 inspection equipment.

The assessment rate recommended by the Committee resulted from consideration of anticipated fiscal year expenses, actual olive tonnage received by handlers during the 2019 crop year, and the amount in the Committee's financial reserve. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve, will be adequate to cover budgeted expenses. Funds in the reserve will be kept within the maximum permitted by the Order of approximately one fiscal year's expenses.

The assessment rate established in this final rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate will be in effect for an indefinite period, the Committee will continue to meet prior to or during each fiscal year to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's budget for subsequent fiscal years will be reviewed and, as appropriate, approved by USDA.

Final Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 800 producers of olives in the production area and two handlers subject to regulation under the Order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $1,000,000, and small agricultural service firms are defined as those whose annual receipts are less than $30,000,000 (13 CFR 121.201).

Based upon National Agricultural Statistics Service (NASS) information as of June 2019, the average price to producers for the 2019 crop year was $766.00 per ton, and total assessable volume for the 2019 crop year was 81,689 tons. Based on production, price paid to producers, and the total number of California olive producers, the average annual producer revenue is less than $1,000,000 ($766.00 times 81,689 tons equals $62,573,774 divided by 800 producers equals an average annual producer revenue of $78,217.22). Thus, the majority of olive producers may be classified as small entities. Both handlers may be classified as large entities under the SBA's definitions because their annual receipts are greater than $30,000,000.

This final rule decreases the assessment rate collected from handlers for the 2020 and subsequent fiscal years from $44.00 to $15.00 per ton of assessable olives. The Committee unanimously recommended 2020 expenditures of $1,035,406 and an assessment rate of $15.00 per ton of assessable olives. The recommended assessment rate of $15.00 is $29.00 lower than the 2019 rate. The quantity of assessable olives for the 2020 fiscal year is 81,689 tons. The $15.00 rate should provide $1,225,335 in assessment revenue. The lower assessment rate is possible because annual receipts for the 2019 crop year are 81,689 tons compared to 17,953 tons for the 2018 crop year. Olives are an alternate-bearing crop, with a small crop followed by a large crop. Income derived from the $15.00 per ton assessment rate, along with funds from the authorized reserve and interest income, should be adequate to meet this fiscal year's expenses.

The major expenditures recommended by the Committee for the 2020 fiscal year include $631,300 for program administration, $123,500 for marketing activities, $225,606 for research, and $55,000 for inspection equipment. Budgeted expenses for these items during the 2019 fiscal year were $713,900 for program administration, $513,500 for marketing activities, $343,523 for research, and $58,000 for inspection equipment. The Committee deliberated many of the expenses, weighed the relative value of various programs or projects, and decreased its expenses for marketing and research activities.

Prior to arriving at this budget and assessment rate, the Committee considered information from various sources including the Committee's Executive, Marketing, Inspection, and Research Subcommittees. Alternate expenditure levels were discussed by these groups, based upon the relative value of various projects to the olive industry and the increased olive production. The assessment rate of $15.00 per ton of assessable olives was derived by considering anticipated expenses, the high volume of assessable olives, and additional pertinent factors.

NASS data indicate the average producer price for the 2019 crop year was $766.00 per ton. Therefore, utilizing the assessment rate of $15.00 per ton, the assessment revenue for the 2020 fiscal year as a percentage of total producer revenue will be approximately 0.02 percent.

This action decreases the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. Some of the additional costs may be passed on to producers. However, decreasing the assessment will reduce the burden on handlers and may reduce the burden on producers.

The Committee's meetings were widely publicized throughout the production area. The olive industry and all interested persons were invited to attend the meetings and participate in Committee deliberations on all issues. Like all Committee meetings, the December 5, 2019 and the January 22, 2020, meetings were public meetings.

All entities, both large and small, were able to express views on this issue.

In accordance with the Paperwork Reduction Act of 1995, (44 U.S.C. chapter 35), the Order's information collection requirements have been previously approved by OMB and assigned OMB No. 0581–0178 Vegetable and Specialty Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they will be submitted to OMB for approval.

This rule imposes no additional reporting or recordkeeping requirements on either small or large California olive handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies. As noted in the initial regulatory flexibility analysis, USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this final rule.

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

A proposed rule concerning this action was published in the **Federal Register** on March 4, 2020 (85 FR 12757). Copies of the proposed rule were provided to all olive producers and handlers. The proposal was made available through the internet by USDA and the Office of the Federal Register. A 30-day comment period ending April 3, 2020, was provided for interested persons to respond to the proposal. No comments were received. Accordingly, no changes will be made to the proposed rule. A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule will tend to effectuate the declared policy of the Act.

List of Subjects in 7 CFR Part 932

Marketing agreements, Olives, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 932 is amended as follows:

PART 932—OLIVES GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 932 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Revise § 932.230 to read as follows:

§ 932.230 Assessment rate.

On and after January 1, 2020, an assessment rate of $15.00 per ton is established for California olives.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–09345 Filed 5–13–20; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 214 and 274a

[CIS No. 2669–20; DHS Docket No. USCIS–2020–0012]

RIN 1615–AC58

Temporary Changes to Requirements Affecting H–2B Nonimmigrants Due to the COVID–19 National Emergency

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Temporary final rule.

SUMMARY: As a result of disruptions and uncertainty to the U.S. economy and international travel caused by the global novel Coronavirus Disease 2019 (COVID–19) public health emergency, the Department of Homeland Security (the Department or DHS), U.S. Citizenship and Immigration Services (USCIS), has decided to temporarily amend the regulations regarding certain temporary nonagricultural workers, and their U.S. employers, within the H–2B nonimmigrant classification. The Department is temporarily removing certain limitations on employers or U.S. agents seeking to hire certain H–2B workers already in the United States to provide temporary labor or services essential to the U.S. food supply chain, and certain H–2B workers, who are essential to the U.S. food supply chain, seeking to extend their stay.

DATES: This final rule is effective from May 14, 2020, through May 15, 2023. Employers may request the flexibilities under this rule by filing an H–2B petition, including the new attestation and all required evidence, on or after the effective date of this rule and until 120 days thereafter. Employers with H–2B petitions that are pending on the effective date of this rule may request the flexibilities made available under this rule by submitting a new attestation during that same 120-day period thereafter, and before the H–2B petition is adjudicated.

FOR FURTHER INFORMATION CONTACT: Charles L. Nimick, Chief, Business and Foreign Workers Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Ave. NW, Suite 1100, Washington, DC 20529–2120, Telephone Number (202)–272–8377 (not a toll-free call). Individuals with hearing or speech impairments may access the telephone numbers above via TTY by calling the toll-free Federal Information Relay Service at 1–877–889–5627 (TTY/TDD).

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I. Background

A. Legal Authority

The Immigration and Nationality Act (INA), as amended, establishes the H–2B nonimmigrant classification for a nonagricultural temporary worker ''having a residence in a foreign country which he has no intention of abandoning who is coming temporarily to the United States to perform . . . temporary [non-agricultural] service or labor if unemployed persons capable of performing such service or labor cannot be found in this country.'' INA section

101(a)(15)(H)(ii)(b), 8 U.S.C. 1101(a)(15)(H)(ii)(b). Employers or U.S. agents must petition DHS for classification of prospective temporary workers as H–2B nonimmigrants. INA section 214(c)(1), 8 U.S.C. 1184(c)(1). DHS must approve this petition before the beneficiary can be considered eligible for an H–2B visa. *Id.* Finally, the INA requires that ''[t]he question of importing any alien as [an H–2B] nonimmigrant . . . in any specific case or specific cases shall be determined by [DHS],[1] after consultation with appropriate agencies of the Government.'' *Id.*

DHS regulations provide that an H–2B petition for temporary employment in the United States must be accompanied by an approved temporary labor certification (TLC) from the Department of Labor (DOL), issued pursuant to regulations established at 20 CFR part 655. 8 CFR 214.2(h)(6)(iii)(A), (C)–(E), (iv)(A); *see also* INA section 214(a) and (c), 8 U.S.C. 1184(a) and (c); INA section 103(a)(6), 8 U.S.C. 1103(a)(6). The TLC serves as DHS's consultation with DOL as to whether a qualified U.S. worker is available to fill the petitioning employer's job opportunity and whether a foreign worker's employment in the job opportunity will adversely affect the wages or working conditions of similarly employed U.S. workers. *See* INA section 214(c)(1), 8 U.S.C. 1184(c)(1); 8 CFR 214.2(h)(6)(iii)(A) and (D).

The INA generally charges the Secretary of Homeland Security (Secretary) with the administration and enforcement of the immigration laws, and provides that the Secretary ''shall establish such regulations . . . and perform such other acts as he deems necessary for carrying out his authority'' under the INA. INA section 103(a)(3), 8 U.S.C. 1103(a)(3). In addition, the Secretary has the authority to issue this regulation under section 102 of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 6 U.S.C. 112, and section 103(a) of the INA, 8 U.S.C. 1103(a), which authorize the Secretary to administer and enforce the immigration and nationality laws. *See also* 6 U.S.C. 202(4) (charging the Secretary with ''[e]stablishing and administering rules . . . governing the granting of visas or other forms of permission . . . to enter the United States to individuals who are not a citizen or an alien lawfully admitted for permanent residence in the United States''). With respect to nonimmigrants, in particular, the INA provides that ''[t]he admission to the United States of any alien as a nonimmigrant shall be for such time and under such conditions as the [Secretary] may by regulations prescribe.'' INA section 214(a)(1), 8 U.S.C. 1184(a)(1); *see also* INA section 274A(h)(3), 8 U.S.C. 1324a(h)(3). Finally, under section 101 of HSA, 6 U.S.C. 111(b)(1)(F), a primary mission of the Department is to ''ensure that the overall economic security of the United States is not diminished by efforts, activities, and programs aimed at securing the homeland.''

B. Description of the H–2B Program

The H–2B nonimmigrant classification applies to alien workers ''coming temporarily to the United States to perform temporary [nonagricultural] service or labor if unemployed persons capable of performing such service or labor cannot be found in this country.'' INA 101(a)(15)(H)(ii)(b), 8 U.S.C. 1101(a)(15)(H)(ii)(b); *see also* 8 CFR 214.1(a)(2). The regulations define an employer's temporary need as employment that is of a temporary nature where the employer's need to fill the position with a temporary worker generally will last no longer than 1 year, unless the employer's need is a one-time event, in which case the need could last up to 3 years. *See* 8 CFR 214.2(h)(1)(ii)(D), (h)(6)(ii), and (h)(6)(vi)(D).

The INA sets the annual number of aliens who may be issued H–2B visas or otherwise provided H–2B nonimmigrant status to perform temporary nonagricultural work at 66,000, to be distributed semi-annually beginning in October and April. *See* INA sections 214(g)(1)(B) and 214(g)(10), 8 U.S.C. 1184(g)(1)(B) and 1184(g)(10). Up to 33,000 aliens may be issued H–2B visas or provided H–2B nonimmigrant status during the first 6 months of a fiscal year, and the remaining annual allocation is left available for employers seeking to hire H–2B workers during the remaining 6 months of the fiscal year.[2] If insufficient petitions are approved to use all H–2B numbers in a given fiscal year, the unused numbers cannot be carried over for petition approvals in the next fiscal year. An H–2B worker who is seeking an extension of H–2B status will not be counted against the H–2B numerical limitation. 8 CFR 214.2(h)(8)(ii)(A).

i. Temporary Labor Certification (TLC) Procedures

As noted above, before filing the H–2B petition with DHS, the petitioning employer or U.S. agent must obtain an approved TLC from DOL for the job opportunity the employer seeks to fill with an H–2B worker(s). To obtain a TLC from DOL, the employer must concurrently submit, at least 75 calendar days but not more than 90 calendar days before the start date of work, an *Application for Temporary Employment Certification* (H–2B application) to DOL's Office of Foreign Labor Certification (OFLC) and a nonagricultural job order to the State Workforce Agency (SWA) that serves the State where the actual work will be performed. 20 CFR 655.15(b), and 20 CFR 655.16(a) (requiring the filing of a job order at the SWA). OFLC reviews the H–2B application and job order and, if they are complete and meet the requirements of 20 CFR part 655, subpart A, issues a Notice of Acceptance, which directs the employer to engage in the recruitment of U.S. workers. 20 CFR 655.15, 655.30, 655.31, 655.32, 655.33. The SWA also reviews the job order and, upon OFLC's acceptance of the H–2B application, initiates the intrastate and interstate recruitment of U.S. workers. 20 CFR 655.16(b), (c). Upon completion of the post-acceptance requirements, including employer-conducted recruitment, OFLC issues the TLC. 20 CFR 655.40–655.46, 655.48, 655.50–655.52.

As noted above, in granting the TLC, DOL certifies that there are no U.S. workers who are qualified and available to fill the temporary position, and that the employment of H–2B workers will not adversely affect the wages and working conditions of workers in the United States similarly employed. 8 CFR 214.2(h)(6)(iii)(A). The employer must comply with applicable regulations, including, but not limited to, contacting former U.S. workers, including any laid-off U.S. workers, who were employed in the job opportunity identified on the TLC during the previous year and soliciting their return to the job. 20 CFR 655.20(w) and 29 CFR 503.16(w). The employer also must continue to accept referrals of all eligible U.S. workers who apply for the job opportunity until 21 days before the start date of need. *See* 20 CFR 655.20(t) and 29 CFR 503.16(t). Finally,

[1] As of March 1, 2003, in accordance with section 1517 of Title XV of the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, any reference to the Attorney General in a provision of the Immigration and Nationality Act describing functions that were transferred from the Attorney General or other Department of Justice official to DHS by the HSA ''shall be deemed to refer to the Secretary'' of Homeland Security. *See* 6 U.S.C. 557 (2003) (codifying HSA, Title XV, § 1517); 6 U.S.C. 542 note; 8 U.S.C. 1551 note.

[2] The Federal Government's fiscal year runs from October 1 of the budget's prior year through September 30 of the year being described. For example, fiscal year 2020 is from October 1, 2019, through September 30, 2020.

as part of the TLC process, the H–2B employer must agree to abide by certain conditions, including the condition that the H–2B employer has not laid off and will not lay off any similarly employed U.S. worker in the occupation that is the subject of the TLC in the area of intended employment within the period beginning 120 calendar days before the date of need through the end of the period of certification, except for lawful job-related reasons such as lack of work at the end of a season if all H–2B workers are laid off before any U.S. worker in corresponding employment. 20 CFR 655.20(v) and 29 CFR 503.16(v).[3]

ii. Petition Procedures

After receiving an approved TLC from DOL, the employer listed on the TLC or the employer's U.S. agent (''H–2B petitioner'') may file the H–2B petition with the appropriate USCIS office. 8 CFR 214.2(h)(2)(i), (h)(6)(iii)(E), and (h)(6)(vi). The H–2B petitioner may petition for one or more named or unnamed H–2B workers, but the total number of workers may not exceed the number of positions indicated on the TLC. 8 CFR 214.2(h)(2)(ii) and (h)(6)(viii). An H–2B petitioner must name an H–2B worker if the worker is in the United States or if that H–2B worker is a national of a country that is not designated as an H–2B participating country. 8 CFR 214.2(h)(2)(iii). USCIS recommends that petitioners submit a separate H–2B petition when requesting a worker(s) who is a national of a country that is not designated as an H–2B participating country. *See* 8 CFR 214.2(h)(2)(ii); *see also Identification of Foreign Countries Whose Nationals Are Eligible To Participate in the H–2A and H–2B Nonimmigrant Worker Programs,* Notice, 85 FR 3067 (Jan. 17, 2020). Petitioners of such aliens must submit evidence demonstrating the factors by which the request for H–2B workers serves the U.S. national interest. 8 CFR 214.2(h)(6)(i)(E)(*2*). USCIS will review each petition naming a national from a country not on the list and all supporting documentation and make a determination on a case-by-case basis.

The employer or U.S. agent generally may submit a new H–2B petition, with a new, approved TLC, to USCIS to request an extension of H–2B nonimmigrant status for the validity of the TLC or for a period of up to 1 year. 8 CFR 214.2(h)(15)(ii)(C). The H–2B petitioner must name the worker on the Form I–129, Petition for Nonimmigrant Worker, since the H–2B worker is in the United States and requesting an extension of stay. Except for certain professional athletes being traded among organizations, H–2B workers seeking to extend their status with a new employer may not begin employment with the new employer until the new H–2B petition is approved. 8 CFR 214.2(h)(2)(i)(D), (h)(6)(vii), 274a.12(b)(9).

iii. Admission and Limitations of Stay

Upon USCIS approval of the H–2B petition, the employer or U.S. agent may hire H–2B worker(s) to fill the job opening. USCIS generally will grant the workers H–2B classification for up to the period of time authorized on the approved TLC. H–2B workers who are outside of the United States may apply for a visa with U.S. Department of State (DOS) at a U.S. Embassy or Consulate abroad, if required, and seek admission to the United States with U.S. Customs and Border Protection (CBP) at a U.S. port of entry. Spouses and children of H–2B workers may request H–4 nonimmigrant status to accompany the principal H–2B workers. The spouse and children of an H nonimmigrant, if they are accompanying or following to join such an H–2B nonimmigrant, may be admitted into the United States, if otherwise admissible, as H–4 nonimmigrants for the same period of admission or extension as the principal spouse or parent. 8 CFR 214.2(h)(9)(iv). Thus, H–4 dependents of H–2B workers are subject to the same limitations on stay, and permission to remain in the country during the pendency of the new employer's petition, as the H–2B beneficiary.

H–2B workers may be admitted into the United States up to 10 days before the beginning validity date listed on the approved H–2B petition so that they may travel to their worksites, but they may not begin work until the beginning validity date on the petition. H–2B workers also may remain in the United States 10 days beyond the expiration date of the approved H–2B petition to prepare for departure or to seek an extension or change of nonimmigrant status. 8 CFR 214.2(h)(13)(i)(A). Under current regulations, with limited exception, H–2B workers do not have employment authorization outside of the validity period listed on the approved petition unless otherwise authorized, and the workers are limited to employment with the H–2B petitioner.[4] *See* 8 CFR 214.2(h)(6)(vii), 274a.12(b)(9).

Also under current regulations, the maximum period of stay for an alien in H–2B classification is 3 years. 8 CFR 214.2(h)(13)(iv) and (h)(15)(C). Generally, once an alien has held H–2B nonimmigrant status for a total of 3 years, the alien must depart and remain outside of the United States for an uninterrupted period of 3 months before seeking readmission as an H–2B nonimmigrant.[5] 8 CFR 214.2(h)(13)(iv).

C. COVID–19 National Emergency

On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency under section 319 of the Public Health Service Act (42 U.S.C. 247d), in response to the Coronavirus Disease 2019 (COVID–19).[6] On March 13, 2020, President Trump declared a National Emergency concerning the COVID–19 outbreak.[7] The President's proclamation declared that the emergency began on March 1, 2020. DOS announced the temporary suspension of routine immigrant and nonimmigrant visa services at the U.S. Embassy in Mexico City and all U.S.

[3] The Department of Labor Appropriations Act, 2016, Division H, Title I of Public Law 114–113 (''2016 DOL Appropriations Act''), prohibited DOL from using any funds to enforce the definition of corresponding employment found in 20 CFR 655.5, or any reference thereto. *See* Sec. 113. This appropriations rider has been included in each subsequent DOL Appropriations Act or relevant continuing resolution since 2016, well as in the Further Consolidated Appropriations Act, 2020, Division A, Title I of Public Law 116–94. Therefore, in order to comply, DOL has removed references to these provisions from the Form ETA–9142B—Appendix B. However, the DOL Appropriations Act and relevant continuing resolutions did not vacate these regulatory provisions, and they remain in effect, thus imposing a legal duty on H–2B employers, even though DOL will not use any funds to enforce them until such time as the appropriations rider may be lifted.

[4] In the case of a traded professional H–2B athlete who is traded from one organization to another organization, employment authorization for the player will automatically continue for a period of 30 days after acquisition by the new organization, within which time the new organization is expected to file a new H–2B petition. If a new H–2B petition is not filed within 30 days, employment authorization will cease. If a new H–2B petition is filed within 30 days, the professional athlete's employment authorization will continue until the petition is adjudicated. If the new petition is denied, employment authorization will cease. 8 CFR 214.2(h)(6)(vii) and 8 CFR 274a.12(b)(9).

[5] If the H–2B worker's accumulated stay is 18 months or less, an absence of at least 45 days will interrupt the 3-year limitation on admission. *See* 8 CFR 214.2(h)(13)(v) (also excepting from the limitations under 8 CFR 214.2(h)(13)(iii) through (iv), with respect to H–2B beneficiaries, aliens who did not reside continually in the United States and whose employment in the United States was seasonal or intermittent or was for an aggregate of 6 months or less per year, as well as aliens who reside abroad and regularly commute to the United States to engage in part-time employment).

[6] HHS, *Determination that a Public Health Emergency Exists, https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx* (last reviewed Jan. 31, 2020). *See also* HHS, *Determination of Public Health Emergency,* 85 FR 7316 (Feb. 7, 2020).

[7] President of the United States, Proclamation 9994 of March 13, 2020, *Declaring a National Emergency Concerning the Coronavirus Disease (COVID–19) Outbreak,* 85 FR 15337 (Mar. 18, 2020).

consulates in Mexico beginning on March 18, 2020.[8] DOS expanded the temporary suspension of routine immigrant and nonimmigrant visa services to all U.S. Embassies and Consulates on March 20, 2020.[9] DOS designated H–2 visas as mission critical, however, and announced that U.S. Embassies and Consulates will continue to process H–2B cases to the extent possible and implemented a change in its procedures, to include interview waivers, in certain categories of cases.[10]

II. Discussion

A. Temporary Changes to DHS Requirements for H–2B Change of Employer Requests and H–2B Maximum Period of Stay Exception During the COVID–19 National Emergency

DHS is committed both to protecting U.S. workers and to helping U.S. businesses receive the documented and work-authorized workers to perform temporary nonagricultural services or labor that they need to mitigate the adverse impact of COVID–19 on the U.S. food supply chain. Due to travel restrictions and limitations on visa services as a result of actions taken to mitigate the spread of COVID–19, as well as the possibility that some U.S. and H–2B workers may become unavailable to work due to COVID–19-related illness, employers or U.S. agents who have approved H–2B petitions or who will be filing H–2B petitions on or after the effective date of this rule might not receive all of the workers requested to fill the temporary positions. Similarly, employers who currently employ U.S. and H–2B workers may lose the services of these workers due to COVID–19-related illness.

On April 20, 2020, the Department published a temporary final rule in the **Federal Register** to amend certain H–2A requirements to help U.S. agricultural employers avoid disruptions in lawful agricultural-related employment, protect the nation's food supply chain, and lessen impacts from the COVID–19 public health emergency on the availability of food in the United States. 85 FR 21739 (Apr. 20, 2020). Under the H–2A temporary final rule, for a period of 120 days after the publication of that rule in the **Federal Register**, all H–2A petitioners with a valid TLC can start employing certain foreign workers who currently are in the United States and in valid H–2A status immediately after USCIS receives the H–2A petition filed by the new employer, but no earlier than the start date of employment listed on the H–2A petition. Additionally, the H–2A temporary final rule allows H–2A workers to extend their stay in the United States beyond the 3-year maximum allowable period.

The Department believes that it is necessary to extend similar flexibilities to H–2B petitioners seeking workers to perform temporary nonagricultural services or labor essential to the U.S. food supply chain that would not qualify for the H–2A temporary agricultural visa classification.[11] Work essential to the U.S. food supply chain includes a variety of industries and occupations where the H–2B worker is performing temporary nonagricultural services or labor, including but not limited to work related to the processing, manufacturing, and packaging of human and animal food; transporting human and animal food from farms, or manufacturing or processing plants, to distributors and end sellers; and the selling of human and animal food through a variety of sellers or retail establishments, including restaurants.

These workers ensure continuity of functions critical to public health and safety, as well as economic and national security and resilience of the nation's critical infrastructure.[12] In the wake of uncertainty inherent in confronting and responding to a public health emergency of this magnitude, DHS is taking steps to ensure that employers who have needs for temporary nonagricultural workers who provide stability to the nation's food supply chain have greater certainty and flexibility to minimize gaps in the flow of H–2B workers. Therefore, through September 11, 2020, the Department is providing H–2B petitioners with opportunity to request the flexibilities discussed herein.

First, the Department is amending its regulations to temporarily permit certain flexibilities for H–2B petitioners seeking workers to perform work essential to the U.S. food supply chain. Under this rule, aliens subject to such petitions may start working upon USCIS' receipt of the new H–2B petitions, accompanied by an attestation to USCIS stating that the alien qualifies for the flexibilities in this rule. The employment authorization begins no earlier than the start date of employment listed on the H–2B petition accompanied by the attestation or no earlier than the date on which USCIS acknowledges in writing the receipt of the H–2B petition, including the properly filed attestation. *See* new 8 CFR 214.2(h)(23) and 8 CFR 274a.12(b)(27).

This temporary provision grants employment authorization to the H–2B worker for 60 days from the date of the receipt notice for the H–2B petition filed by the new employer or 60 days from the start date of employment indicated in the H–2B petition, whichever is later. Employment is not authorized under this temporary final rule if an H–2B petition, which must include a valid TLC and attestation, is not received by USCIS as indicated by Form I–797 (Notice of Action). The 60-day employment authorization associated with the filed petition will automatically terminate 15 days after the date of denial if USCIS denies the petition, or 15 days after the date on which the petition is withdrawn.

USCIS will also apply this rule to any petition that was filed with USCIS on or after March 1, 2020, and remains pending as of May 14, 2020, beginning on the date that USCIS acknowledges the receipt of the aforementioned attestation. USCIS will acknowledge the receipt of the attestation in writing in order for the alien to begin employment before the H–2B petition is approved. The 60-day clock will begin to run as of the date USCIS acknowledges receipt of the attestation in writing. The 15-day termination provision described in the preceding paragraph will also apply in this case. It is the separate responsibility of an H–2B employer and H–2B worker to maintain appropriate records to establish that each has met the requirements outlined in 8 CFR

[8] DOS, *Status of U.S. Consular Operations in Mexico in Light of COVID–19, https://mx.usembassy.gov/status-of-u-s-consular-operations-in-mexico-in-light-of-covid-19/* (last updated Apr. 13, 2020).

[9] DOS, *Suspension of Routine Visa Services, https://travel.state.gov/content/travel/en/News/visas-news/suspension-of-routine-visa-services.html* (last updated Mar. 20, 2020).

[10] *See* DOS website, *Important Announcement on H2 Visas, https://travel.state.gov/content/travel/en/News/visas-news/important-announcement-on-h2-visas.html* (last updated Mar. 26, 2020).

[11] DHS recognizes that H–2B employers may also employ workers for purposes other than food supply chain matters that are nonetheless critical to public health and safety, or the economic and national security and resilience of the nation's critical infrastructure. DHS will continue to monitor the situation and assess employer needs and those of the U.S. population. For now, however, DHS believes that it is critical to offer the flexibilities announced in this rule to at least the employers described herein.

[12] The Cybersecurity and Infrastructure Security Agency (CISA) within DHS has issued guidance regarding essential critical infrastructure workers, including workers that perform essential food supply chain-related functions. *See, e.g.,* DHS, *Memorandum on Identification of Essential Critical Infrastructure Workers During COVID–19 Response, https://www.cisa.gov/sites/default/files/publications/Version_3.0_CISA_Guidance_on_Essential_Critical_Infrastructure_Workers_4.pdf* (Apr. 17, 2020). This list is generally advisory in nature, and is not produced for purposes related to immigration programs. USCIS nonetheless intends to consult the list as it administers this rule and interprets the scope of the flexibilities provided in this rule.

214.2(h)(23) and 8 CFR 274a.12(b)(27) if questions arise in future proceedings.

Since every H–2B petition must be accompanied by an approved TLC, all H–2B petitioners must have completed a test of the U.S. labor market, as a result of which DOL determined that there were no qualified U.S. workers available to fill these temporary positions. The Department believes that granting H–2B workers already in the United States the option to begin employment with new H–2B petitioners as soon as the H–2B petitions are received by USCIS will benefit employers in the United States and provide stability to the nation's food supply chain during the unique challenges the country faces because of COVID–19.

Second, the Department has determined that it is necessary to create a temporary exception to its regulations at 8 CFR 214.2(h)(13)(i)(B), (h)(13)(iv), (h)(13)(v), and (h)(15)(ii)(C), to allow the aforementioned aliens to extend their H–2B period of stay beyond the 3-year limitation, without first requiring them to remain outside of the United States for an uninterrupted period of 3 months.[13] This flexibility with respect to the 3-year limitation applies both to extensions of stay with the same employer as well as extensions of stay with a new employer.

Again, in order to use these flexibilities, H–2B employers in the United States must conduct (or must have conducted) a test of the U.S. labor market and be unable to find qualified, available U.S. workers to fill the positions. This is because this temporary final rule does not change applicable regulations pursuant to which employers in the United States must recruit U.S. workers before filing an H–2B petition with USCIS. In addition, beyond the flexibilities identified in this temporary final rule, DHS is not changing any other H–2B petition requirements or the adjudication process, including the requirement that the H–2B position qualify as temporary services or labor as defined in 8 CFR 214.2(h)(6)(ii).[14] This flexibility also is limited to aliens who are and have been complying with the terms of their H–2B status.

In addition to meeting all applicable substantive eligibility requirements, to be approved under this temporary final rule, the H–2B nonimmigrant must have been in the United States in valid nonimmigrant status on or after March 1, 2020.[15] In addition, an H–2B petition for an extension of stay must have been received on or after March 1, 2020, and remain pending as of the effective date of this rule, or received on or after the effective date of this rule and no later than September 11, 2020. However, for purposes of extensions of stay with a new employer or U.S. agent, employment with the new H–2B petitioner without an approved petition cannot begin before the effective date of this rule and before the start date of employment listed in the H–2B petition. If the new petition is approved, the H–2B worker's extension of stay may be granted for the validity of the approved petition for a period not to exceed the validity period of the TLC.

To ensure H–2B petitioners' continued access to workers who provide temporary labor or services essential to the stability of the nation's food supply chain during the National Emergency, the ability of H–2B petitioners and H–2B workers to take advantage of the flexibilities in this temporary final rule will automatically terminate at the end of September 11, 2020. USCIS will apply the provisions of this rule to H–2B petitions received on or before September 11, 2020, even if such petitions remain pending after the expiration of this rule.

At this time, DHS believes that 120 days is sufficient to address the needs of employers engaged in nonagricultural services or labor essential to the U.S. food supply chain, such as those described above, who need to hire H–2B workers after having obtained a TLC demonstrating that they have been unable to find available, qualified U.S. workers to fill these positions. DHS has determined that a 120-day filing period is appropriate as it provides immediate relief to these H–2B petitioners who have been impacted by the disruptions and uncertainties caused by the COVID–19 public health emergency and is a reasonable period of time for DHS to implement the flexibilities described in this rule. The 120-day filing period does not affect or change the H–2B petitioner's validity period requested on the H–2B petition. In addition, the 120-day filing period is consistent with the 120-day filing period provided in a similar DHS temporary final rule, *Temporary Changes to Requirements Affecting H–2A Nonimmigrants Due to the COVID–19 National Emergency.*[16] The H–2A temporary final rule also addressed the need to secure the U.S. food supply chain, given the current economic conditions in the United States. However, after the publication of this temporary final rule, DHS will continue to monitor the rapidly evolving circumstances surrounding the public health emergency, and may issue a new temporary final rule to extend its applicability in the event DHS determines that economic circumstances demonstrate a continued need for these temporary changes to the regulatory requirements involving H–2B nonagricultural employers and workers essential to the nation's food supply chain.

Any H–2B petition received after the termination of this temporary final rule will be adjudicated in accordance with the existing permanent regulatory requirements. *See* 8 CFR 214.2(h)(2)(i)(D).

III. Statutory and Regulatory Requirements

A. Administrative Procedure Act

This rule is being issued without prior notice and opportunity to comment and with an immediate effective date pursuant to 5 U.S.C. 553(b) and (d).

1. Good Cause To Forgo Notice and Comment Rulemaking

The Administrative Procedure Act (APA), 5 U.S.C. 551 *et seq.,* 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.'' 5 U.S.C. 553(b)(B). The good-cause exception for forgoing notice-and-comment rulemaking ''excuses notice and comment in emergency situations, or where delay could result in serious harm.'' *Jifry* v. *FAA,* 370 F.3d 1174, 1179 (D.C. Cir. 2004). Although the good cause exception is ''narrowly construed and only reluctantly countenanced,'' *Tenn. Gas Pipeline Co.* v. *FERC,* 969 F.2d 1141, 1144 (D.C. Cir. 1992), the Department has appropriately invoked the exception in this case, for the reasons set forth below.

As also discussed earlier in this preamble, on January 31, 2020, the

[13] If the H–2B worker's accumulated stay is 18 months or less, an absence of at least 45 days will interrupt the 3-year limitation on admission. *See* 8 CFR 214.2(h)(13)(v).

[14] The temporary flexibility DHS is granting for the aforementioned H–2B aliens to remain in the United States beyond the 3-year limitation described in 8 CFR 214.2(h)(13)(i)(B), (h)(13)(iv), (h)(13)(v), and (h)(15)(ii)(C) to address the need to secure the U.S. food supply chain does not modify the requisite nature of the petitioner's need for the temporary services or labor as described in 8 CFR 214.2(h)(6)(ii).

[15] DHS notes that in circumstances when an extension of stay is considered timely filed under 8 CFR 214.1(c)(4), the H–2B worker must still meet the requirements listed in that provision, including requirements that the H–2B worker has not violated his or her status by, for example, engaging in unauthorized employment.

[16] 85 FR 21739 (Apr. 20, 2020).

Secretary of Health and Human Services declared a public health emergency under section 319 of the Public Health Service Act in response to COVID–19.[17] On March 13, 2020, President Trump declared a National Emergency concerning the COVID–19 outbreak, retroactive to March 1, 2020, to control the spread of the virus in the United States.[18] In response to the Mexican government's call to increase social distancing in that country, DOS announced the temporary suspension of routine immigrant and nonimmigrant visa services processed at the U.S. Embassy in Mexico City and all U.S. consulates in Mexico beginning on March 18, 2020.[19] DOS expanded the temporary suspension of routine immigrant and nonimmigrant visa services at all U.S. Embassies and Consulates on March 20, 2020.[20]

DOS designated H–2 visas as mission critical, and announced that U.S. Embassies and Consulates will continue to process H–2 cases to the extent possible and implemented a change in its procedures, to include interview waivers.[21] Due to travel restrictions, limitations on visa services as a result of actions taken to mitigate the spread of COVID–19, as well as the possibility that some U.S. and H–2B workers may become unavailable due to illness related to the spread of COVID–19, U.S. employers engaged in services or labor essential to the U.S. food supply chain, and who have approved TLCs and either approved H–2B petitions or who will be filing H–2B petitions on or after the effective date of this temporary final rule, might not receive, or be able to continuously employ, any or all of the workers requested to fill all of their DHS-approved temporary nonagricultural positions. Due to these potential labor shortages, employers who serve essential functions in the U.S. food supply chain may experience adverse economic impacts to their operations. To address these concerns, DHS is acting expeditiously to put in place rules that will facilitate the continued employment of H–2B workers already present in the United States. This action will help employers fill these critically necessary nonagricultural job openings, protect U.S. businesses' economic investments in their operations, and contribute to the stability of the nation's food supply chain.

Courts have found ''good cause'' under the APA when an agency is moving expeditiously to avoid significant economic harm to a program, program users, or an industry. Courts have held that an agency may use the good-cause exception to address ''a serious threat to the financial stability of [a government] benefit program,'' *Nat'l Fed'n of Fed. Emps.* v. *Devine,* 671 F.2d 607, 611 (D.C. Cir. 1982), or to avoid ''economic harm and disruption'' to a given industry, which likely would result in higher consumer prices, *Am. Fed'n of Gov't Emps.* v. *Block,* 655 F.2d 1153, 1156 (D.C. Cir. 1981). Consistent with the above authorities, the Department is bypassing notice and comment to expeditiously and, on a temporary basis, facilitate the employment of certain H–2B workers already in the United States who will perform temporary nonagricultural work that is essential to the U.S. food supply chain, and prevent potential economic harms to H–2B nonagricultural employers, as well as other potential downstream effects. *See Bayou Lawn & Landscape Servs.* v. *Johnson,* 173 F. Supp. 3d 1271, 1285 & n.12 (N.D. Fla. 2016).

2. Good Cause To Proceed With an Immediate Effective Date

The APA requires a 30-day delayed effective date for a substantive rule, but contains an exception for ''a substantive rule which grants or recognizes an exemption or relieves a restriction.'' 5 U.S.C. 553(d)(1). This is such a rule; therefore, no delayed effective date is required. The APA also authorizes agencies to make a rule effective immediately, upon a showing of good cause, instead of imposing a 30-day delay. 5 U.S.C. 553(d)(3). The good-cause exception to the 30-day effective date requirement is easier to meet than the good-cause exception for forgoing notice and comment rulemaking. *Riverbend Farms, Inc.* v. *Madigan,* 958 F.2d 1479, 1485 (9th Cir. 1992); *Am. Fed'n of Gov't Emps., AFL–CIO* v. *Block,* 655 F.2d 1153, 1156 (DC Cir. 1981); *U.S. Steel Corp.* v. *EPA,* 605 F.2d 283, 289–90 (7th Cir. 1979). An agency can show good cause for eliminating the 30-day delayed effective date when it demonstrates urgent conditions the rule seeks to correct or unavoidable time limitations. *U.S. Steel Corp.,* 605 F.2d at 290; *United States* v. *Gavrilovic,* 511 F.2d 1099, 1104 (8th Cir. 1977). For the same reasons set forth above, we also conclude that the Department has good cause to dispense with the 30-day effective date requirement given that this rule is necessary to prevent serious economic harms to U.S. employers caused by unavailability of workers due to COVID–19.

B. Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review)

Executive Orders (E.O.) 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 (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule is designated a significant regulatory action under E.O. 12866. Accordingly, the Office of Management and Budget (OMB) has reviewed this regulation. DHS, however, is proceeding under the emergency provision of Executive Order 12866 Section 6(a)(3)(D) based on the need to move expeditiously during the current public health emergency to secure temporary labor for businesses that contribute to the stability of the nation's food supply chain.

This rule will help employers fill critically necessary nonagricultural job openings and protect U.S. businesses that contribute to the stability of the nation's food supply chain. DHS believes this benefit to employers and businesses outweighs any additional impacts imposed by the new requirement to file an attestation form with DHS. In addition, this rule will benefit certain H–2B workers already in the United States by making it easier for employers to hire them, and allowing them to remain employed, if applicable, longer than the 3-year maximum limitation on their stay.

[17] HHS, *Determination that a Public Health Emergency Exists, https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx* (last reviewed Jan. 31, 2020). *See also* HHS, *Determination of Public Health Emergency,* 85 FR 7316 (Feb. 7, 2020).

[18] Proclamation 9994 of March 13, 2020, *Declaring a National Emergency Concerning the Coronavirus Disease (COVID–19) Outbreak,* 85 FR 15337 (Mar. 18, 2020). *See also* White House, Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak, *https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/* (last visited May 4, 2020).

[19] DOS, *Status of U.S. Consular Operations in Mexico in Light of COVID–19, https://mx.usembassy.gov/status-of-u-s-consular-operations-in-mexico-in-light-of-covid-19/* (last updated Apr. 13, 2020).

[20] DOS, *Suspension of Routine Visa Services, https://travel.state.gov/content/travel/en/News/visas-news/suspension-of-routine-visa-services.html* (last updated Mar. 20, 2020).

[21] *See* DOS website, *Important Announcement on H2 Visas, https://travel.state.gov/content/travel/en/News/visas-news/important-announcement-on-h2-visas.html* (last updated Mar. 26, 2020).

C. Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601 through 612 (RFA), imposes certain requirements on Federal agency rules that are subject to the notice and comment requirements of the APA. *See* 5 U.S.C. 603(a), 604(a). This temporary final rule is exempt from notice and comment requirements for the reasons stated above in Part III.A. Therefore, the requirements of the RFA applicable to final rules, 5 U.S.C. 604, do not apply to this final rule. Accordingly, the Department is not required to either certify that the final rule would not have a significant economic impact on a substantial number of small entities or conduct a regulatory flexibility analysis.

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, 2 U.S.C. 1501 through 1571 (UMRA), is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of the Act requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed rule, or final rule for which the agency published a proposed rule that includes any Federal mandate that may result in $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector. 2 U.S.C. 1532. This rule does not contain such a mandate. The requirements of Title II of UMRA, therefore, do not apply, and DHS has not prepared a statement under UMRA.

E. Executive Order 13132 (Federalism)

This rule does 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 section 6 of E.O. 13132, 64 FR 43255, 43258 (Aug. 4, 1999), this rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

F. Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of E.O. 12988, 61 FR 4729 (Feb. 5, 1996).

G. Congressional Review Act

The Office of Information and Regulatory Affairs, of the Office of Management and Budget, has determined that this temporary final rule is not a ''major rule'' as defined by the applicable section of the Congressional Review Act, 5 U.S.C. 804(2), and thus is not subject to a 60-day delay in the rule becoming effective. DHS will send this temporary final rule to Congress and to the Comptroller General under the Congressional Review Act, 5 U.S.C. 801 through 808.

H. National Environmental Policy Act

DHS analyzes actions to determine whether the National Environmental Policy Act, Public Law 91–190, 42 U.S.C. 4231 through 4347 (NEPA), applies to them and, if so, what degree of analysis is required. DHS Directive 023–01 Rev. 01 (Directive) and Instruction Manual 023–01–001–01 Rev. 01 (Instruction Manual) establish the policies and procedures that DHS and its components use to comply with NEPA and the Council on Environmental Quality (CEQ) regulations for implementing NEPA, 40 CFR parts 1500–1508.

The CEQ regulations allow federal agencies to establish, with CEQ review and concurrence, categories of actions (''categorical exclusions'') which experience has shown do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment (EA) or Environmental Impact Statement (EIS). 40 CFR 1507.3(b)(2)(ii), 1508.4. Categorical exclusions established by DHS are set forth in Appendix A of the Instruction Manual. Under DHS NEPA implementing procedures, for an action to be categorically excluded, it must satisfy each of the following three conditions: (1) The entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect. Instruction Manual section V.B(2)(a)–(c). This rule temporarily amends regulations governing the H–2B nonimmigrant visa program to facilitate the continued employment of certain H–2B nonimmigrants in the United States, who are essential to the U.S. food supply chain, by allowing them to change employers in the United States and begin working in the same visa classification for a period not to exceed 60 days before the nonimmigrant visa petition is approved, due to the National Emergency caused by the COVID–19 global pandemic. It also establishes a temporary exception from the 3-year limit on the maximum period of stay for H–2B workers. This rule does not change the number of H–2B workers that may be employed by U.S. employers as H–2B workers seeking extensions of status are generally exempt from the annual statutory limit. It also does not change rules for where H–2B nonimmigrants may be employed; only employers with approved TLCs for workers to perform certain temporary nonagricultural work may be allowed to employ H–2B workers under these temporary provisions. Generally, DHS believes NEPA does not apply to a rule intended to make it easier for H–2B employers to hire workers who are already in the United States in addition to, or instead of, also hiring H–2B workers from abroad because any attempt to analyze its potential impacts would be largely speculative, if not completely so. DHS cannot reasonably estimate how many petitions will be filed under these temporary provisions, and therefore how many H–2B workers already in the United States will be employed by different employers, or be employed with current or new employers beyond 3 years, as opposed to how many petitions would have been filed for H–2B workers employed under normal circumstances. DHS has no reason to believe that the temporary amendments to H–2B regulations would change the environmental effect, if any, of the existing regulations. Therefore, DHS has determined that even if NEPA were to apply to this action, this rule clearly fits within categorical exclusion A3(d) in the Instruction Manual, which provides an exclusion for ''promulgation of rules . . . that amend an existing regulation without changing its environmental effect.''

This rule maintains the current human environment by helping to prevent irreparable harm to certain U.S. businesses and to prevent significant adverse effects on the human environment that would likely result from loss of jobs or income, or disruption of the nation's economy. This rule is not a part of a larger action and presents no extraordinary circumstances creating the potential for significant environmental effects. Therefore, this action is categorically excluded and no further NEPA analysis is required.

I. Paperwork Reduction Act (PRA)

Under the PRA, 44 U.S.C. 3501 *et seq.,* USCIS generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by OMB under the PRA and displays a currently valid

OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. USCIS has submitted the Information Collection Request (ICR) contained in this rule to OMB using emergency clearance procedures outlined at 5 CFR 1320.13. That review is ongoing, and USCIS will publish a notice announcing the results of that review.

This rule includes a new form, Form ATT–H2B, Attestation for Employers Seeking To Employ H–2B Nonimmigrant Workers Essential to the U.S. Food Supply Chain, that petitioners will file with DHS. Petitioners will use this form to make the attestation described above. While USCIS will provide a more specific burden estimate in the package submitted to OMB, for the purposes of this TFR DHS notes that such an estimate is difficult to provide with any certainty. For more information on this collection, please see *reginfo.gov.*

Overview of Information Collection

(1) *Type of Information Collection:* New Collection.

(2) *Title of the Form/Collection:* Attestation for Employers Seeking to Employ H–2B Nonimmigrant Workers Essential to the U.S. Food Supply Chain.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* Form ATT–H2B; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. As of the effective date of this temporary final rule, employers who submitted or are submitting Form I–129, Petition for a Nonimmigrant Worker to request an extension of stay and a change of employer and/or an extension of stay beyond the maximum 3 years (including with the same employer) pursuant to 8 CFR 214.2(h)(23), will be able to submit the Attestation to affirm that the workers named in the petition will be performing temporary nonagricultural services or labor that are essential to the U.S. food supply chain as described in 8 CFR 214.2(h)(23)(i). Receipt of the H–2B petition and Attestation, or just Attestation for H–2B petitioners whose petitions were pending on the effective date of this rule, triggers the flexibilities under this temporary final rule.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* USCIS is not able to estimate the total number of respondents for the information collection Form ATT–H2B because it cannot reasonably predict how many H–2B petitioners will file an H–2B petition for an extension of stay during the 120 days after the publication of this temporary final rule, or how many of those employers will be requesting the flexibilities under this temporary final rule and able to attest that H–2B workers will be performing temporary nonagricultural services or labor essential to the U.S. food supply chain. The estimated hour burden per response is 0.167 hours (10 minutes).

(6) *An estimate of the total public burden (in hours) associated with the collection:* Because USCIS cannot reasonably estimate the number of H–2B petitioners who will be able to attest that H–2B workers will be be performing temporary nonagricultural servies or labor essential to the U.S. food supply chain, USCIS is not able to provide a total estimated annual hour burden associated with this collection of information.

(7) *An estimate of the total public burden (in cost) associated with the collection:* USCIS is not able to estimate the total annual cost burden associated with this collection of information because it is not able to predict how many H–2B petitioners will be able to attest that H–2B workers will be performing temporary nonagricultural services or labor essential to the U.S. food supply chain, and thus the number of respondents for this information collection.

J. Signature

The Acting Secretary of Homeland Security, Chad F. Wolf, having reviewed and approved this document, is delegating the authority to electronically sign this document to Chad R. Mizelle, who is the Senior Official Performing the Duties of the General Counsel for DHS, for purposes of publication in the **Federal Register**.

List of Subjects

8 CFR Part 214

Administrative practice and procedure, Aliens, Cultural exchange programs, Employment, Foreign officials, Health professions, Reporting and recordkeeping requirements, Students.

8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Accordingly, DHS amends chapter I of title 8 of the Code of Federal Regulations as follows:

PART 214—NONIMMIGRANT CLASSES

■ 1. The authority citation for part 214 continues to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305, 1356, and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 115–218.

■ 2. Amend § 214.2 by adding paragraph (h)(23) to read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(h) * * *

(23) *Change of employers and extensions beyond 3 years during COVID–19 National Emergency for H–2B aliens essential to the U.S. food supply chain.* (i) This paragraph (h)(23) relates to certain H–2B workers providing temporary nonagricultural services or labor essential to the U.S. food supply chain.

(ii) A prospective new H–2B employer or U.S. agent who is seeking to employ an H–2B alien to provide temporary nonagricultural services or labor essential to the U.S. food supply chain under this paragraph (h)(23) may file an H–2B petition on Form I–129, accompanied by an approved temporary labor certification and attestation described in paragraph (h)(23)(v)(A) of this section, requesting an extension of the alien's stay in the United States. If the new petition is approved, the extension of stay may be granted for the validity of the approved petition for a period not to exceed the validity period of the temporary labor certification. Notwithstanding paragraph (h)(2)(i)(D) of this section, an alien in valid H–2B nonimmigrant status on or after March 1, 2020:

(A) Whose new petitioner files an H–2B petition on or after May 14, 2020, is authorized to begin employment with the new petitioner to perform work that is essential to the U.S. food supply chain after the petition described in this paragraph (h)(23), including the attestation described in paragraph (h)(23)(v)(A) of this section, is received by USCIS and before the H–2B petition is approved, but no earlier than the start

date of employment indicated in the H–2B petition; or

(B) Whose new petitioner filed an H–2B petition on or after March 1, 2020 and the petition was pending on or after May 14, 2020, is authorized to begin employment with the new petitioner to perform work that is essential to the U.S. food supply chain after the attestation described in paragraph (h)(23)(v)(A) is received by USCIS and before the H–2B petition is approved.

(iii)(A) With respect to a petition described in paragraph (h)(23)(ii)(A) of this section, and subject to the requirements of 8 CFR 274a.12(b)(27), the new period of employment described in paragraph (h)(23)(ii) may last for up to 60 days beginning on the Received Date on Form I–797 (Notice of Action) or, if the start date of employment occurs after the I–797 Received Date, for a period of up to 60 days beginning on the start date of employment indicated in the H–2B petition. Employment is not authorized under this paragraph (h)(23) if USCIS does not receive the attestation described in paragraph (h)(23)(v)(A) of this section.

(B) With respect to a petition described in paragraph (h)(23)(ii)(B) of this section, the new period of employment described in paragraph (h)(23)(ii) may last for up to 60 days beginning on the date that USCIS acknowledges in writing the receipt of a properly filed attestation described paragraph (h)(23)(v). Employment under this paragraph (h)(23) is not authorized if USCIS does not receive the attestation described in paragraph (h)(23)(v)(A) of this section.

(C) With respect to either type of petition, if USCIS adjudicates the petition prior to the expiration of this 60-day period and denies the petition for extension of stay, or if the petition is withdrawn by the petitioner before the expiration of the 60-day period, the employment authorization associated with the filing of that petition under 8 CFR 274a.12(b)(27) will automatically terminate 15 days after the date of the denial decision or 15 days after the date on which the petition is withdrawn. Nothing in this paragraph (h)(23) is intended to alter the availability of employment authorization related to professional H–2B athletes who are traded between organizations pursuant to paragraph (h)(6)(vii) of this section and 8 CFR 274a.12(b)(9).

(iv) Notwithstanding paragraphs (h)(13)(i)(B), (h)(13)(iv) and (v), and (h)(15)(ii)(C) of this section, an H–2B petition seeking an extension of stay for H–2B aliens who are essential to the U.S. food supply chain to work, and submitted with an approved temporary labor certification, may be approved on the basis of this paragraph (h)(23), even if any of the aliens requested in the H–2B petition have otherwise exhausted the applicable 3-year maximum period of stay in the United States and have not thereafter been absent from the United States for an uninterrupted period of 3 months, or if any such aliens would exceed the 3-year limit as a consequence of the approval of the extension.

(v) In addition to meeting all other requirements for the H–2B classification, to commence employment and be approved under this paragraph (h)(23):

(A) The H–2B petitioner must submit an attestation indicating that the H–2B alien will be performing work that is essential to the U.S. food supply chain;

(B) The alien must have been in valid H–2B nonimmigrant status on or after March 1, 2020; and

(C) The H–2B petition must have been—

(*1*) Received on or after March 1, 2020, and pending as of May 14, 2020, so long as the H–2B worker did not begin work with the new employer before May 14, 2020, or

(*2*) Received on or after May 14, 2020, but no later than September 11, 2020.

(vi) Authorization to initiate employment changes pursuant to paragraphs (h)(23)(ii) and (iii) of this section, or be approved for employment exceeding 3 years in duration pursuant to paragraph (h)(23)(iv) of this section, begins on May 14, 2020, and ends at the end of September 11, 2020.

* * * * *

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

■ 3. The authority citation for part 274a continues to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; Title VII of Pub. L. 110–229; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599; Pub. L. 115–218.

■ 4. Amend § 274a.12 by adding paragraph (b)(27) to read as follows:

§ 274a.12 Classes of aliens authorized to accept employment.

* * * * *

(b) * * *

(27)(i) Pursuant to 8 CFR 214.2(h)(23) and notwithstanding 8 CFR 214.2(h)(2)(i)(D) and the second sentence of 8 CFR 274a.12(b)(9), an alien is authorized to be employed, beginning no earlier than the start date of employment indicated in the H–2B petition and no earlier than May 14, 2020, by a new employer that has filed an H–2B petition, which includes the attestation described in 8 CFR 214.2(h)(23)(v)(A) naming the alien as a beneficiary and requesting an extension of stay for the alien. The authorization is for a period not to exceed 60 days beginning on the later of the following three dates: The ''Received Date'' on Form I–797 (Notice of Action) acknowledging receipt of the petition requesting the extension of stay, which includes the attestation described in 8 CFR 214.2(h)(23)(v)(A); the date on which USCIS acknowledges in writing the receipt of the properly filed attestation described in 8 CFR 214.2(h)(23)(v)(A) submitted while the H–2B petition is pending; or the start date of employment if the start date of employment indicated in the H–2B petition occurs after the filing. However, if USCIS adjudicates the petition prior to the expiration of this 60-day period and denies the petition for extension of stay, or if the petitioner withdraws the petition before the expiration of the 60-day period, the employment authorization under this paragraph (b)(27) will automatically terminate 15 days after the date of the denial decision or 15 days after the date on which the petition is withdrawn. Nothing in this section is intended to alter the availability of employment authorization related to professional H–2B athletes who are traded between organizations pursuant to paragraph (b)(9) of this section and 8 CFR 214.2(h)(6)(vii).

(ii) Authorization to initiate employment changes pursuant to 8 CFR 214.2(h)(23)(ii) and (iii) and this paragraph (b)(27) begins at 12 a.m. on May 14, 2020, and ends at the end of September 11, 2020.

* * * * *

Chad R. Mizelle,

Senior Official Performing the Duties of the General Counsel, U.S. Department of Homeland Security.

[FR Doc. 2020–10486 Filed 5–12–20; 3:00 pm]

BILLING CODE 9111–97–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0002; Airspace Docket No. 19–ACE–10]

RIN 2120–AA66

Amendment of VOR Federal Airways V–125, V–178, V–313, and V–429 in the Vicinity of Cape Girardeau, MO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends VHF Omnidirectional Range (VOR) Federal airways V–125, V–178, V–313, and V–429 in the vicinity of Cape Girardeau, MO. The modifications are necessary due to the planned decommissioning of the VOR portion of the Cape Girardeau, MO, VOR/Distance Measuring Equipment (VOR/DME) navigation aid (NAVAID), which provides navigation guidance for portions of the affected airways. The Cape Girardeau VOR is being decommissioned as part of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Effective date 0901 UTC, July 16, 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.

ADDRESSES: 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: Colby Abbott, 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.

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA–2020–0002 in the **Federal Register** (85 FR 3299; January 21, 2020), amending VOR Federal airways V–125, V–178, V–313, and V–429 in the vicinity of Cape Girardeau, MO, due to the planned decommissioning of the VOR portion of the Cape Girardeau, MO, VOR/DME. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

Subsequent to the NPRM, the FAA published a rule for Docket No. FAA–2020–0008 in the **Federal Register** (85 FR 26601; May 5, 2020), amending VOR Federal airway V–178 by removing the airway segment between the Cunningham, KY, VOR/DME and the New Hope, KY, VOR/DME. The airway amendment, effective July 16, 2020, is included in this rule.

VOR Federal airways are published in paragraph 6010(a) 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 VOR Federal airways 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.

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.

The Rule

The FAA is amending Title 14 Code of Federal Regulations (14 CFR) part 71 by modifying VOR Federal airways V–125, V–178, V–313, and V–429. The planned decommissioning of the VOR portion of the Cape Girardeau, MO, VOR/DME NAVAID has made this action necessary. The VOR Federal airway changes are outlined below.

V–125: V–125 extends between the Cape Girardeau, MO, VOR/DME and the St Louis, MO, VOR/Tactical Air Navigation (VORTAC). The NIKEL fix in the airway description is amended to describe it as the intersection of the Farmington, MO, VORTAC 046° and Marion, IL, VOR/DME 282° radials. Additionally, the airway segment overlying the Cape Girardeau, MO, VOR/DME between the Cape Girardeau, MO, VOR/DME and the intersection of the Farmington, MO, VORTAC 046° and Marion, IL, VOR/DME 282° radials (NIKEL fix) is removed. The unaffected portion of the existing airway remain as charted.

V–178: V–178 extends between the Hallsville, MO, VORTAC and the Cunningham, KY, VOR/DME; and between the New Hope, KY, VOR/DME and the Bluefield, WV, VOR/DME. The airway segment overlying the Cape Girardeau, MO, VOR/DME between the Farmington, MO, VORTAC and the Cunningham, KY, VOR/DME is removed. The unaffected portions of the existing airway remain as charted.

V–313: V–313 extends between the Malden, MO, VORTAC and the Pontiac, IL, VOR/DME. The airway segment overlying the Cape Girardeau, MO, VOR/DME between the Malden, MO, VORTAC and the Centralia, IL, VORTAC is removed. The unaffected portions of the existing airway remain as charted.

V–429: V–429 extends between the Cape Girardeau, MO, VOR/DME and the Bible Grove, IL, VORTAC; and between the Champaign, IL, VORTAC and the Joliet, IL, VOR/DME. The airway segment overlying the Cape Girardeau, MO, VOR/DME between the Cape Girardeau, MO, VOR/DME and the Marion, IL, VOR/DME is removed. The unaffected portions of the existing airway remain as charted.

All radials in the route descriptions below are stated in True degrees.

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. 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 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 of modifying VOR Federal airways V–125, V–178, V–313, and V–429, due to the planned decommissioning of the VOR portion of the Cape Girardeau, MO, VOR/DME NAVAID, qualifies for categorical exclusion under the National Environmental Policy Act and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5–6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5–2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List 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(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(a) Domestic VOR Federal Airways.

* * * * *

V–125 [Amended]

From INT Farmington, MO, 046° and Marion, IL, 282° radials; to St Louis, MO.

* * * * *

V–178 [Amended]

From Hallsville, MO; INT Hallsville l83° and Vichy, MO, 32l° radials; Vichy; to Farmington, MO. From New Hope, KY; Lexington, KY; to Bluefield, WV.

* * * * *

V–313 [Amended]

From Centralia, IL; Adders, IL; to Pontiac, IL.

* * * * *

V–429 [Amended]

From Marion, IL; INT Marion 011° and Bible Grove, IL, 207° radials; to Bible Grove. From Champaign, IL; Roberts, IL; to Joliet, IL.

* * * * *

Issued in Washington, DC.

Scott M. Rosenbloom,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2020–10157 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–13–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 240

[Release No. 34–88616; File No. S7–23–16]

RIN 3235–AL48

Definition of ''Covered Clearing Agency''

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is adopting amendments to the definitions of ''covered clearing agency,'' ''central securities depository services,'' and ''sensitivity analysis'' pursuant to Section 17A of the Securities Exchange Act of 1934 (''Exchange Act'') and the Payment, Clearing, and Settlement Supervision Act of 2010 (''Clearing Supervision Act''), enacted in Title VIII of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (''Dodd-Frank Act'').

DATES: *Effective date:* July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Matthew Lee, Assistant Director, or Jesse Capelle, Special Counsel, Office of Clearance and Settlement, Division of Trading and Markets, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–7010, at (202) 551–5710.

SUPPLEMENTARY INFORMATION: The Commission is amending 17 CFR 240.17Ad–22(a)(5) (''Rule 17Ad–22(a)(5)'') to define ''covered clearing agency'' to mean a registered clearing agency that provides the services of a central counterparty (''CCP'') or central securities depository (''CSD''). The Commission also is amending 17 CFR 240.17Ad–22(a)(3) (''Rule 17Ad–22(a)(3)'') to define ''central securities depository'' to mean a clearing agency that is a securities depository as described in Section 3(a)(23)(A) of the Exchange Act.[1] In addition, the Commission is amending the definition of ''sensitivity analysis'' in 17 CFR 240.17Ad–22(a)(16) (''Rule 17Ad–22(a)(16)'') so that the policies and procedures of all covered clearing agencies that are CCPs provide for a sensitivity analysis that considers the most volatile relevant periods, where practical, that have been experienced by the markets served by the covered clearing agency. The Commission is not adopting the proposed definition of ''securities settlement system.''

In developing these rule amendments, Commission staff has consulted with the Financial Stability Oversight Council (''FSOC''), Commodity Futures Trading Commission (''CFTC''), and Board of Governors of the Federal Reserve System (''FRB'').[2] The Commission has also considered the relevant international standards as required by Section 805(a)(2)(A) of the Clearing Supervision Act.[3] The relevant

[1] 15 U.S.C. 78c(a)(23)(A).

[2] *See* 12 U.S.C. 5472.

[3] 12 U.S.C. 5464(a)(2)(A).

international standards for CCPs and CSDs are the *Principles for Financial Market Infrastructures.*[4]

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I. Background

In 2012, the Commission adopted 17 CFR 240.17Ad–22 (''Rule 17Ad–22'') under the Exchange Act to strengthen the substantive regulation of registered clearing agencies and promote their safe and reliable operation.[5] In 2016, the Commission also took an important step in the development of its regulatory framework for registered clearing agencies by adding 17 CFR 240.17Ad–22(e) (''Rule 17Ad–22(e)''),[6] which strengthened the existing framework by establishing requirements for registered clearing agencies that meet the definition of a ''covered clearing agency.'' Rule 17Ad–22(e) includes requirements for covered clearing agencies intended to address the activity and risks that their size, operation, and importance pose to the U.S. securities markets, the risks inherent in the products they clear, and the goals of both the Exchange Act and the Dodd-Frank Act. Of particular note, the requirements in Rule 17Ad–22(e) that address policies and procedures for transparency, governance, financial risk management, and operational risk management help ensure that covered clearing agencies are robust and stable.[7]

As adopted in 2016, Rule 17Ad–22(e) established enhanced requirements for an initial group of registered clearing agencies.[8] The Commission also contemporaneously proposed to amend the definition of ''covered clearing agency'' and certain other definitions to expand coverage of Rule 17Ad–22(e) to all registered clearing agencies providing the services of a CCP, CSD, or securities settlement system.[9] The Commission received several comments in response to the proposed amendments.[10] In this document, the Commission is adopting amendments to the definitions of ''covered clearing agency'' in Rule 17Ad–22(a)(5), ''central securities depository services'' in Rule 17Ad–22(a)(3), and ''sensitivity analysis'' in Rule 17Ad–22(a)(16), and the Commission is not adopting the proposed definition of ''securities settlement system.'' The effect of these amendments is to expand the coverage of Rule 17Ad–22(e) so that all registered clearing agencies providing the services of a CCP or CSD are subject to Rule 17Ad–22(e).

II. Amendments to Rule 17Ad–22

A. Rule 17Ad–22(a)(5)

1. Proposed Amendment and Comment Received

As discussed in the CCA Definition proposing release, the previous definition of ''covered clearing agency'' in Rule 17Ad–22(a)(5) stated that ''covered clearing agency'' means a designated clearing agency or a clearing agency involved in activities with a more complex risk profile for which the Commodity Futures Trading Commission is not the Supervisory Agency as defined in Section 803(8) of the Payment, Clearing and Settlement Supervision Act of 2010 (12 U.S.C. 5461 *et seq.*).[11] The Commission proposed to amend the definition of ''covered clearing agency'' in Rule 17Ad–22(a)(5) to mean a registered clearing agency that provides the services of a CCP, CSD, or securities settlement system.

The Commission received one comment regarding the proposed amendment to the definition of ''covered clearing agency.''[12] The commenter opposed adoption of the proposed amendment, stating that, in contrast to existing Rule 17Ad–22, the proposal fails to meaningfully enhance (i) the precision with which the entities are defined, (ii) the public's understanding of each category, and (iii) the public's trust that an entity will then behave in and be regulated in expected ways.[13]

The Commission disagrees that the amendment to the definition of ''covered clearing agency'' fails to meaningfully enhance the precision with which the entities are defined. The Commission believes that the amended definition is more precise than the previous definition because it is simpler and more accessible, consolidating all of the relevant concepts and factors into one definition in Rule 17Ad–22 and requiring a less subjective analysis to determine whether a clearing agency is subject to the requirements in Rule 17Ad–22(e). The Commission notes that the previous definition of ''covered clearing agency'' included a number of separate factors that a reader must interpret and apply to determine whether a clearing agency is subject to the enhanced risk management requirements in Rule 17Ad–22(e). Those factors, which are largely but not entirely contained in the previous Rule 17Ad–22(a)(5), include whether a registered clearing agency has been designated as systemically important under Title VIII of the Dodd-Frank Act by FSOC, whether the Commission or the CFTC is the supervisory agency for the registered clearing agency, and whether the registered clearing agency is involved in activities with a more

[4] *See* Committee on Payment and Settlement Systems and Technical Committee of the International Organization of Securities Commissions, Principles for Financial Market Infrastructures (Apr. 16, 2012) (''PFMI''), *http://www.bis.org/publ/cpss101a.pdf.*

[5] *See* 17 CFR 240.17Ad–22; Release No. 34–68080 (Oct. 22, 2012), 77 FR 66219, 66225–26 (Nov. 2, 2012) (''Clearing Agency Standards adopting release'').

[6] Release No. 34–78961 (Sept. 28, 2016), 81 FR 70786, 70902–05 (Oct. 13, 2016) (''CCA Standards adopting release'').

[7] CCA Standards adopting release, *supra* note 6, at 70793, 70801–10, 70837–38.

[8] Release No. 34–71699 (Mar. 12, 2014), 79 FR 16865 (Mar. 26, 2014), corrected at 79 FR 29507 (May 22, 2014) (''CCA Standards proposing release'').

[9] Release No. 34–78963 (Sept. 28, 2016), 81 FR 70744 (Oct. 13, 2016) (''CCA Definition proposing release'').

[10] Letters from Chris Barnard, dated Dec. 9, 2016 (''Barnard''); Keith Bishop, former California Commissioner of Corporations, dated Oct. 10, 2016 (''Bishop''); Ashley Burrowes, dated Oct. 28, 2016 (''Burrowes''); Carrie Devorah, dated Oct. 18, 2016 (''Devorah''); Andrew Helmin, dated Dec. 9, 2016 (''Helmin''); Karl Muth, dated Nov. 20, 2016 (''Muth''); Suzanne Shatto, dated Jan. 24, 2017 (''Shatto''). The comment letters are available on the Commission's website at *https://www.sec.gov/comments/s7-23-16/s72316.htm.*

In addition, two commenters expressed views unrelated to the proposed amendments. For example, one commenter expressed views on the regulation of clearing brokers and another expressed views on counterparty default, margin requirements, failed trades, and the use of shortselling. *See* Devorah (expressing views regarding J.P. Morgan Chase & Co.'s activity as a clearing broker) and Shatto (expressing views on counterparty default, margin requirements, failed trades, and the use of shortselling). Because these comments are not relevant to the rule amendments adopted in this document, they have not been addressed in Part II.

[11] *See* CCA Definition proposing release, *supra* note 9, at 70749.

[12] *See* Muth. Comments directed specifically to the ''securities settlement system'' element of the proposed definition are discussed in Part II.D.

[13] *See* Muth.

complex risk profile.[14] Readers seeking to understand how to apply and interpret the term ''clearing agency involved in activities with a more complex risk profile'' must look to 17 CFR 240.17Ad–22(a)(4) and engage in additional analysis, including considering: (i) Whether the clearing agency provides central counterparty services for security-based swaps; (ii) whether the Commission has made a determination that a clearing agency is involved in activities with a more complex risk profile at the time of its initial registration (thereby requiring a reader to look to Commission orders approving the registration of a registered clearing agency); and (iii) whether, subsequent to approving a clearing agency's initial registration, the Commission has made a determination pursuant to another rule, 17 CFR 240.17Ab2–2, that the clearing agency is involved in activities with a more complex risk profile.[15]

In addition, and as first explained in the CCA Definition proposing release, the Commission believes that consideration of these types of factors could result in conflicting outcomes where certain CCPs and CSDs, now or in the future, are excluded from the definition of ''covered clearing agency,'' resulting in competitive asymmetries between registered clearing agencies that otherwise provide similar clearing agency services.[16] Similarly, the Commission also believes that the amended definition of ''covered clearing agency'' should enhance public trust that an entity will behave and be regulated in expected ways because the proposed definition eliminates the potential for different regulatory treatment, and therefore different regulatory behaviors and outcomes, across clearing agencies that provide the same clearing agency services and present similar risks to the U.S. securities markets.

With respect to whether the amended definition of ''covered clearing agency'' enhances the public's understanding of each category of covered clearing agency, the Commission also disagrees with the commenter. In contrast to the previous definition, the amendment bases the definition of ''covered clearing agency'' solely on the particular clearing agency services provided by registered clearing agencies—namely, CCP and CSD services—and therefore enables a clearer understanding and regulatory approach, based on the single and well-understood factor of clearing agency activity, across registered clearing agencies that perform these critical functions.[17] By amending the definition of ''covered clearing agency'' so that it references only clearing agency functions, the Commission believes that the amendment better aligns the meaning of ''covered clearing agency'' with the services that such a clearing agency would provide. In addition, these two functions implicate the concentration and management of risk (in particular financial risks, such as credit and liquidity risk) and the potential transmission of systemic risk—activities which, by virtue of their significance to the U.S. financial system generally, and the national system for clearance and settlement in particular, warrant the application of the enhanced requirements in Rule 17Ad–22(e).[18]

Further, since the 2007–2009 financial crisis, the Commission understands that the terms CCP and CSD have become widespread and well-known among market participants,[19] and therefore the Commission believes that using terminology consistent with industry practice in the definition of ''covered clearing agency'' should help enhance the public's understanding of the relevant clearing agency services that meet the definition of a ''covered clearing agency.''

2. Final Rule

The Commission is adopting the proposed definition of ''covered clearing agency'' but modifying it to remove reference to ''securities settlement system,'' as further discussed in Part II.D.[20] Accordingly, Rule 17Ad–22(a)(5) as adopted defines ''covered clearing agency'' to mean a registered clearing agency that provides the services of a CCP or CSD.

a. Overview of the Definitions of CCP and CSD

In light of the amended definition, as of the effective date, all CCPs and CSDs registered with the Commission (that do not already meet the existing definition of ''covered clearing agency'') will become subject to examinations for compliance with Rule 17Ad–22(e) and, when filing proposed rule changes under 17 CFR 240.19b–4, will need to consider how rule changes are consistent with Rule 17Ad–22(e).[21] In addition, entities seeking to register as a clearing agency that provide CCP or CSD services, as of the effective date, would also be subject to Rule 17Ad–22(e). The Commission would therefore review any applications on Form CA–1 submitted by such an entity for consistency with Rule 17Ad–22(e). The Commission previously provided guidance on these topics in the CCA Standards adopting release.[22] In the CCA Definition proposing release, the Commission also discussed the important services that CCPs and CSDs provide and how those services support the application of the enhanced requirements in Rule 17Ad–22(e).[23] Below, the Commission is providing further guidance on the types of services that CCPs and CSDs generally provide.

As defined in 17 CFR 240.17Ad–22(a)(2) (''Rule 17Ad–22(a)(2)''), ''central counterparty'' means a clearing agency that interposes itself between the counterparties to a trade, acting functionally as the buyer to every seller and the seller to every buyer.[24] The definition includes two core concepts: (i) Interposing between the counterparties to a trade; and (ii) acting functionally as the buyer to every seller and vice versa. These concepts encompass a wide variety of practices, and differences in the practices of CCPs may reflect the risk characteristics of the instruments that the CCP clears, the characteristics of the participants for which the CCP clears, other external factors, or the design of the CCP's risk-management framework.[25] For example, the Commission has previously explained that a CCP often assumes a central role in ensuring the performance

[14] *See* 17 CFR 240.17Ad–22(a)(5).

[15] *See* 17 CFR 240.17Ad–22(a)(4).

[16] *See* CCA Definition proposing release, *supra* note 9, at 70753, 70768.

[17] *See* CCA Standards adopting release, *supra* note 6, at 70787 (describing clearing agency functions).

[18] *See* CCA Definition proposing release, *supra* note 9, at 70750.

[19] *See, e.g.,* Commission, CFTC & FRB, Risk Management Supervision of Designated Clearing Entities, (2011) at 7, *https://www.sec.gov/news/studies/2011/813study.pdf.*

[20] Comments on the proposed definition of ''securities settlement system'' are discussed in Part II.D.

[21] As a result of the amended definition, as of the effective date, ICE Clear Credit, which provides CCP services for security-based swap transactions, will be a covered clearing agency subject to Rule 17Ad–22(e). The existing CCPs that are already covered clearing agencies and subject to the provisions of Rule 17Ad–22(e) are Banque Centrale De Compensation, Fixed Income Clearing Corporation, ICE Clear Europe, National Securities Clearing Corporation, and The Options Clearing Corporation. The Depository Trust Company is the only CSD registered as a clearing agency in the United States, and it was also already a covered clearing agency subject to Rule 17Ad–22(e).

[22] *See* CCA Standards adopting release, *supra* note 6, at 70848–49 (in the discussion of effective and compliance dates).

[23] *See* CCA Definition proposing release, *supra* note 9, at 70750–52 (discussing the critical functions common among and specific to CCPs and CSDs).

[24] *See* 17 CFR 240.17Ad–22(a)(2); Clearing Agency Standards adopting release, *supra* note 5, at 66229.

[25] *See* PFMI, *supra* note 4, at 155–57 (describing the variety in CCP structure and operations).

of open contracts and facilitating the clearance and settlement of trades through risk management tools such as: Novating and guaranteeing trades, netting, and collecting clearing fund contributions from members.[26] In novating and guaranteeing trades, a CCP assumes the original parties' contractual obligations to each other and assumes their credit risk.[27] In netting, a CCP reduces its overall exposure to its counterparties.[28] By collecting clearing fund contributions, a CCP can maintain sufficient financial resources in the event a member defaults on its obligations to the CCP.[29] In describing these aspects of CCP practices, the Commission stated its belief that a CCP, through its core functions and use of its risk management tools, helps reduce credit, market, and liquidity risk among and to its counterparties.[30] Ultimately, the Commission believes that the essence of a CCP is its role in managing and mitigating credit exposures and liquidity risk.

Like CCPs, CSDs encompass a wide variety of practices. For example, a clearing agency performs CSD services when it (i) acts as a custodian of securities in connection with a system for the central handling of securities whereby all securities of a particular class or series of any issuer deposited within the system are treated as fungible and may be transferred, loaned, or pledged by bookkeeping entry without physical delivery of securities certificates; or (ii) otherwise permits or facilitates the settlement of securities transactions or the hypothecation or lending of securities without physical delivery of securities certificates.[31] As a result, the Commission believes that a range of activities could meet the definition of CSD.

b. Registered Clearing Agencies That Are Not Covered Clearing Agencies

As discussed in the CCA Definition proposing release,[32] registered clearing agencies that are not covered clearing agencies, such as registered clearing agencies that do not provide CCP or CSD services, will continue to be governed by other provisions of Rule 17Ad–22, including 17 CFR 240.17Ad–22(d) (''Rule 17Ad–22(d)''), which contain requirements for various aspects of the payment, clearance, and settlement process.[33]

B. Rule 17Ad–22(a)(3)

The Commission proposed to amend the defined term ''central securities depository services'' in Rule 17Ad–22(a)(3) by deleting the word ''services'' so that the rule would instead define the term ''central securities depository'' to mean a clearing agency that is a securities depository as described in Section 3(a)(23)(A) of the Exchange Act. While the Commission proposed to amend the defined term, it did not propose to amend the meaning of the term as set forth in Rule 17Ad–22(a)(3). The purpose of this proposed amendment was to ensure consistency with the use of the defined term ''central counterparty'' in Rule 17Ad–22(a)(2) in the proposed definition of ''covered clearing agency.''

The Commission received one comment regarding the amendment to the definition of ''central securities depository services.''[34] This commenter stated that the proposed definition is ''unnecessary surplusage'' because Rule 17Ad–22(a)(3) already defines ''central securities depository services.''[35] The Commission notes that the purpose of the proposed modification was to conform the defined term ''central securities depository'' with the defined term ''central counterparty'' in Rule 17Ad–22(a)(2) by removing the reference to ''services'' in the term. As previously discussed, the term ''central securities depository,'' like the term ''central counterparty,'' is widely known and used among market participants, as CSDs and CCPs are critical financial market utilities.[36] Further, the Commission continues to believe that the amendment improves consistency with the use of ''central counterparty'' throughout Rule 17Ad–22 and helps make the amended definition of ''covered clearing agency'' clear. Finally, and for the reasons just given above, the amendment removes a term in Rule 17Ad–22(a)(3) that the Commission believes to be in excess of what is necessary to ensure consistency in expressing a well understood concept both across the Commission's rules as well as market participants' application of such terms. For these reasons, the Commission believes that the amendment is appropriate.

For the reasons discussed above, the Commission is adopting the amended definition of ''central securities depository'' in Rule 17Ad–22(a)(3) as proposed.

C. Rule 17Ad–22(a)(16)

As discussed in the CCA Definition proposing release, a covered clearing agency that provides CCP services must establish, implement, maintain and enforce written policies and procedures reasonably designed to regularly review, test, and verify its risk-based margin system by conducting a sensitivity analysis of its margin model, among other things.[37] The Commission proposed two amendments to the definition of ''sensitivity analysis'' in Rule 17Ad–22(a)(16). First, in conjunction with the proposed definition of ''covered clearing agency,'' the Commission proposed to amend the definition of ''sensitivity analysis'' to remove the reference to ''a covered clearing agency involved in activities with a more complex risk profile'' from paragraph (a)(16)(ii). Second, in order to improve consistency among the elements within the definition of sensitivity analysis, the Commission proposed to separate the two elements in paragraph (a)(16)(i) into two separate paragraphs and renumber the existing paragraphs accordingly.

Thus, taking these two proposed amendments together, the proposed definition of ''sensitivity analysis'' would apply to covered clearing agencies that provide CCP services and would mean an analysis that involves analyzing the sensitivity of a model to its assumptions, parameters, and inputs that (i) considers the impact on the model of both moderate and extreme changes in a wide range of inputs, parameters, and assumptions, including correlations of price movements or returns if relevant, which reflect a variety of historical and hypothetical market conditions; (ii) uses actual portfolios and, where applicable, hypothetical portfolios that reflect the characteristics of proprietary positions and customer positions; (iii) considers the most volatile relevant periods, where practical, that have been experienced by the markets served by the clearing agency; and (iv) tests the sensitivity of the model to stressed market conditions, including the market conditions that may ensue after the default of a member and other extreme but plausible conditions as defined in a covered clearing agency's risk policies.

In response to the proposal, one commenter suggested that the Commission specifically refer to reverse stress testing in the amendments to the

[26] Release No. 34–80295 (Mar. 22, 2017), 82 FR 15564, 15566 (Mar. 29, 2017).

[27] *See id.*

[28] *See id.*

[29] *See id.*

[30] *See id.* at 15567.

[31] *See* 15 U.S.C. 78c(a)(23)(A); 17 CFR 240.17Ad–22(a)(3).

[32] *See* CCA Definition proposing release, *supra* note 9, at 70747 n.35.

[33] *See* 17 CFR 240.17Ad–22(d)(1)–(13).

[34] *See* Bishop.

[35] *See id.*

[36] *See supra* note 19 and accompanying text.

[37] *See* CCA Definition proposing release, *supra* note 9, at 70754–55.

rule.[38] The Commission previously addressed this issue in the CCA Standards adopting release. As explained there, Rule 17Ad–22(e) does not preclude a covered clearing agency from performing reverse stress testing as part of its financial risk management; indeed, the Commission indicated that a covered clearing agency generally should consider using reverse stress testing to evaluate the adequacy of financial resources.[39] However, the Commission continues to believe that each covered clearing agency should retain flexibility, subject to its obligations and responsibilities as an SRO under the Exchange Act, to develop its stress testing framework in light of the ever-evolving challenges and risks inherent in the securities markets. Further, the Commission notes that reverse stress testing, which can be a useful tool to evaluate the adequacy of financial resources held by a covered clearing agency, is a distinct concept from sensitivity analysis, which in the context of Rule 17Ad–22(a)(16) concerns how assumptions, parameters, and inputs into a covered clearing agency's margin model react to potential changes in market conditions.

For the reasons discussed above, the Commission is adopting the amended definition of ''sensitivity analysis'' in Rule 17Ad–22(a)(16) as proposed.

D. Proposed Definition of ''Securities Settlement System''

In the CCA Definition proposing release, the Commission proposed to define ''securities settlement system'' to mean a clearing agency that enables securities to be transferred and settled by book entry according to a set of predetermined multilateral rules.[40]

Several commenters raised concerns regarding the proposed definition, stating that it was unclear,[41] ambiguous,[42] and superfluous.[43] Commenters raised these concerns because the term ''securities settlement system'' does not appear in the Exchange Act,[44] and one commenter did not understand the meaning of ''multilateral rules'' as used in the definition.[45]

In consideration of these comments, the Commission is not adopting the proposed definition of ''securities settlement system.'' At this time, no registered clearing agency currently provides only the services of a securities settlement system. Rather, as explained in the CCA Definition proposing release, clearing agencies provide differing clusters of services for their participants, and the Commission has registered several clearing agencies over the years that provide the services of a securities settlement system along with other services.[46] For example, in the past, the Commission has included book-entry transfers among the services provided by either a CSD or a securities settlement system.[47] As another example, one registered clearing agency currently provides both CSD services and the services of a securities settlement system for the U.S. securities markets.[48] Because the services of a securities settlement system have not been offered as standalone services historically and are not currently,[49] the Commission believes that the amended definition of ''covered clearing agency,'' as adopted and discussed in Part II.A, covers substantially the same scope of clearing agency activity as the proposed definition.

Thus, in response to the concerns identified by commenters and to eliminate ambiguity, the Commission is not adopting the proposed definition of ''securities settlement system.''[50]

III. Economic Analysis

The Commission is sensitive to the economic consequences and effects of the adopted amendments, including their benefits and costs. Under Section 3(f) of the Exchange Act, whenever the Commission engages in rulemaking under the Exchange Act and is required to consider or determine whether an action is necessary or appropriate in the public interest, it must consider, in addition to the protection of investors, whether the action will promote efficiency, competition, and capital formation.[51] Further, as noted above, Section 17A of the Exchange Act directs the Commission, when using its authority to facilitate the establishment of a national system for clearance and settlement of securities transactions, to have due regard for the public interest, the protection of investors, the safeguarding of securities and funds, and maintenance of fair competition among brokers and dealers, clearing agencies, and transfer agents.[52] Section 23(a)(2) of the Exchange Act also prohibits the Commission from adopting any rule that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act.[53]

The Commission is amending the definition of ''covered clearing agency'' in Rule 17Ad–22(a)(5) by focusing directly on clearing agency functions. Thus the amended definition of ''covered clearing agency'' covers all clearing agencies that provide the services of a CCP or CSD. The Commission is also adopting a conforming amendment to the definition of ''central securities depository services'' in Rule 17Ad–22(a)(3), and the Commission is amending the definition of ''sensitivity analysis'' in Rule 17Ad–22(a)(16). As discussed in Part II, these amendments expand the scope of registered clearing agencies subject to Rule 17Ad–22(e) and encompass one additional registered clearing agency that now meets the definition of a ''covered clearing agency'' and is subject to the requirements of Rule 17Ad–22(e).

A. Economic Background

As the Commission has noted before, registered clearing agencies have become an essential part of the infrastructure of the U.S. securities markets.[54] While central clearing generally benefits the markets in which it is available, clearing agencies can pose substantial risk to the financial system as a whole, due in part to the fact that central clearing concentrates risk in the clearing agency.[55] Disruption to a

[38] Barnard.

[39] *See* CCA Standards adopting release, *supra* note 6, at 70815.

[40] *See* CCA Definition proposing release, *supra* note 9, at 70754.

[41] *See* Bishop.

[42] *See* Burrowes.

[43] *See id.*

[44] *See* Bishop; Burrowes.

[45] *See* Helmin.

[46] *See* CCA Definition proposing release, *supra* note 9, at 70752 & nn.83–88.

[47] *See id.* at 70748, 70752.

[48] *See id.*

[49] As described in the CCA Definition proposing release, over the years the Commission has registered a number of entities as clearing agencies that provide a variety of services, including securities settlement services for transactions executed by specialists on an exchange, for mortgage-backed securities transactions, and for cross-border transactions. *See id.* at 70752.

[50] Because the Commission is not adopting the definition of ''securities settlement system,'' the numbering for the definition of ''sensitivity analysis'' will be different than proposed, and the definitions of ''stress testing,'' ''systemically important in multiple jurisdictions,'' and ''transparent'' will retain their original numbering, rather than be renumbered as proposed.

[51] *See* 15 U.S.C. 78c(f).

[52] *See* CCA Definition proposing release, *supra* note 9, at 70745–46.

[53] *See* 15 U.S.C. 78w(a)(2).

[54] *See* CCA Definition proposing release, *supra* note 9, at 70756; *see also* CCA Standards adopting release, *supra* note 6, at 70849.

[55] For example, the default and liquidation of a clearing agency would be costly and disruptive to financial markets. *See, e.g.,* CCA Standards adopting release, *supra* note 6, at 70866; *see also* Robert Cox & Robert Steigerwald, *A CCP is a CCP is a CCP,* (Fed. Reserve Bank of Chi. Policy Discussion Paper 2017–01, Apr. 2017), at 13–14, *https://www.chicagofed.org/publications/policy-*

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clearing agency's operations, or failure on the part of a clearing agency to meet its obligations, could therefore serve as a potential source of contagion, resulting in significant costs not only to the clearing agency itself or its members but also to other market participants or the broader U.S. financial system.[56] As a result, proper management of the risks associated with central clearing is necessary to ensure the stability of the U.S. securities markets and the broader U.S. financial system. When a clearing agency provides CCP services, central clearing replaces bilateral counterparty exposures with exposures against the clearing agency. Consequently, a move to central clearing of security-based swaps, holding the volume of security-based swap transactions constant, increases economic exposures against clearing agencies that centrally clear security-based swaps. Increased exposures in turn raise the possibility that these clearing agencies may serve as a transmission mechanism for systemic events.

As the Commission discussed in the CCA Definition proposing release, clearing agencies have incentives to implement a risk management framework that can effectively manage the risks posed by central clearing, but these incentives can also be tempered by pressures to reduce costs and maximize profits that are distinct from goals set forth in governing statutes.[57] In addition, regulatory reforms, including efforts to mandate central clearing for OTC derivatives, can alter incentives to manage risks for both CCPs and clearing members. These factors may cause CCPs to choose risk management policies that do not fully reflect the costs and benefits that accrue to other financial market participants as a result of their decisions, and these choices may have implications for financial stability.

B. Baseline

In order to assess the economic effects of the amendments to Rule 17Ad–22, the Commission uses an economic baseline that considers the current market for clearance and settlement services. As discussed in the CCA Definition proposing release,[58] the Commission believes that the amendment to the definition of ''covered clearing agency'' will likely result in one additional registered clearing agency, ICE Clear Credit (''ICC''), becoming subject to the requirements in Rule 17Ad–22(e), and may also affect ICE Clear Europe (''ICEU'') because ICEU is a potential substitute provider of CCP services for security-based swaps to ICC's clearing members, even though the amendment to the definition of ''covered clearing agency'' does not affect ICEU's current status as a covered clearing agency.[59] Since publication of the CCA Definition proposing release, the Commission has registered Banque Central de Compensation, which conducts business under the name LCH SA (''LCH SA''), as a clearing agency to provide CCP services for U.S. persons for security-based swaps, including single-name credit default swaps, through its CDSClear business unit. Similar to ICEU, the Commission believes that ICC becoming subject to the requirements in Rule 17Ad–22(e) may also affect CDSClear because LCH SA is also a potential substitute provider of CCP services for security-based swaps to ICC's clearing members, even though the amendment to the definition of ''covered clearing agency'' does not affect LCH SA's current status as a covered clearing agency.[60] The Commission's baseline therefore includes these three entities in the market for clearance and settlement services, the current market practices at these entities, as well as the regulatory framework for these entities, including rules adopted by other regulators to the extent that these rules affect the cost structure, business, and market practices of the above-mentioned entities. Accordingly, Table 1 below provides membership statistics for ICC, ICEU, and LCH SA's CDSClear as of February 2020.

TABLE 1—MEMBERSHIP STATISTICS FOR ICE CLEAR CREDIT, ICE CLEAR EUROPE, AND LCH SA'S CDSCLEAR[61]

	Number
ICE	
Clear Credit Members	29
Clear Europe Members	89
—*Clear Europe Members that clear CDS	30
LCH	
SA Members	119
—CDSClear Members	26

With respect to the regulatory framework and current practices, the Commission discussed each at length in the CCA Definition proposing release.[62] The regulatory framework, which includes Section 17A of the Exchange Act, Section 19 of the Exchange Act, Titles VII and VIII of the Dodd-Frank Act, Rule 17Ad–22 under the Exchange Act, and certain regulations adopted by the CFTC, remains substantially unchanged. The current practices of ICC and ICEU also remain substantially unchanged, except that the Commission has approved the following proposed rule changes at ICC and ICEU since

discussion-papers/2017/pdp-1. Further, clearing members face risks if losses borne by clearing agencies, including the default of one member, are mutualized across non-defaulting members. *See, e.g.,* CCA Standards adopting release, *supra* note 6, at 70854–59 (describing the risks clearing agencies face, including, among others, counterparty credit risk, liquidity risk, and operational risk).

[56] *See generally* Dietrich Domanski, Leonardo Gambacorta, & Cristina Picillo, *Central Clearing: Trends and Current Issues,* BIS Q. Rev., Dec. 2015, at 59, *https://www.bis.org/publ/qtrpdf/r_qt1512g.pdf* (describing links between CCP financial risk management and systemic risk); Darrell Duffie, Ada Li, & Theo Lubke, *Policy Perspectives on OTC Derivatives Market Infrastructure,* (Fed. Reserve Bank of N.Y. Staff Report No. 424, Jan. 2010), at 9, *http://www.newyorkfed.org/research/staff_reports/sr424.pdf* (''If a CCP is successful in clearing a large quantity of derivatives trades, the CCP is itself a systemically important financial institution. The failure of a CCP could suddenly expose many major market participants to losses. Any such failure, moreover, is likely to have been triggered by the failure of one or more large clearing members, and therefore to occur during a period of extreme market fragility.''); Craig Pirrong, *The Inefficiency of Clearing Mandates* (CATO Inst. Policy Analysis No. 655, July 21, 2010), at 11–14, 16–17, 24–26, *http://www.cato.org/pubs/pas/PA665.pdf* (stating, among other things, that ''CCPs are concentrated points of potential failure that can create their own systemic risks,'' that ''[a]t most, creation of CCPs changes the topology of the network of connections among firms, but it does not eliminate these connections,'' that clearing may lead speculators and hedgers to take larger positions, that a CCP's failure to effectively price counterparty risks may lead to moral hazard and adverse selection problems, that the main effect of clearing would be to ''redistribute losses consequent to a bankruptcy or run,'' and that clearing entities have failed or come close to failing in the past, including in connection with the 1987 market break); Froukelien Wendt, *Central Counterparties: Addressing Their Too Important to Fail Nature* (IMF Working Paper No. 15/21, Jan. 2015), *https://www.imf.org/en/Publications/WP/Issues/2016/12/31/Central-Counterparties-Addressing-their-Too-Important-to-Fail-Nature-42637* (assessing the potential channels for contagion arising from CCP interconnectedness); Manmohan Singh, *Making OTC Derivatives Safe—A Fresh Look* (IMF Working Paper No. 11/66, Mar. 2011), at 5–11, *http://www.imf.org/external/pubs/ft/wp/2011/wp1166.pdf* (addressing factors that could lead central counterparties to be ''risk nodes'' that may threaten systemic disruption). *See also* Ben Bernanke, *Clearing and Settlement during the Crash,* 3 Rev. Fin. Stud. 133 (1990) for a discussion of the risks affecting clearing and settlement during the October 1987 stock market crash.

[57] *See id.*

[58] *See id.* at 70757.

[59] *See infra* Part III.C.1.c. Because ICC, ICEU, and LCH SA's CDSClear overlap in the products they clear, the amendments could potentially cause business to shift among these three clearing agencies.

[60] *See* supra note 59 and accompanying text.

[61] Membership statistics are taken from the websites of each of the listed clearing agencies as of February 2020: ICE Clear Credit Participants, *https://www.theice.com/clear-credit/participants;* ICE Clear Europe Membership, *https://www.theice.com/clear-europe/membership;* LCH SA Member Search, *https://www.lch.com/membership/member-search.*

[62] *See* CCA Definition proposing release, *supra* note 9, at 70757–64.

publication of the CCA Definition proposing release:

• With respect to risk management, ICC has expanded the scope of credit default swap contracts for which it provides clearing services,[63] revised its risk management framework,[64] revised its liquidity risk management and stress testing frameworks,[65] revised policies and procedures regarding liquidity thresholds,[66] amended policies and procedures for end-of-day price discovery,[67] revised and formalized its model validation framework,[68] revised and formalized its back-testing framework,[69] revised and formalized its new initiatives approval policy and procedural framework,[70] and revised and formalized its risk parameter setting and review policy;[71]

• With respect to risk management, ICEU has modified rules relating to its own contribution to CDS default resources,[72] allowed new transaction types,[73] revised policies and procedures concerning end-of-day price discovery,[74] amended its loss-given default framework,[75] amended its collateral and haircut policy,[76] modified its procyclicality framework,[77] amended its stress testing policy,[78] amended its liquidity plan,[79] amended its finance procedures,[80] amended its single name CDS liquidity charge methodology,[81] modified rules relating to its model risk governance framework,[82] revised its back-testing policy,[83] revised its risk policy,[84] and revised its policies relating to liquidity management;[85]

• With respect to client clearing, ICEU modified its rules to permit indirect client clearing arrangements;[86]

• With respect to recovery and wind-down plans, both ICC and ICEU amended their clearing rules relating to default management, recovery, and wind-down;[87]

• With respect to policies and procedures for default management, both ICC and ICEU revised their rules relating to the application of default provisions[88] and revised their auction procedures for a defaulting clearing participant's open CDS positions;[89]

• With respect to recognizing credit events, both ICC and ICEU modified their clearing rules to reflect ISDA's Narrowly Tailored Credit Event supplement;[90]

• With respect to treasury operations, ICC amended its treasury operations policies and procedures;[91]

• With respect to clearing membership policy, ICEU formalized and added requirements for applications for CDS clearing membership;[92] and

• With respect to operational risk, both ICC and ICEU amended their operational risk management frameworks.[93]

In addition, the Commission approved LCH SA's registration as a clearing agency after publication of the CCA Definition proposing release, and since then the Commission has also approved rule changes by LCH SA concerning its policies and procedures for risk management, including with respect to liquidity risk, margin, and default fund management.[94]

The Commission believes that ICEU's rule changes, LCH SA's registration, and LCH SA's subsequent rule changes would not substantially affect the preliminary assessment of most of the economic effects set forth in the CCA Definition proposing release, except to the extent that uniform regulatory requirements among ICEU, LCH SA, and ICC may enable clearing members to shift their business from ICEU or LCH SA to ICC.[95] The Commission also believes that the ICC rule changes may affect the Commission's preliminary assessment of benefits, costs, and the effect on competition, efficiency, and capital formation in two ways, as follows. First, to the extent that changes to ICC's risk management framework result in changes to ICC's clearing fund deposits, margin deposits, and deposits collected in lieu of margin, the updated calculations in Part III.C.1.a below include the effects of such rule changes in estimating the anticipated benefits for clearing members. Second, to the extent that these rule changes improve compliance with any aspect of Rule 17Ad–22(e) or the CFTC's comparable rules, ICC may have lower costs of complying with the amendments to Rule 17Ad–22 than first estimated in 2016.

[63] *See, e.g.,* Release Nos. 34–87297 (Oct. 15, 2019), 84 FR 56270 (Oct. 21, 2019); 34–84130 (Sept. 18, 2018), 83 FR 47665 (Sept. 20, 2018); 34–82853 (Mar. 12, 2018), 83 FR 11570 (Mar. 15, 2018); 34–81646 (Sept. 18, 2017), 82 FR 44477 (Sept. 22, 2017); 34–79892 (Jan. 27, 2017), 82 FR 9086 (Feb. 2, 2017); 34–79197 (Oct. 31, 2016), 81 FR 76987 (Nov. 4, 2016).

[64] *See, e.g.,* Release Nos. 34–87297 (Oct. 15, 2019), 84 FR 56270 (Oct. 21, 2019); 34–84457 (Oct. 19, 2018), 83 FR 53917 (Oct. 25, 2018); 34–83832 (Aug. 13, 2018), 83 FR 41118 (Aug. 17, 2018); 34–82853 (Mar. 12, 2018), 83 FR 11570 (Mar. 15, 2018); 34–79220 (Nov. 2, 2016), 81 FR 78677 (Nov. 8, 2016).

[65] *See, e.g.,* Release Nos. 34–86838 (Aug. 30, 2019), 84 FR 47019 (Sept. 9, 2019); 34–86378 (July 15, 2019), 84 FR 34990 (July 19, 2019); 34–82853 (Mar. 12, 2018), 83 FR 11570 (Mar. 15, 2018); 34–81797 (Oct. 2, 2017), 82 FR 46844 (Oct. 6, 2017); 34–81347 (Aug. 8, 2017), 82 FR 37917 (Aug. 14, 2017).

[66] Release No. 34–80324 (Mar. 28, 2017), 82 FR 16244 (Apr. 3, 2017).

[67] *See, e.g.,* Release Nos. 34–87297 (Oct. 15, 2019), 84 FR 56270 (Oct. 21, 2019); 34–82960 (Mar. 28, 2018), 83 FR 14300 (Apr. 3, 2018); 34–81186 (July 21, 2017), 82 FR 34997 (July 27, 2017); 34–80858 (June 5, 2017), 82 FR 26824 (June 9, 2017).

[68] *See, e.g.,* Release No. 34–86039 (June 5, 2019), 84 FR 27167 (June 11, 2019); 34–83690 (July 24, 2018), 83 FR 36655 (July 30, 2018).

[69] Release No. 34–85357 (Mar. 19, 2019), 84 FR 11146 (Mar. 25, 2019).

[70] Release No. 34–85105 (Feb. 11, 2019), 84 FR 4570 (Feb. 15, 2019).

[71] Release No. 34–85495 (Apr. 3, 2019), 84 FR 14158 (Apr. 9, 2019).

[72] Release No. 34–81076 (July 5, 2017), 82 FR 32037 (July 11, 2017).

[73] Release No. 34–82890 (Mar. 16, 2018), 83 FR 12630 (Mar. 22, 2018).

[74] *See, e.g.,* Release Nos. 34–84033 (Sept. 5, 2018), 83 FR 46005 (Sept. 11, 2018); 34–83389 (June 6, 2018), 83 FR 27356 (June 12, 2018); 34–81031 (June 27, 2017), 82 FR 30918 (July 3, 2017); 34–80978 (June 20, 2017), 82 FR 28919 (June 26, 2017).

[75] *See supra* note 73.

[76] Release No. 34–82659 (Feb. 8, 2018), 83 FR 6660 (Feb. 14, 2018).

[77] Release No. 34–82313 (Dec. 13, 2017), 82 FR 60254 (Dec. 19, 2017).

[78] Release Nos. 34–85236 (Mar. 1, 2019), 84 FR 8348 (Mar. 7, 2019); 34–83243 (May 15, 2018), 83 FR 23506 (May 21, 2018).

[79] Release No. 34–84754 (Dec. 7, 2018), 83 FR 64171 (Dec. 13, 2018).

[80] Release No. 34–84375 (Oct. 5, 2018), 83 FR 51715 (Oct. 12, 2018).

[81] Release No. 34–85776 (May 3, 2019), 84 FR 20454 (May 9, 2019).

[82] *See, e.g.,* Release No. 34–85128 (Feb. 13, 2019), 84 FR 5137 (Feb. 20, 2019).

[83] *See, e.g.,* Release Nos. 34–87360 (Oct. 18, 2019), 84 FR 57100 (Oct. 24, 2019); 34–85236 (Mar. 1, 2019), 84 FR 8348 (Mar. 7, 2019).

[84] *See, e.g.,* Release Nos. 34–85236 (Mar. 1, 2019), 84 FR 8348 (Mar. 7, 2019); 34–81680 (Sept. 22, 2017), 82 FR 45339 (Sept. 28, 2017).

[85] Release No. 34–86891 (Sept. 6, 2019), 84 FR 48191 (Sept. 12, 2019).

[86] Release No. 34–82422 (Dec. 29, 2017), 83 FR 546 (Jan. 4, 2018).

[87] *See, e.g.,* Release Nos. 34–86783 (Aug 28, 2019), 84 FR 46575 (Sept. 4, 2019); 34–86364 (July 12, 2019), 84 FR 34455 (July 18, 2019); 34–86259 (July 1, 2019), 84 FR 32483 (July 8, 2019); 34–83651 (July 17, 2018), 83 FR 34891 (July 23, 2018); 34–79750 (Jan. 6, 2017), 82 FR 3831 (Jan. 12, 2017).

[88] *See, e.g.,* Release Nos. 34–86838 (Aug. 30, 2019), 84 FR 47019 (Sept. 9, 2019); 34–80304 (Mar. 24, 2017), 82 FR 15733 (Mar. 30, 2017).

[89] Release No. 34–87804 (Dec. 19, 2019), 84 FR 71501 (Dec. 27, 2019).

[90] *See, e.g.,* Release Nos. 34–87971 (Jan. 15, 2020), 85 FR 3724 (Jan. 22, 2020); 34–88013 (Jan. 22, 2020), 85 FR 5058 (Jan. 28, 2020).

[91] *See, e.g.,* Release Nos. 34–87859 (Dec. 26, 2019), 85 FR 157 (Jan. 2, 2020); 34–84312 (Sept. 28, 2018), 83 FR 50124 (Oct. 4, 2018); 34–81386 (Aug. 14, 2017), 82 FR 39484 (Aug. 18, 2017).

[92] Release No. 34–86359 (July 11, 2019), 84 FR 34241 (July 17, 2019).

[93] *See, e.g.,* Release Nos. 34–86184 (June 24, 2019), 84 FR 31132 (June 28, 2019); 34–83071 (Apr. 19, 2018), 83 FR 18108 (Apr. 25, 2018).

[94] *See, e.g.,* Release Nos. 34–88039 (Jan. 24, 2020), 85 FR 5489 (Jan. 30, 2020); 34–87881 (Jan. 2, 2020), 85 FR 947 (Jan. 8, 2020); 34–86376 (July 15, 2019), 84 FR 34955 (July 19, 2019); 34–83691 (July 24, 2018), 83 FR 36635 (July 30, 2018); 34–82345 (Dec. 18, 2017), 82 FR 60781 (Dec. 22, 2017); 34–81056 (June 30, 2017), 82 FR 31364 (July 6, 2017); 34–80849 (June 2, 2017), 82 FR 26721 (June 8, 2017); 34–80848 (June 2, 2017), 82 FR 26728 (June 8, 2017).

[95] *See infra* Part III.C.1.c.

C. Consideration of Benefits, Costs, and the Effect on Competition, Efficiency, and Capital Formation

As discussed in the CCA Definition proposing release, the aggregate economic effects of the amendments to Rule 17Ad–22 arise from two sources: (i) The amendments' likely effects on existing registered clearing agencies, and (ii) the amendments' likely effects on clearing agencies that may register with the Commission in the future. Thus, the below discussion considers the benefits, costs, and likely effects on efficiency, competition, and capital formation that may arise from these two sources separately.[96] Further, when viewed in isolation, the economic effects related to existing registered clearing agencies are likely to be low in magnitude but, when taken together with the economic effects related to future registrants, could be substantial. This is particularly true because the rules subject future registrants that are CCPs or CSDs to the enhanced requirements in Rule 17Ad–22(e), and these clearing agencies are likely to play critical roles in the U.S. clearance and settlement system.

1. Economic Effects Related to Registered Clearing Agencies

The Commission continues to believe that the addition of ICC as a covered clearing agency will incrementally extend the systemic benefits of risk management first discussed in the CCA Standards adopting release and previously explained in the CCA Definition proposing release. These benefits consist of improved financial stability,[97] a reduction in the ambiguity associated with holding cleared assets in the presence of credit and settlement risk, and a reduction in market fragmentation arising from different requirements across regulatory regimes.[98] The Commission also continues to believe that the extension of these benefits will likely be incremental and will only appear to the extent that the amendments would result in changes to ICC policies and procedures because, as explained in the CCA Definition proposing release, ICC is regulated as a systemically important derivatives clearing organization (''SIDCO'') by the CFTC, and Rule 17Ad–22(e) is consistent with comparable regulatory provisions adopted by the CFTC.[99] The following sections attempt to estimate particular benefits that could accrue to ICC and its members as a result of ICC being more likely to qualify as a Qualified CCP (''QCCP'') under the amended definitions,[100] and then they discuss the costs and the effect on efficiency, competition, and capital formation.

a. Benefits

As explained in the CCA Definition proposing release, the amendments to Rule 17Ad–22 make it more likely that ICC will qualify as a QCCP for security-based swap transactions in foreign jurisdictions that have adopted the BCBS capital framework's QCCP definition.[101] In particular, ICC's qualification as a QCCP would result in its foreign bank clearing members and foreign bank indirect participants facing lower capital requirements with respect to cleared security-based swap transactions relative to the baseline in which foreign banking regulators do not determine ICC to be a QCCP.[102]

As explained in the CCA Definition proposing release, the BCBS capital framework affects capital requirements for bank exposures to CCPs in two important ways: (i) Generally, trade exposures held against a QCCP are assigned a risk weight of two percent rather than risk weights ranging from 20 to 100 percent depending on counterparty credit risk; and (ii) the risk weight applied to default fund contributions to a QCCP are generally lower than those applied to default fund contributions to a non-QCCP.[103] In the proposing release, the Commission used a method permitted under the interim BCBS capital requirements to estimate an upper bound for the benefits to clearing members of lower capital requirements for exposures to QCCPs.[104] Since the CCA Definition proposing release, the BCBS capital framework updated the capital requirements for bank exposures to CCPs. In contrast to the interim approach that was in force until January 1, 2017, the current requirements permit only one method for computing capital requirements for default fund contributions to QCCPs.[105] Under the current requirements, a bank clearing member's default fund contribution has a capital requirement that is the greater of either (i) the hypothetical capital requirement of the CCP reflecting all of its counterparty credit risk exposures multiplied by the proportion of the bank clearing member's contribution to the CCP's default fund or (ii) eight percent multiplied by two percent multiplied by the clearing member bank's default fund contribution.[106] Although the change in capital requirements affects the magnitude of benefits that bank clearing members might experience as a result of QCCP status, the Commission continues to expect that bank clearing members subject to the BCBS capital framework may benefit from an improved capital position and lowering funding costs relative to the bank clearing members of non-qualifying CCPs.

As set forth in the CCA Definition proposing release, the Commission has attempted to quantify the benefits of achieving QCCP status using publicly available information with regard to ICC.[107] To estimate the upper bound for the potential benefits accruing to bank clearing members at ICC as a result of its QCCP status, the Commission identified the sample of 15 bank holding companies and foreign equivalents of bank holding companies that own clearing members and, for each, collected information about total assets, risk-weighted assets, net income, and tier-one capital ratio at the holding company level for 2019.[108] The

[96] CCA Definition proposing release, *supra* note 9, at 70764.

[97] *See id.* at 70765; *see also* CCA Standards adopting release, *supra* note 6, at 70867–80.

[98] *See* CCA Definition proposing release, *supra* note 9, at 70765; *see also* CCA Standards adopting release, *supra* note 6, at 70861–62.

[99] *See* CCA Definition proposing release, *supra* note 9, at 70765.

[100] The BCBS capital framework, as well as the rules adopted by the FRB and Office of the Comptroller of the Currency consistent with that framework, applies lower risk weights to indirect exposures of banks to QCCPs. *See* BCBS, Capital Requirements for Bank Exposures to Central Counterparties (Dec. 2019), *https://www.bis.org/basel_framework/chapter/CRE/54.htm?inforce=20191215&export=pdf* (''BCBS capital framework''); *see also* Regulatory Capital Rules: Regulatory Capital, Implementation of Basel III, Capital Adequacy, Transition Provisions, Prompt Corrective Action, Standardized Approach for Risk-Weighted Assets, Market Discipline and Disclosure Requirements, Advanced Approaches Risk-Based Capital Rule, and Market Risk Capital Rule, 76 FR 62017, 62099 (Oct. 11, 2013), at 62103.

[101] *See* CCA Definition proposing release, *supra* note 9, at 70765.

[102] The benefits to bank clearing members are contingent upon regulators in other jurisdictions taking action to recognize ICC's QCCP status following adoption of the amended definition of ''covered clearing agency.''

[103] *See* CCA Definition proposing release, *supra* note 9, at 70765.

[104] *See* BCBS, Capital Requirements for Bank Exposures to Central Counterparties (July 2012), *https://www.bis.org/publ/bcbs227.pdf.*

[105] *See* CCA Definition proposing release, *supra* note 9, at 70765, for a discussion of the 2014 methods for calculating capital requirements for bank exposures to CCPs; see also *supra* note 104 and accompanying text.

[106] *See* BCBS capital framework, *supra* note 100; *see also supra* note 101.

[107] *See* CCA Definition proposing release, *supra* note 9, at 70765–66.

[108] The Commission used the set of entities it identified as banks on ICC's member list available at *https://www.theice.com/clear-credit/participants.* For U.S. bank holding companies, 2019 total assets, risk weighted assets, net income, and tier-one capital ratios were collected from Y–9C reports from the National Information Center, available at *https://www.ffiec.gov/nicpubweb/nicweb/*

Commission then allocated trade exposures and default fund exposures across the sample of bank clearing members based on the level of risk-weighted assets.[109] The Commission measured the impact on risk-weighted assets for foreign bank clearing members under two different capital treatment regimes. In the first regime, ICC does not obtain QCCP status, and bank clearing members are subject to a 100 percent risk weight for trade exposures and a 1250 percent risk weight for default fund exposures. In the second regime, ICC obtains QCCP status, and bank clearing members can apply a two percent risk weight to trade exposures and the greater of either (i) ICC's hypothetical capital requirement multiplied by the proportion of the bank clearing member's contribution to the CCP's default fund, or (ii) 0.16 percent of the bank clearing member's default fund contribution.[110] If ICC is determined to be a QCCP, then the increase in risk-weighted assets will be smaller in magnitude, implying a smaller adjustment at lower cost. Using data through December 2019, the Commission now estimates that the benefits of lower capital requirements against exposures to QCCPs as a result of the amendments to Rule 17Ad–22 have an upper bound of $17.8 million per year (up from the estimate of $12.9 million provided in the CCA Definition proposing release, which was based on data through August 2016), or approximately 0.01 percent of the total net income reported by the bank holding companies and foreign equivalent of bank holding companies that own ICC clearing members in 2019.[111]

As previously explained in the CCA Definition proposing release, the Commission's analysis here is limited in several respects and relies on several assumptions about the nature of trade exposures to ICC,[112] as discussed further below. First, the Commission is using the balance of ICC's margin account and default fund as proxies for trade exposures and guaranty fund deposits, respectively. These likely include deposits both by bank clearing members, who would directly experience lower capital requirements under the BCBS capital framework, and non-bank subsidiaries of bank holding companies and foreign equivalents of bank holding companies, who would experience effects through the lower capital requirements of their parent bank holding companies. Furthermore, the guaranty fund deposits may include deposits by non-bank client clearing participants. For the purposes of this analysis, the Commission continues to assume, to establish an upper bound for the benefits to market participants that are associated with QCCP status for ICC under the adopted rules, that ICC's guaranty fund accounts are attributable only to bank clearing members. Additionally, the Commission continues to assume an extreme case where, in the absence of QCCP status, trade exposures against a CCP would be assigned a 100 percent risk weight, causing the largest possible shock to risk-weighted assets for affected banks.

Second, lower capital requirements on exposures to ICC would produce effects in the real economy only under certain conditions. For example, agency problems, taxes, or other capital market imperfections could result in banks targeting a particular capital structure. Additionally, the BCBS capital framework must constrain bank clearing members such that these banks cannot either use capital to invest in assets whose returns exceed the banks' cost of capital or return capital to shareholders because these actions would decrease their capital ratios below regulatory minimums. Using publicly available data, however, it remains unfeasible to determine to what extent the finalized BCBS capital requirements will constrain bank clearing members. Instead, the Commission continues to assume that all bank clearing members of ICC act as if they are at their minimum allowed tier-one capital ratios before accounting for exposures to CCPs.[113]

Third, the Commission continues to assume that banks choose to adjust to new capital requirements by deleveraging. In particular, the Commission has assumed that banks would respond by reducing risk-weighted assets equally across all risk classes until they reach the minimum tier-one capital ratio under the BCBS capital framework.[114] The Commission continues to measure the ongoing costs to each foreign bank clearing member by multiplying the implied change in total assets by each bank's return on assets, using up to 12 years of annual financial statement data.[115]

Fourth, the BCBS capital framework yields additional benefits for QCCPs that the Commission remains unable to quantify due to a lack of data concerning client clearing arrangements by banks. For client exposures to clearing members, the BCBS capital framework allows participants to reflect the shorter close-out period of cleared transactions in their capitalized exposures. The BCBS capital framework's treatment of exposures to CCPs also applies to client exposures to CCPs through clearing members. This may increase the likelihood that bank

nichome.aspx. For the foreign equivalent of bank holding companies, Commission staff obtained corresponding data from financial statements and supplementary financial materials posted to company websites. Where necessary, values were converted back to U.S. dollars at September 30, 2019 or December 31, 2019 (depending on the most recently reported quarterly financial results) exchange rates obtained from the Federal Reserve at *http://www.federalreserve.gov/releases/h10/hist/.*

[109] For example, one bank in the sample, with 8.52 percent of total risk-weighted assets, was assigned 8.52 percent of the total trade and default fund exposures while another bank in the sample, with 3.01 percent of total risk weighted assets, was assigned 3.01 percent of these exposures. Because trade exposures of ICC members against ICC are nonpublic, the Commission used the balance of ICC margin deposits in house accounts held by ICC, $11.1 billion, as a proxy for trade exposures. ICC's clearing participant guaranty fund deposits as of September 30, 2019 were valued at $2.28 billion. *See* ICC 2019 Q3 Quantitative Disclosure, *https://www.theice.com/clear-credit/regulation#quantitative-disclosures.*

[110] *See* BCBS capital framework, *supra* note 100. ICC's hypothetical capital requirement (''KCCP'') as of September 30, 2019 was $126.38 million. *See* supra note 109 and accompanying text (discussing ICC's guaranty fund deposits).

[111] The Commission quantified the benefits related to ICC's attaining QCCP status for ICC's bank clearing members and indirect participants with respect to all reported exposures. Over the period of March 2009 through December 2019, the gross notional value of security-based swap transactions cleared by ICE Clear Credit comprised 9.6 percent of the total value of all CDS transactions cleared (*see https://www.theice.com/clear-credit*). Based on this information, the Commission arrived at the benefits to ICC's bank clearing members and bank indirect participants from ICC's attaining QCCP status with respect to security-based swap transactions by multiplying the total benefits by 0.096.

[112] *See* CCA Definition proposing release, *supra* note 9, at 70766–77.

[113] The Commission notes that, at present, no bank in its sample of bank clearing members of ICC has only the minimum amount of capital required by the BCBS capital framework. For U.S. bank holding companies, tier-one capital ratios were collected from Y–9C reports from the National Information Center, available at *https://www.ffiec.gov/nicpubweb/nicweb/nichome.aspx.* For the foreign equivalent of bank holding companies, Commission staff obtained corresponding data from financial statements and supplementary financial materials posted to company websites. The Commission used data from 2019 for its sample of clearing members. This sample's minimum tier-one capital ratio is 12.2 percent, and the minimum amount by which a clearing member exceeds its tier-one capital requirement is two percent.

[114] Each bank, bank holding company, and foreign equivalent of a bank holding company faces the same six percent base tier-one capital ratio requirement and 2.5 percent capital conservation buffer. Additionally, each bank holding company has a buffer for being a globally or domestically systemically important bank, ranging from one percent to 3.5 percent. Lastly, some jurisdictions have instituted countercyclical capital buffers.

[115] This data has been taken from Compustat. Due to data limitations, for certain banks a shorter window was used for this calculation. The minimum sample window was nine years.

clients of bank clearing members subject to the BCBS capital framework share some of the benefits of QCCP status.

Fifth, the BCBS capital framework may impact competition and concentration. For example, while the amendments to Rule 17Ad–22 may extend lower capital requirements to certain bank clearing members, the costs of overall compliance with Rule 17Ad–22 may be borne by all clearing members, regardless of whether or not they are supervised as banks. A potential consequence of this allocation of costs and benefits may be a ''crowding out'' of non-bank members of QCCPs, including any such subsidiaries of bank holding companies, who may not experience any or all of the benefits with respect to the BCBS capital framework. This may result in an unintended consequence of an increased concentration of clearing activity among ICC's bank clearing members. This increased concentration could mean that each of the remaining clearing members becomes more important from the standpoint of systemic risk transmission since, for example, clearing agencies would have fewer non-defaulting members to take on a defaulting member's portfolio, and clearing agencies that rely on clearing members to participate in default auctions would hold auctions with fewer participants.

Sixth, the Commission continues to believe that the benefits of ICC attaining QCCP status may depend on whether foreign bank clearing members of ICC are currently able to shift their clearing business from ICC to alternative clearing agencies that serve similar markets. In this regard, the Commission notes that ICC has several overlapping members with ICEU and LCH SA's CDSClear. ICEU and CDSClear also clear many of the same contracts that ICC does.[116] ICEU clears all of the European corporate single name CDS and Western European sovereign single name CDS. Additionally, compared to ICC's 250 North American corporate single name reference entities, LCH SA clears contracts on 153 North American entities, with significant overlap. Thus, in a situation where ICEU and LCH SA are QCCPs and ICC is not, common foreign bank clearing members of the three agencies may obtain many of the same benefits of ICC having QCCP status by moving their clearing business to either ICEU or LCH SA's CDSClear. However, under such a scenario, the full range of benefits stemming from ICC having QCCP status would not be fully realized because: (i) Some clearing members of ICC are not clearing members of either ICEU or LCH SA's CDSClear; (ii) some participants that have a client clearing agreement with ICC may not have a client clearing agreement with ICEU; and (iii) ICC clears contracts that neither ICEU or LCH SA's CDSClear does. Thus, even common bank members may not be able to move their entire clearing business to another CCP.

b. Costs

As previously discussed, ICC is a SIDCO regulated by the CFTC under a regime that is consistent and comparable with Rule 17Ad–22(e). In light of the similarity among the two regulatory frameworks, the Commission continues to believe that the economic costs ICC will bear as a result of the amendments to Rule 17Ad–22 will be related to the establishment, implementation, and maintenance of certain policies and procedures under Rule 17Ad–22(e). The Commission now estimates that these costs will at most include one-time costs of approximately $752,673 [117] and annual costs of approximately $158,594.[118] As noted above in Part III.B, to the extent that rule changes implemented by ICC since 2016 facilitate compliance with Rule 17Ad–22(e), the actual cost to ICC may be lower.

c. Effects on Efficiency, Competition, and Capital Formation

As previously discussed, the amendments to Rule 17Ad–22 do not alter the status of existing covered clearing agencies.[119] The Commission continues to believe that the amendments will not change the behavior of market participants associated with these entities and will therefore not generate any economic benefits or costs for these entities. Further, even though the amendments do not alter the status of ICEU or LCH SA, the Commission continues to believe that the amendments are likely to generate economic effects for these entities because ICC clears many of the same security-based swap transactions that are cleared by ICEU and LCH SA. Because the amendments are likely to result in uniform regulatory requirements for similar risks at these clearing agencies, they could potentially cause business to shift from ICEU or LCH SA to ICC. This could translate into a loss of economies of scale for ICEU or LCH SA which, in turn, would result in higher clearing fees and higher transaction costs in cleared products. Furthermore, it may reduce the benefits of netting and portfolio margining, which could result in higher margins and consequently transaction costs for clearing participants.

2. Economic Effects Related to Future Registrants

In addition to the effects imposed on the existing set of registered clearing agencies, the amendments to Rule 17Ad–22 will affect the regulation of clearing agencies that register with the Commission in the future. As previously discussed in the CCA Definition proposing release, any clearing agency

[116] ICEU clears all of the European corporate security-based swaps and Western European sovereign security-based swaps that ICC does. CDSClear only clears corporate security-based swaps that reference constituents of the index products it accepts. The 153 unique North American reference entities have a substantial overlap with the North American corporate security-based swaps that ICC clears. The Commission used the description of ICEU cleared contracts available at *https://www.theice.com/clear-europe/cds* and CDSClear cleared contracts available at *https://www.lch.com/services/cdsclear/what-we-clear.*

[117] Calculated as ((Assistant General Counsel for 440 hours at $478 per hour) + (Chief Compliance Officer for 146 hours at $544 per hour) + (Chief Financial Officer for 50 hours at $1,111 per hour) + (Compliance Attorney for 377 hours at $374 per hour) + (Computer Operations Department Manager for 344 hours at $452 per hour) + (Financial Analyst for 70 hours at $281 per hour) + (Senior Business Analyst for 85 hours at $281 per hour) + (Senior Programmer for 75 hours at $340 dollars per hour) + (Senior Risk Management Specialist for 114 hours at $367 per hour)) = $752,673. These dollar amounts have been updated since the CCA Definition proposing release to account for inflation since 2016.

To monetize these costs and those set forth below, Commission staff used data from two SIFMA publications, Management and Professional Earnings in the Security Industry—2013, and Office Salaries in the Securities Industry—2013, modified to account for an 1,800-hour work year and multiplied by 5.35 (professionals) or 2.93 (office) to account for bonuses, firm size, employee benefits and overhead. Inflation adjustments use data published by the Bureau of Labor Statistics.

Commission staff separately estimated an hourly rate for a chief financial officer, using the website *www.salary.com,* which reports median salaries of $378,564, and a Grant Thornton LLP 2019 survey, which estimates that Russell 2000 financial services chief financial officers receive a median annual salary of $368,815. Using an approximate midpoint of these two estimates of $373,690 per year, and dividing by an 1,800-hour work year and multiplying by the 5.35 factor, which normally is used to include benefits but here is used as an approximation to offset the fact that New York salaries are typically higher than the rest of the country, the result is $1,111 per hour.

[118] Calculated as ((Administrative Assistant for 20 hours at $82 per hour) + (Compliance Attorney for 279 hours at $374 per hour) + (Computer Operations Department Manager for 12 hours at $452 per hour) + (Risk Management Specialist for 183 hours at $204 per hour) + (Senior Business Analyst for 22 hours at $281 per hour) + (Senior Risk Management Specialist for 10 hours at $367 per hour)) = $158,594 per year.

[119] *See supra* note 21 (discussing the six CCPs and one CSD that, prior to the amendments, were already covered clearing agencies subject to Rule 17Ad–22(e)).

that provides the services of a CCP or CSD will now be a covered clearing agency.[120] This means that covered clearing agencies will no longer be limited to those that have been designated by FSOC or that are involved in activities with a complex risk profile. Nor will clearing agencies be excluded when the CFTC is the supervisory agency under the Clearing Supervision Act.

Because the Commission continues to be unable to predict the number of clearing agencies likely to register in the future, much less the number that are likely to be CCPs or CSDs, it continues to be unable to quantify the aggregate economic effects that could flow to future registrants from the amendments to Rule 17Ad–22.[121] The Commission continues to believe that the amendments would generally increase the likelihood that Rule 17Ad–22(e) would apply to a new registrant; in recent years, however, the Commission has received, on average, fewer than one application for registration as a clearing agency per year.[122] Where possible, the Commission has attempted to estimate the benefits and costs it would expect the amendments to Rule 17Ad–22 to have on a single new registrant.

a. Benefits

As discussed in the CCA Definition proposing release, the Commission continues to believe that the amendments to Rule 17Ad–22 may reduce the costs that potential new providers of clearance and settlement services expect to incur in determining whether they would need to meet the enhanced requirements of covered clearing agencies.[123] Under the amendments, any registered clearing agency that expects to provide the services of a CCP or CSD would also expect to be subject to Rule 17Ad–22(e) without requiring additional information about FSOC designation or a Commission determination that its activities have a more complex risk profile. To the extent that this reduces the need for potential entrants that engage in those services to assess whether they are likely to be regulated as covered clearing agencies, the amendments could reduce the costs associated with registration. The Commission continues to believe that a reasonable estimate of cost reduction a single registrant is likely to experience is $4,208, attributable to reduced legal expenses associated with determining whether or not the registrant will also be regulated as a covered clearing agency.[124]

In the absence of the amendments to Rule 17Ad–22, and without designation by FSOC or engagement in activities with a more complex risk profile, a registered clearing agency would instead be subject to Rule 17Ad–22(d). The amendments therefore increase the likelihood that new entrants into the market for clearance and settlement services would be subject to Rule 17Ad–22(e). Generally, to the extent that Rule 17Ad–22(e) imposes higher risk management standards on potential entrant CCPs and CSDs, the Commission believes the amendments to Rule 17Ad–22 may improve financial stability. As previously discussed, some of this increased stability may come as a result of lower activity, as Rule 17Ad–22(e) causes participants of these new entrants to internalize a greater proportion of the costs that their activity imposes on the financial system, reducing the costs of default when a default event occurs. Increased stability may also come as a result of the higher risk management standards at potential entrants, effectively lowering the probability that either the entrant clearing agencies or their members default.[125]

b. Costs

As previously discussed, in the absence of these amendments to Rule 17Ad–22, a registered clearing agency that has not been designated by FSOC or subject to a Commission determination would be subject to Rule 17Ad–22(d) rather than Rule 17Ad–22(e). To the extent that the requirements under Rule 17Ad–22(e) impose additional costs on potential entrants who would otherwise have been regulated under Rule 17Ad–22(d), the Commission continues to believe that the amendments may impose additional costs on such potential entrants.

In the CCA Definition proposing release and the CCA Standards adopting release,[126] the Commission estimated specific costs that registered clearing agencies would bear related to holding sufficient qualifying liquid resources under 17 CFR 240.17Ad–22(e)(7) (''Rule 17Ad–22(e)(7)''). Because the organizational and governance structures of covered clearing agencies vary, as do the composition of their members and the products they clear, the Commission remains unable to provide precise estimates of the costs associated with these requirements that potential entrants may bear as a result of the amendments to Rule 17Ad–22. However if a potential entrant resembles the average covered clearing agency, the Commission continues to expect that compliance with Rule 17Ad–22(e)(7) would cost the entrant between $24 million and $40 million per year.[127] In addition, the Commission continues to estimate the startup compliance costs associated with policies and procedures for a potential entrant that is not a CSD to be substantially similar to the costs estimated in the CCA Standards adopting release: $691,309, after adjusting for inflation.[128] Furthermore, 17 CFR 240.17Ad–22(e)(3), (4), (6), (7), (15), and (21) each include elements of review by either a covered clearing agency's board or its management on an ongoing basis. The Commission continues to estimate the cost of ongoing review for these rules at approximately $40,000 per year for a

[120] *See* CCA Definition proposing release, *supra* note 9, at 70767–68.

[121] The comments received did not provide any additional information regarding the likelihood of new registrant clearing agencies.

[122] The Commission notes that, for new registrants seeking to provide CCP or CSD services, the amendments ensure that Rule 17Ad–22(e) would apply to such registrants, but clearing agencies can perform other functions as well.

[123] *See* CCA Definition proposing release, *supra* note 9, at 70768.

[124] The Commission calculated this reduction in costs as ((Assistant General Counsel for 2 hours at $478 per hour) + (Compliance Attorney for 3 hours at $374 per hour) + (Outside Counsel for 5 hours at $426 per hour = $4,208. These dollar amounts have been updated since the CCA Definition proposing release to account for inflation since 2016.

[125] *See* CCA Definition proposing release, *supra* note 9, at 70768; CCA Standards adopting release, *supra* note 6, at 70881.

[126] *See* CCA Definition proposing release, *supra* note 9, at 70768; CCA Standards adopting release, *supra* note 6, at 70870–73.

[127] To arrive at this range, the Commission divided the maximum and minimum costs associated with compliance estimated in the CCA Standards adopting release by five covered clearing agencies. *See* CCA Definition proposing release, *supra* note 9, at 70768.

[128] CCA Standards adopting release, *supra* note 6, at 70881 & n.757. The total initial cost for an entrant that is not a CSD and does engage in activities with a more complex risk profile was calculated as follows: ((Assistant General Counsel for 428 hours at $478 per hour) + (Compliance Attorney for 365 hours at $374 per hour) + (Administrative Assistant for 2 hours at $82 per hour) + (Computer Operations Department Manager for 300 hours at $452 per hour) + (Senior Business Analyst for 85 hours at $281 per hour) + (Senior Risk Management Specialist for 114 hours at $367 per hour) + (Chief Compliance Office for 102 hours at $544 per hour) + (Senior Programmer for 53 hours at $340 per hour) + (Chief Financial Officer for 50 hours at $1,111 per hour) + (Financial Analyst for 70 hours at $281 per hour)) = $691,309. These dollar amounts have been updated since the CCA Definition proposing release to account for inflation since 2016. Because only 17 CFR 240.17Ad–22(e)(11) applies solely to CSDs and many of the other parts of Rule 17Ad–22(e) do not apply to CSDs, the Commission believes the initial cost of an entrant that is a CSD would be lower.

potential entrant, as estimated in the CCA Standards adopting release.[129]

c. Effects on Efficiency, Competition, and Capital Formation

The Commission continues to believe that substantial direct effects on efficiency and capital formation are unlikely to flow from the impact of the amendments to Rule 17Ad–22 on potential entrants; however, potential effects on competition may arise from how the amendments affect the regulatory treatment of registered clearing agencies and the barriers to entry into the market for services provided by CCPs and CSDs.

As discussed in the CCA Definition proposing release, the amendments are likely to result in more consistent regulatory treatment of firms that provide similar services to the securities markets.[130] By imposing Rule 17Ad–22(e) on all CCPs and CSDs, regardless of FSOC designation or their engagement in activities with a more complex risk profile, the amendments mitigate the risk that registered clearing agencies with similar businesses are subject to substantially different regulatory regimes. The Commission continues to believe that more uniform treatment may provide a more level playing field. By contrast, in the absence of the amendments to Rule 17Ad–22, an entrant CCP or CSD that did not engage in activity with a more complex risk profile could initially receive a competitive advantage by being regulated under Rule 17Ad–22(d) until becoming a designated clearing agency and internalizing less of the risk it poses to the financial system.

On the other hand, as previously discussed in the CCA Standards adopting release and the CCA Definition proposing release, costs resulting from regulation under Rule 17Ad–22(e) as a result of the amendments may have the effect of raising already high barriers to entry.[131] As the potential entry of new clearing agencies becomes more remote, existing clearing agencies may be able to reduce service quality, restrict the supply of services, or increase fees above marginal cost in an effort to earn economic rents from participants in cleared markets.[132]

3. Alternatives to the Amended Definition

In the CCA Definition proposing release, the Commission proposed including registered clearing agencies that provided the services of a securities settlement system in the definition of ''covered clearing agency.'' Among the alternatives discussed in the proposing release was a definition that excluded securities settlement services from the definition of a covered clearing agency,[133] which the Commission is adopting in this document for the reasons set forth above in Parts II.A and D.

IV. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (''PRA'') imposes certain requirements on federal agencies in connection with the conducting or sponsoring of any ''collection of information.'' [134] An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid control number. Further, 44 U.S.C. 3507(a) provides that, before adopting or revising a collection of information requirement, an agency must, among other things, publish notice in the **Federal Register** stating that the agency has submitted the proposed collection of information to the Office of Management and Budget (''OMB'') and setting forth certain required information, including (i) a title for the collection of information; (ii) a summary of the collection of information; (iii) a brief description of the need for the information and the proposed use of the information; (iv) a description of the likely respondents and proposed frequency of response to the collection of information; (v) an estimate of the paperwork burden that shall result from the collection of information; and (vi) notice that comments may be submitted to the agency and director of OMB.[135]

Certain provisions of Rule 17Ad–22(e) impose collection of information requirements under the PRA. The Commission submitted these collections of information to the OMB for review in accordance with 44 U.S.C. 3507 and 5 CFR 1320.11. Because the Commission is revising the respondents under Rule 17Ad–22(e) to account for amended Rule 17Ad–22(a)(5), the Commission will use the same title and control number: ''Clearing Agency Standards for Operation and Governance,'' OMB Control No. 3235–0695.

The Commission provided notice of the PRA estimates in the CCA Definition proposing release and received no comments in response. The Commission continues to believe that the PRA estimates set forth in the CCA Definition proposing release are correct, except where changes are noted below.

A. Summary of Collection of Information and Use of Information [136]

As described above, the Commission is adopting amendments to three definitions in Rules 17Ad–22(a) and is not altering any of the requirements in Rule 17Ad–22(e).[137] Accordingly, the Collection of Information and Use of Information for Rule 17Ad–22(e) previously set forth in the CCA Standards adopting release and the CCA Definition proposing release remain unchanged.[138]

B. Respondent Clearing Agencies

The requirements in Rule 17Ad–22(e) impose a PRA burden on covered clearing agencies. Under the prior definition of ''covered clearing agency'' adopted in 2016, Rule 17Ad–22(e) applied to five registered clearing agencies, including four registered clearing agencies that provide CCP services and one registered clearing agency that provides CSD services, and the Commission estimated that two additional entities might seek to register with the Commission. Accordingly, the Commission estimated that the majority of the requirements under Rule 17Ad–22(e) would have seven respondents, of which (i) six would be CCPs and one would be a CSD, and (ii) two would be

[129] CCA Standards adopting release, *supra* note 6, at 70880 & n.755. To estimate the cost of board review for these rules, the Commission has used a report by Bloomberg stating that the average director works 250 hours and earns $251,000, resulting in an estimated $1,000 per hour for board review. *See* Jeff Green & Hideki Suzuki, *Board Pay Hits Record $251,000 for 250 Hours,* Bloomberg, May 30, 2013, *https://www.bloomberg.com/news/articles/2013-05-30/board-director-pay-hits-record-251-000-for-250-hours.* As a proxy for the cost of management review, the Commission is estimating $461 per hour, based upon the Director of Compliance cost data from SIFMA. The Commission estimates the total cost of review for each clearing agency as follows: ((Board Review for 32 hours at $1,000 per hour) + (Management Review for 16 hours at $500 per hour)) = $40,000. The estimate for management review has been updated since the CCA Definition proposing release to account for inflation since 2016.

[130] *See* CCA Definition proposing release, *supra* note 9, at 70768.

[131] CCA Definition proposing release, *supra* note 9, at 70769; *see also* CCA Standards adopting release, *supra* note 6, at 70864–66.

[132] *See, e.g.,* Clearing Agency Standards adopting release, *supra* note 5, at 66263 n.481.

[133] *See* CCA Definition proposing release, *supra* note 9, at 70769.

[134] *See* 44 U.S.C. 3501 *et seq.;* 44 U.S.C. 3502(3).

[135] *See* 44 U.S.C. 3507(a)(1)(D); *see also* 5 CFR 1320.5(a)(1)(iv).

[136] The Commission notes that the policies and procedures required by Rule 17Ad–22(e) would also be used by the Commission as part of its ongoing efforts to monitor and enforce compliance with the federal securities laws through, among other things, examinations and inspections.

[137] *See supra* Parts I and II.

[138] CCA Standards adopting release, *supra* note 6, at 70881–90; CCA Definition proposing release, *supra* note 9, at 70769–83.

security-based swap clearing agencies. The Commission further clarified that 17 CFR 240.17Ad–22(e)(6) (''Rule 17Ad–22(e)(6)'') would only have six respondents because it only applies to CCPs, 17 CFR 240.17Ad–22(e)(11) (''Rule 17Ad–22(e)(11)'') would only have one respondent because it only applies to CSDs, and 17 CFR 240.17Ad–22(e)(14) (''Rule 17Ad–22(e)(14)'') would only have two respondents because it only applies to security-based swap clearing agencies.

Under the amended definition of ''covered clearing agency'' adopted in this document, the Commission estimates that Rule 17Ad–22(e) now applies to seven registered clearing agencies, including six registered clearing agencies that provide CCP services and one registered clearing agency that provides CSD services.[139] The Commission continues to believe that one additional entity might seek to register with the Commission in the next three years.[140] Accordingly, the Commission estimates that a majority of the requirements under Rule 17Ad–22(e) have eight respondents, of which (i) seven are CCPs and one is a CSD, and (ii) three are security-based swap clearing agencies. The Commission also notes that Rule 17Ad–22(e)(6) now has seven respondents because it applies to CCPs, Rule 17Ad–22(e)(11) continues to have one respondent because it only applies to CSDs, and Rule 17Ad–22(e)(14) now has three respondents because it only applies to security-based swap clearing agencies.

The PRA analysis for seven of the eight respondents appears in the CCA Standards adopting release. Below, the Commission provides a PRA analysis for the one additional respondent subject to Rule 17Ad–22(e) under the amended definition of ''covered clearing agency,'' thereby reflecting the incremental annual reporting and recordkeeping burdens resulting from the amended definition. Because the one remaining respondent provides CCP services and does not provide CSD services, the analysis below does not include Rule 17Ad–22(e)(11).[141]

C. Total Annual Reporting and Recordkeeping Burdens

The amendments adopted in this document increase by one the estimated number of respondent clearing agencies for some aspects of Rule 17Ad–22(e), as previously discussed. The amendments do not affect the Commission's rationales and estimates for the annual reporting and recordkeeping burdens under Rule 17Ad–22(e) as set forth in the CCA Standards adopting release.[142] Below, the Commission therefore summarizes the initial and annual burden estimates for each rule that the Commission expects will impose a burden on a new respondent clearing agency subject to Rule 17Ad–22(e) under the amended definition of ''covered clearing agency'' and then provides the corresponding increase in the total burden estimate that results under Rule 17Ad–22(e).

1. Initial and Annual Burden Estimates

For 17 CFR 240.17Ad–22(e)(1), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of eight hours and an annual burden of three hours.[143]

For 17 CFR 240.17Ad–22(e)(2), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 25 hours and an annual burden of five hours.[144]

For 17 CFR 240.17Ad–22(e)(3), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 57 hours and an annual burden of 49 hours.[145]

For 17 CFR 240.17Ad–22(e)(4), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 219 hours and an annual burden of 62 hours.[146]

For 17 CFR 240.17Ad–22(e)(5), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 42 hours and an annual burden of 36 hours.[147]

For Rule 17Ad–22(e)(6), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 180 hours and an annual burden of 60 hours.[148]

For Rule 17Ad–22(e)(7), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 330 hours and an annual burden of 128 hours.[149]

For 17 CFR 240.17Ad–22(e)(8), (9), (10), and (12), the Commission continues to estimate, for each rule, that a respondent clearing agency incurs an initial burden of 12 hours and an annual burden of five hours.[150]

For 17 CFR 240.17Ad–22(e)(13), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 41 hours and an annual burden of seven hours.[151]

[139] The additional respondent clearing agency subject to Rule 17Ad–22(e) under the amended definition of ''covered clearing agency'' was a registered clearing agency subject to Rule 17Ad–22(d).

[140] In 2016, the Commission registered a new security-based swap clearing agency that was not previously a registered clearing agency.

[141] In addition, in the CCA Definition proposing release, the Commission included 17 CFR 240.17Ad–22(c)(1) (''Rule 17Ad–22(c)(1)'') in the PRA discussion. Because the number of respondents for Rule 17Ad–22(c)(1) is unchanged, the analysis below does not include Rule 17Ad–22(c)(1).

[142] *See* CCA Standards adopting release, *supra* note 6, at 70891–99.

[143] These figures were calculated as follows: Assistant General Counsel for 2 hours + Compliance Attorney for 6 hours = 8 hours of initial burden; Compliance Attorney for 3 hours = 3 hours of annual burden.

[144] These figures were calculated as follows: Assistant General Counsel for 14 hours + Compliance Attorney for 11 hours = 25 hours of initial burden; Compliance Attorney for 5 hours = 5 hours of annual burden.

[145] These figures were calculated as follows: Assistant General Counsel for 25 hours + Compliance Attorney for 18 hours + (Senior Risk Management Specialist for 7 hours + Computer Operations Manager for 7 hours = 57 hours of initial burden; Compliance Attorney for 8 hours + Administrative Assistant for 3 hours + Senior Business Analyst for 5 hours + Risk Management Specialist for 33 hours = 49 hours of annual burden.

[146] These figures were calculated as follows: Assistant General Counsel for 74 hours + Compliance Attorney for 45 hours + Senior Risk Management Specialist for 30 hours + Computer Operations Manager for 45 hours + Chief Compliance Officer for 15 hours + Senior Programmer for 10 hours = 219 hours of initial burden; Compliance Attorney for 26 hours + Administrative Assistant for 3 hours + Senior Business Analyst for 3 hours + Risk Management Specialist for 30 hours = 62 hours of annual burden.

The CCA Definition proposing release incorrectly stated the calculations for the initial burden (as 200 hours) and annual burden (as 60 hours). These estimates have been corrected for this release and reflect the PRA estimates that the Commission provided to OMB for this rulemaking.

[147] These figures were calculated as follows: Assistant General Counsel for 16 hours + Compliance Attorney for 12 hours + Senior Risk Management Specialist for 7 hours + Computer Operations Manager for 7 hours = 42 hours of initial burden; Compliance Attorney for 6 hours + Risk Management Specialist for 30 hours = 36 hours of annual burden.

[148] These figures were calculated as follows: Assistant General Counsel for 50 hours + Compliance Attorney for 40 hours + Senior Risk Management Specialist for 25 hours + Computer Operations Manager for 40 hours + Chief Compliance Officer for 15 hours + Senior Programmer for 10 hours = 180 hours of initial burden; Compliance Attorney for 24 hours + Administrative Assistant for 3 hours + Senior Business Analyst for 3 hours + Risk Management Specialist for 30 hours = 60 hours of annual burden.

[149] These figures were calculated as follows: Assistant General Counsel for 95 hours + Compliance Attorney for 85 hours + Senior Risk Management Specialist for 45 hours + Computer Operations Manager for 60 hours + Chief Compliance Officer for 30 hours + Senior Programmer for 15 hours = 330 hours of initial burden; Compliance Attorney for 48 hours + Administrative Assistant for 5 hours + Senior Business Analyst for 5 hours + Risk Management Specialist for 60 hours + Senior Risk Management Specialist for 10 hours = 128 hours of annual burden.

[150] These figures were calculated as follows: Assistant General Counsel for 2 hours + Compliance Attorney for 6 hours + Senior Business Analyst for 2 hours + Computer Operations Manager for 2 hours = 12 hours of initial burden; Compliance Attorney for 5 hours = 5 hours of annual burden.

[151] These figures were calculated as follows: Assistant General Counsel for 6 hours + Compliance

Continued

For Rule 17Ad–22(e)(14), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 36 hours and an annual burden of six hours.[152]

For 17 CFR 240.17Ad–22(e)(15), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 210 hours and an annual burden of 48 hours.[153]

For 17 CFR 240.17Ad–22(e)(16), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 20 hours and an annual burden of six hours.[154]

For 17 CFR 240.17Ad–22(e)(17), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 28 hours and an annual burden of six hours.[155]

For 17 CFR 240.17Ad–22(e)(18), (19), and (20), the Commission continues to estimate, for each rule, that a respondent clearing agency incurs an initial burden of 44 hours and an annual burden of seven hours.[156]

For 17 CFR 240.17Ad–22(e)(21), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 32 hours and an annual burden of 11 hours.[157]

For 17 CFR 240.17Ad–22(e)(22), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 24 hours and an annual burden of five hours.[158]

For 17 CFR 240.17Ad–22(e)(23), the Commission continues to estimate that a respondent clearing agency incurs an initial burden of 138 hours and an annual burden of 34 hours.[159]

2. Total Burden Estimate

For the rules above, the Commission estimates that a respondent clearing agency incurs a total initial burden of 1,570 hours and an annual burden of 507 hours.[160]

D. Collection of Information is Mandatory

The collection of information requirements for the rules above continue to be mandatory.

E. Confidentiality

As required under Rule 17Ad–22(e), the policies and procedures developed pursuant to the rules above would be communicated, as applicable, to the participants of each respondent clearing agency and the public. A respondent clearing agency is also required to preserve such policies and procedures in accordance with, and for the periods specified in, 17 CFR 240.17a–1 and 240.17a–4(e)(7). To the extent that the Commission receives confidential information pursuant to this collection of information, such information would be kept confidential subject to the provisions of applicable law.[161]

V. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (''RFA'') requires the Commission, in promulgating rules, to consider the impact of those rules on small entities.[162] Section 603(a) of the Administrative Procedure Act,[163] as amended by the RFA, generally requires the Commission to undertake a regulatory flexibility analysis of all proposed rules to determine the impact of such rulemaking on ''small entities.'' [164] The Commission certified in the CCA Definition proposing release, pursuant to Section 605(b) of the RFA, that the proposed rules would not, if adopted, have a significant impact on a substantial number of small entities.[165] The Commission received no comments on this certification.

A. Registered Clearing Agencies

The amendments to Rule 17Ad–22 apply to registered clearing agencies that are CCPs and CSDs. For the purposes of Commission rulemaking and as applicable to the amendments to Rule 17Ad–22, a small entity includes, when used with reference to a clearing agency, a clearing agency that (i) compared, cleared, and settled less than $500 million in securities transactions during the preceding fiscal year, (ii) had less than $200 million of funds and securities in its custody or control at all times during the preceding fiscal year (or at any time that it has been in business, if shorter), and (iii) is not affiliated with any person (other than a natural person) that is not a small business or small organization.[166]

Based on the Commission's existing information about the clearing agencies currently registered with the Commission,[167] the Commission

Attorney for 11 hours + Senior Business Analyst for 12 hours + Computer Operations Manager for 12 hours = 41 hours of initial burden; Compliance Attorney for 7 hours = 7 hours of annual burden.

The CCA Definition proposing release incorrectly stated the calculations for the initial burden (as 60 hours) and annual burden (as 9 hours). These estimates have been corrected for this release and reflect the PRA estimates that the Commission provided to OMB for this rulemaking.

[152] These figures were calculated as follows: Assistant General Counsel for 12 hours + Compliance Attorney for 10 hours + Computer Operations Manager for 7 hours + Senior Business Analyst for 7 hours = 36 hours of initial burden; Compliance Attorney for 6 hours = 6 hours of annual burden.

[153] These figures were calculated as follows: Assistant General Counsel for 40 hours + Compliance Attorney for 30 hours + Computer Operations Manager for 10 hours + Senior Business Analyst for 10 hours + Financial Analyst for 70 hours + Chief Financial Officer for 50 hours = 210 hours of initial burden; Compliance Attorney for 42 hours + Administrative Assistant for 3 hours + Senior Business Analyst for 3 hours = 48 hours of annual burden.

[154] These figures were calculated as follows: Assistant General Counsel for 4 hours + Compliance Attorney for 8 hours + Senior Business Analyst for 4 hours + Computer Operations Manager for 4 hours = 20 hours of initial burden; Compliance Attorney for 6 hours = 6 hours of annual burden.

[155] These figures were calculated as follows: Assistant General Counsel for 4 hours + Compliance Attorney for 8 hours + Computer Operations Manager for 6 hours + Senior Business Analyst for 4 hours + Chief Compliance Officer for 4 hours + Senior Programmer for 2 hours = 28 hours of initial burden; Compliance Attorney for 6 hours = 6 hours of annual burden.

[156] These figures were calculated as follows: Assistant General Counsel for 10 hours + Compliance Attorney for 7 hours + Computer Operations Manager for 15 hours + Senior Business Analyst for 5 hours + Chief Compliance Officer for 5 hours + Senior Programmer for 2 hours = 44 hours of initial burden; Compliance Attorney for 7 hours = 7 hours of annual burden.

[157] These figures were calculated as follows: Assistant General Counsel for 10 hours + Compliance Attorney for 7 hours + Computer Operations Manager for 10 hours + Senior Business Analyst for 5 hours = 32 hours of initial burden; Compliance Attorney for 5 hours + Administrative Assistant for 3 hours + Senior Business Analyst for 3 hours = 11 hours of annual burden.

[158] These figures were calculated as follows: Assistant General Counsel for 2 hours + Compliance Attorney for 6 hours + Computer Operations Manager for 7 hours + Senior Business Analyst for 2 hours + Chief Compliance Officer for 5 hours + Senior Programmer for 2 hours = 24 hours of initial burden; Compliance Attorney for 5 hours = 5 hours of annual burden.

[159] These figures were calculated as follows: Assistant General Counsel for 38 hours + Compliance Attorney for 24 hours + Computer Operations Manager for 32 hours + Senior Business Analyst for 18 hours + Chief Compliance Officer for 18 hours + Senior Programmer for 8 hours = 138 hours of initial burden; Compliance Attorney for 34 hours = 34 hours of annual burden.

[160] The Commission notes that these estimates are slightly higher than those stated in the CCA Definition proposing release after correcting for the errors previously noted above. *See supra* notes 146 and 151.

[161] *See, e.g.,* 5 U.S.C. 552. Exemption 4 of the Freedom of Information Act provides an exemption for trade secrets and commercial or financial information obtained from a person and privileged or confidential. *See* 5 U.S.C. 552(b)(4). Exemption 8 of the Freedom of Information Act provides an exemption for matters that are contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions. *See* 5 U.S.C. 552(b)(8).

[162] *See* 5 U.S.C. 601 *et seq.*

[163] 5 U.S.C. 603(a).

[164] Section 601(b) of the RFA permits agencies to formulate their own definitions of ''small entities.'' *See* 5 U.S.C. 601(b). The Commission has adopted definitions for the term ''small entity'' for the purposes of rulemaking in accordance with the RFA. These definitions, as relevant to this rulemaking, are set forth in 17 CFR 240.0–10.

[165] *See* 5 U.S.C. 605(b).

[166] *See* 17 CFR 240.0–10(d).

[167] In 2018, DTCC processed $1.854 quadrillion in financial transactions. Within DTCC, DTC settled $122.6 trillion of securities and held securities valued at $52.2 trillion, NSCC processed an average daily value of $1269.7 billion in equity securities,

believes that all such registered clearing agencies exceed the thresholds defining ''small entities'' set out above. While other clearing agencies may emerge and seek to register as clearing agencies with the Commission, the Commission does not believe that any such entities would be ''small entities'' as defined in 17 CFR 240.0–10(d).[168] Accordingly, the Commission believes that any such registered clearing agencies will exceed the thresholds for ''small entities'' set forth in in 17 CFR 240.0–10.

B. Certification

For the reasons described above, the Commission certifies that the amendments to Rule 17Ad–22 will not have a significant economic impact on a substantial number of small entities.

VI. Other Matters

If any of the provisions of these rules, or the application thereof to any person or circumstance, is held to be invalid, such invalidity shall not affect other provisions or application of such provisions to other persons or circumstances that can be given effect without the invalid provision or application.

Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs has designated these rules as not a major rule, as defined by 5 U.S.C. 804(2).

VII. Statutory Authority

Pursuant to the Exchange Act, particularly Section 17A thereof, 15 U.S.C. 78q–1, and Section 805 of the Clearing Supervision Act, 12 U.S.C. 5464, the Commission is adopting amendments to Rule 17Ad–22.

and FICC cleared $1.165 quadrillion of transactions in government securities and $58.7 trillion of transactions in agency mortgage-backed securities. DTCC, 2018 Annual Report, *http://www.dtcc.com/annuals/2018/#/financial-performance.* OCC cleared more than 5.2 billion contracts and held margin of $111.8 billion at the end of 2018. OCC, 2018 Annual Report, *https://www.theocc.com/components/docs/about/annual-reports/occ-2018-annual-report.pdf.* In addition, Intercontinental Exchange (''ICE'') averaged daily trade volume of over 6.2 million and revenues of $5 billion in 2018. *See* ICE at a glance, *https://www.theice.com/publicdocs/ICE_at_a_glance.pdf.* LCH SA cleared €612 billion in 2018 with clearing fee revenue of €19.9 million. LCH SA, 2018 Financial Statements, *https://www.lch.com/system/files/media_root/LCH%20Group%20Holdings%20Limited%20-%202018%20%20Financial%20Statements.pdf.*

[168] The Commission based this determination on its review of public sources of financial information about registered clearing agencies. In addition, Parts III (Economic Analysis) and IV (Paperwork Reduction Act) above discuss, among other things, the economic impact, including the estimated compliance costs and burdens, of the amended definition.

List of Subjects in 17 CFR Part 240

Reporting and recordkeeping requirements, Securities.

Text of Amendment

In accordance with the foregoing, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78*l,* 78m, 78n, 78n–1, 78*o,* 78*o*–4, 78*o*–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78*ll,* 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, and 7201 *et. seq.,* and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; Pub. L. 111–203, 939A, 124 Stat. 1376 (2010); and Pub. L. 112–106, sec. 503 and 602, 126 Stat. 326 (2012), unless otherwise noted.

* * * * *

Section 240.17Ad–22 is also issued under 12 U.S.C. 5461 *et seq.*

* * * * *

■ 2. Amend § 240.17Ad–22 by revising paragraphs (a)(3), (5), and (16) to read as follows:

§ 240.17Ad–22 Standards for clearing agencies.

(a) * * *

(3) *Central securities depository* means a clearing agency that is a securities depository as described in Section 3(a)(23)(A) of the Act (15 U.S.C. 78c(a)(23)(A)).

* * * * *

(5) *Covered clearing agency* means a registered clearing agency that provides the services of a central counterparty or central securities depository.

* * * * *

(16) *Sensitivity analysis* means an analysis that involves analyzing the sensitivity of a model to its assumptions, parameters, and inputs that:

(i) Considers the impact on the model of both moderate and extreme changes in a wide range of inputs, parameters, and assumptions, including correlations of price movements or returns if relevant, which reflect a variety of historical and hypothetical market conditions;

(ii) Uses actual portfolios and, where applicable, hypothetical portfolios that reflect the characteristics of proprietary positions and customer positions;

(iii) Considers the most volatile relevant periods, where practical, that have been experienced by the markets served by the clearing agency; and

(iv) Tests the sensitivity of the model to stressed market conditions, including the market conditions that may ensue after the default of a member and other extreme but plausible conditions as defined in a covered clearing agency's risk policies.

* * * * *

By the Commission.

Dated: April 9, 2020.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2020–07905 Filed 5–13–20; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9897]

RIN 1545–BN68

The Treatment of Certain Interests in Corporations as Stock or Indebtedness

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations regarding the treatment of certain interests in corporations as stock or indebtedness. The final regulations generally affect corporations, including those that are partners of certain partnerships, when those corporations or partnerships issue purported indebtedness to related corporations or partnerships.

DATES:

Effective date: These regulations are effective on May 14, 2020.

Applicability dates: For dates of applicability, see §§ 1.385–3(j)(1) and (k) and 1.385–4(g).

FOR FURTHER INFORMATION CONTACT: Azeka J. Abramoff or D. Peter Merkel of the Office of Associate Chief Counsel (International) at (202) 317–6938 or Jeremy Aron-Dine of the Office of Associate Chief Counsel (Corporate) at (202) 317–6848 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

I. Overview

Section 385 authorizes the Secretary of the Treasury (Secretary) to prescribe rules to determine whether an interest in a corporation is treated as stock or indebtedness (or as in part stock and in

part indebtedness). On October 21, 2016, the Treasury Department and the IRS published T.D. 9790 in the **Federal Register** (81 FR 72858), which included final regulations under section 385 and temporary regulations under section 385 (2016 Final Regulations and Temporary Regulations, respectively, and together, the 2016 Regulations). On the same date, the Treasury Department and the IRS also published a notice of proposed rulemaking (REG–130314–16) in the **Federal Register** (81 FR 72751) (2016 Proposed Regulations) by cross-reference to the Temporary Regulations, which included §§ 1.385–3T and 1.385–4T. Technical corrections to the 2016 Regulations were published in the **Federal Register** (82 FR 8169) on January 24, 2017.

The 2016 Regulations and the 2016 Proposed Regulations address the classification of certain related-party debt as stock or indebtedness (or as in part stock and in part indebtedness) for U.S. Federal income tax purposes. The 2016 Final Regulations included documentation rules set forth in § 1.385–2 (the Documentation Regulations). The 2016 Regulations also included §§ 1.385–3, 1.385–3T, and 1.385–4T, which treat certain indebtedness as stock that is issued by a corporation to a controlling shareholder in a distribution or in another related-party transaction that achieves an economically similar result (the Distribution Regulations). The Distribution Regulations apply to taxable years ending on or after January 19, 2017.

The Temporary Regulations set forth rules regarding the treatment under the Distribution Regulations of certain qualified short-term debt instruments, transactions involving controlled partnerships, and transactions involving consolidated groups. The Temporary Regulations apply to taxable years ending on or after January 19, 2017. The Temporary Regulations expired on October 13, 2019. *See* section 7805(e); § 1.385–3T(l); § 1.385–4T(h).

The 2016 Proposed Regulations are proposed to apply to taxable years ending on or after January 19, 2017. The preamble to the 2016 Regulations requested comments on all aspects of the Temporary Regulations, and the preamble to the 2016 Proposed Regulations requested comments on all aspects of the 2016 Proposed Regulations. REG–130314–16, 81 FR 72751, 72858 (October 21, 2016). The preamble to the 2016 Regulations also requested comments on certain aspects of the exception for qualified short-term debt instruments.

On October 28, 2019, the Treasury Department and the IRS issued Notice 2019–58, 2019–44 I.R.B. 1022, which announced that, following the expiration of the Temporary Regulations, a taxpayer may rely on the 2016 Proposed Regulations until further notice is given in the **Federal Register**, provided that the taxpayer consistently applies the rules in the 2016 Proposed Regulations in their entirety. On November 4, 2019, the Treasury Department and the IRS published an advance notice of proposed rulemaking in the **Federal Register** (84 FR 59318) (the ANPRM), which announced that the Treasury Department and the IRS intend to propose more streamlined and targeted Distribution Regulations. The ANPRM also obsoleted Notice 2019–58 and announced that a taxpayer may rely on the 2016 Proposed Regulations until further notice is given in the **Federal Register**, provided that the taxpayer consistently applies the rules in the 2016 Proposed Regulations in their entirety. This Treasury decision finalizes the 2016 Proposed Regulations without any substantive change (the 2020 Final Regulations).

II. Executive Order 13789

Executive Order 13789 (E.O. 13789), issued on April 21, 2017, instructed the Secretary to review all significant tax regulations issued on or after January 1, 2016, and to take concrete action to alleviate the burdens of regulations that (i) impose an undue financial burden on U.S. taxpayers; (ii) add undue complexity to the Federal tax laws; or (iii) exceed the statutory authority of the IRS. E.O. 13789 further instructed the Secretary to submit to the President within 60 days a report (First Report) that identifies regulations that meet these criteria. The First Report, Notice 2017–38, 2017–30 I.R.B. 147, which was published on July 24, 2017, included the 2016 Regulations in a list of eight regulations identified by the Secretary in the First Report as meeting at least one of the first two criteria specified in E.O. 13789.

E.O. 13789 further instructed the Secretary to submit to the President a report (Second Report) that recommended specific actions to mitigate the burden imposed by regulations identified in the First Report. On October 16, 2017, the Secretary published in the **Federal Register** the Second Report (82 FR 48013), which stated that (i) the Treasury Department and the IRS were considering a proposal to revoke the Documentation Regulations as issued and (ii) the Treasury Department will reassess the distribution regulations in light of impending tax reform, and the Treasury Department and the IRS may then propose more streamlined and targeted regulations. On September 24, 2018, the Treasury Department and the IRS published proposed regulations in the **Federal Register** that proposed removal of the Documentation Regulations from the Code of Federal Regulations. *See* 83 FR 48265 (September 24, 2018) (2018 Proposed Regulations). On November 4, 2019, the Treasury Department and the IRS published T.D. 9880 in the **Federal Register** (84 FR 59297), which finalized without change the proposed regulations removing the Documentation Regulations.

In response to E.O. 13789 and the 2018 Proposed Regulations, several comments recommended that the Treasury Department and the IRS revoke the Distribution Regulations in addition to the Documentation Regulations, while one comment recommended that the Treasury Department and the IRS issue more streamlined and targeted Distribution Regulations. The ANPRM stated that the Treasury Department and the IRS are cognizant that a complete withdrawal of the Distribution Regulations could restore incentives for multinational corporations to generate additional interest deductions without new investment. Accordingly, the Treasury Department and the IRS determined that the Distribution Regulations continue to be necessary at this time. The ANPRM also announced that the Treasury Department and the IRS intend to propose more streamlined and targeted Distribution Regulations.

The 2016 Proposed Regulations cross-reference the Temporary Regulations, a part of the Distribution Regulations, which expired on October 13, 2019. Because of the general determination that the Distribution Regulations continue to be necessary at this time, the Treasury Department and the IRS are issuing the 2020 Final Regulations, which finalize the 2016 Proposed Regulations, while the Treasury Department and the IRS study the appropriate approach to revising the Distribution Regulations, as discussed in the ANPRM.

III. The Distribution Regulations

Under the Distribution Regulations' general rule, the issuance of a debt instrument by a member of an expanded group to another member of the same expanded group in a distribution, or an economically similar acquisition transaction, may result in the treatment of the debt instrument as stock. *See* § 1.385–3(b)(2). The Distribution Regulations also include a funding rule

that treats as stock a debt instrument that is issued as part of a series of transactions that achieves a result similar to a general rule transaction. *See* § 1.385–3(b)(3)(i). Specifically, § 1.385–3(b) treats as stock a debt instrument that was issued in exchange for property, including cash, to fund a distribution to an expanded group member or another acquisition transaction that achieves an economically similar result. *Id.* Furthermore, the Distribution Regulations include a per se rule, which treats a debt instrument as funding a distribution to an expanded group member or other acquisition transaction with a similar economic effect if it was issued in exchange for property during the period beginning 36 months before and ending 36 months after the issuer of the debt instrument made the distribution or undertook an acquisition transaction with a similar economic effect. *See* § 1.385–3(b)(3)(iii). The Distribution Regulations also include several exceptions limiting their scope. *See, e.g.,* § 1.385–3(c).

The Distribution Regulations generally apply to transactions among members of an expanded group of corporations, which is generally defined by reference to the term ''affiliated group'' in section 1504(a), with several modifications, such as including foreign corporations in the expanded group. *See* § 1.385–1(c)(4). The Distribution Regulations also generally apply only to ''covered debt instruments'' that are issued by ''covered members'' other than certain regulated financial companies and regulated insurance companies. *See* § 1.385–3(g)(3)(i). A covered member is a member of an expanded group that is a domestic corporation. *See* § 1.385–1(c)(2). A covered debt instrument is generally a debt instrument that is issued after April 4, 2016, other than certain excluded specialized debt instruments. *See* § 1.385–3(g)(3). In addition to these scope limitations, the funding rule also excludes qualified short-term debt instruments, as defined in § 1.385–3(b)(3)(vii). *See* § 1.385–3(b)(3)(i).

Summary of Comments

The Treasury Department and the IRS have not received any comments specifically in response to the Temporary Regulations or the 2016 Proposed Regulations. Accordingly, the 2016 Proposed Regulations are adopted as final regulations without any substantive change. In addition, the Temporary Regulations are withdrawn. Comments on the 2016 Regulations that are not specific to the particular matters addressed in the Temporary Regulations or the 2016 Proposed Regulations are beyond the scope of this rulemaking and are not addressed in this preamble.

Pursuant to E.O. 13789 and the ANPRM, the Treasury Department and the IRS intend to issue proposed regulations modifying the Distribution Regulations to make them more streamlined and targeted, including by withdrawing the per se rule. In connection with the intended revisions, the Treasury Department and the IRS continue to study all appropriate modifications to the Distribution Regulations.

Applicability Dates

The amendments to § 1.385–3, other than § 1.385–3(f)(4)(iii), apply to taxable years ending after January 19, 2017. Sections 1.385–3(f)(4)(iii) and 1.385–4 provide rules applicable to members of consolidated groups and are issued under section 1502. Section 1503(a) provides in general, that in any case in which a consolidated return is made or is required to be made, the tax shall be determined, computed, assessed, collected, and adjusted in accordance with the regulations under section 1502 prescribed before the last day prescribed by law for the filing of such return. Thus, §§ 1.385–3(f)(4)(iii) and 1.385–4 apply to taxable years for which the U.S. Federal income tax return is due, without extensions, after May 14, 2020.

The Temporary Regulations apply to taxable years ending on or after January 19, 2017, and before their expiration on October 13, 2019. For rules applying §§ 1.385–3T(f)(4)(iii) and 1.385–4T to taxable years ending on or after January 19, 2017 and for which the U.S. Federal income tax return was due, without extensions, on or before May 14, 2020, see §§ 1.385–3T and 1.385–4T (as contained in 26 CFR in part 1 revised as of April 1, 2019). The provisions in the Temporary Regulations and the corresponding provisions in the 2020 Final Regulations are substantially identical.

For certain taxable years for which the U.S. Federal income tax return was due, without extensions, on or before May 14, 2020, there may be a period after October 13, 2019, to which neither §§ 1.385–3T(f)(4)(iii) and 1.385–4T nor §§ 1.385–3(f)(4)(iii) and 1.385–4 apply. The 2020 Final Regulations allow a taxpayer to choose to apply §§ 1.385–3(f)(4)(iii), 1.385–4, or both to such period, provided that all members of the expanded group apply that section or sections. Accordingly, a taxpayer can choose to apply the 2020 Final Regulations to the period, if any, to which neither the Temporary Regulations nor the 2020 Final Regulations apply.

Special Analyses

I. Regulatory Planning and Review—Economic Analysis

These regulations are not subject to review under section 6(b) of Executive Order 12866 pursuant to the Memorandum of Agreement (April 11, 2018) between the Treasury Department and the Office of Management and Budget regarding review of tax regulations.

II. Paperwork Reduction Act

These regulations do not establish a new collection of information nor modify an existing collection that requires the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

III. Regulatory Flexibility Act

Pursuant to the Regulatory Flexibility Act (5 U.S.C. Chapter 6), it is hereby certified that the 2020 Final Regulations will not have a significant economic impact on a substantial number of small entities.

Section 1.385–3 provides that certain interests in a corporation that are held by a member of the corporation's expanded group and that otherwise would be treated as indebtedness for Federal tax purposes are treated as stock. The regulations under Section 1.385–3 finalized in the 2020 Final Regulations provide that for certain debt instruments issued by a controlled partnership, the holder is deemed to transfer all or a portion of the debt instrument to the partner or partners in the partnership in exchange for stock in the partner or partners. Section 1.385–4 provides rules regarding the application of § 1.385–3 to members of a consolidated group. Section 1.385–3 includes multiple exceptions that limit its application. In particular, the threshold exception provides that the first $50 million of expanded group debt instruments that otherwise would be reclassified as stock or deemed to be transferred to a partner in a controlled partnership under § 1.385–3 will not be reclassified or deemed transferred under § 1.385–3. Although it is possible that the classification rules in the 2020 Final Regulations could have an effect on small entities, the threshold exception of the first $50 million of debt instruments otherwise subject to recharacterization or deemed transfer under §§ 1.385–3 and 1.385–4 makes it unlikely that a substantial number of

small entities will be affected by these provisions.

Pursuant to section 7805(f) of the Code, the proposed regulations preceding these final regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business. No comments were received concerning the economic impact on small entities from the Small Business Administration.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a state, local, or tribal government, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. This rule does not include any Federal mandate that may result in expenditures by state, local, or tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

Executive Order 13132 (entitled ''Federalism'') prohibits an agency from publishing any rule that has federalism implications if the rule either imposes substantial, direct compliance costs on state and local governments, and is not required by statute, or preempts state law, unless the agency meets the consultation and funding requirements of section 6 of the Executive order. This final rule does not have federalism implications and does not impose substantial direct compliance costs on state and local governments or preempt state law within the meaning of the Executive order.

Statement of Availability of IRS Documents

IRS Notices and other guidance cited in this preamble are published in the Internal Revenue Bulletin and are available from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402, or by visiting the IRS website at *http://www/irs.gov.*

Drafting Information

The principal authors of these final regulations are Azeka J. Abramoff and D. Peter Merkel of the Office of Associate Chief Counsel (International). However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the entries for §§ 1.385–3T and 1.385–4T and adding an entry for § 1.385–4 in numerical order to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

* * * * *

Section 1.385–4 also issued under 26 U.S.C. 385 and 1502.

* * * * *

§ 1.385–1 [Amended]

■ **Par. 2.** Section 1.385–1 is amended by:

■ 1. In paragraph (c)(4)(vii), designating *Examples 1* through *4* as paragraphs (c)(4)(vii)(A) through (D), respectively.

■ 2. In newly designated paragraphs (c)(4)(vii)(A) through (D), redesignating the paragraphs in the first column as the paragraphs in the second column:

Old paragraphs	New paragraphs
(c)(4)(vii)(A)(i) and (ii)	(c)(4)(vii)(A)(*1*) and (*2*).
(c)(4)(vii)(B)(i) and (ii)	(c)(4)(vii)(B)(*1*) and (*2*).
(c)(4)(vii)(C)(i) and (ii)	(c)(4)(vii)(C)(*1*) and (*2*).
(c)(4)(vii)(D)(i) and (ii)	(c)(4)(vii)(D)(*1*) and (*2*).

■ 3. Revise the last sentence of newly redesignated paragraph (c)(4)(vii)(B)(*1*).

■ 4. In newly designated paragraphs (c)(4)(vii)(C)(*2*) and (c)(4)(vii)(D)(*2*), redesignating the paragraphs in the first column as the paragraphs in the second column:

Old paragraphs	New paragraphs
(c)(4)(vii)(C)(*2*)(A) and (B).	(c)(4)(vii)(C)(*2*)(*i*) and (*ii*).
(c)(4)(vii)(D)(*2*)(A) through (C).	(c)(4)(vii)(D)(*2*)(*i*) through (*iii*).

■ 5. For each paragraph listed in the table, remove the language in the ''Remove'' column wherever it appears and add in its place the language in the ''Add'' column as set forth below:

Paragraph	Remove	Add
(a)	1.385–4T	1.385–4.
(c) introductory text	1.385–4T(e)	1.385–4(e).
(c)(4)(i) introductory text	corporations described in section 1504(b)(8)	S corporations.
(c)(4)(i) introductory text	not described in section 1504(b)(6) or (b)(8) (an expanded group parent).	that is not an S corporation or a regulated investment company or a real estate investment trust subject to tax under subchapter M of chapter 1 of the Internal Revenue Code (a RIC or a REIT, respectively) (such common parent corporation, an expanded group parent).
(c)(4)(vii) introductory text	described in section 1504(b)(6) or (b)(8)	an S corporation, a RIC, or a REIT.
(c)(4)(vii)(B)(*2*)	P is a real estate investment trust described in section 1504(b)(6).	P is a REIT.
(c)(4)(vii)(B)(*2*)	Although S2 is a corporation described in section 1504(b)(6), a corporation described in section 1504(b)(6) may.	Although S2 is a corporation that is a REIT, a REIT may.
(c)(4)(vii)(D)(*1*)	*Example 3*	paragraph (c)(4)(vii)(C)(*1*) of this section (*Example 3*).
(d)(1)(iv)(A)	1.385–3T(d)(4)	1.385–3(d)(4).
(d)(1)(iv)(B)	1.385–3T(f)(4)	1.385–3(f)(4).

The revision reads as follows:

§ 1.385–1 General provisions.

* * * * *

(c) * * *

(4) * * *

(vii) * * *

(B) * * *

(*1*) * * * Both P and S2 are REITs.

* * * * *

■ **Par. 3.** Section 1.385–3 is amended by:

■ 1. Revising the section heading.

■ 2. For each paragraph listed in the table, remove the language in the ''Remove'' column wherever it appears and add in its place the language in the ''Add'' column as set forth below:

Paragraph	Remove	Add
(a)	1.385–4T	1.385–4.
(b)(4) introductory text	1.385–3T	1.385–3.
(b)(4)(i) introductory text	1.385–3T	1.385–3.
(b)(4)(i)(E)	1.385–3T(k)(2)	1.385–3(k)(2).
(b)(4)(ii) introductory text	1.385–3T	1.385–3.
(b)(4)(ii)(D)	1.385–4T	1.385–4.
(c)(1)	1.385–3T(f)	1.385–3(f).
(c)(2)(i)(C)	1.385–3T	1.385–3.
(c)(2)(iv)	1.385–3T(f)(2)	1.385–3(f)(2).
(c)(2)(v)(B)	1.385–3T(d)(4)	1.385–3(d)(4).
(c)(2)(v)(C)	1.385–3T(f)(4) or (5)	1.385–3(f)(4) or (5).
(c)(3)(i)(C)(*4*)	1.385–3T(f)(4)(i)	1.385–3(f)(4)(i).
(c)(3)(ii)(D)(*6*)	1.385–3T	1.385–3.
(d)(2)(ii)(A)	1.385–4T(c)(2)	1.385–4(c)(2).
(d)(2)(ii)(B)	1.385–3T(f)(5)(i)	1.385–3(f)(5)(i).
(d)(7)(ii)	1.385–3T(d)(4)	1.385–3(d)(4).
(g) introductory text	1.385–3T and 1.385–4T	1.385–3 and 1.385–4.
(g)(3)(iii)(D)	1.385–3T	1.385–3.
(j)(2)(i)	1.385–1, 1.385–3T, and 1.385–4T	1.385–1, 1.385–3, and 1.385–4.
(j)(2)(ii)	1.385–1, 1.385–3T, and 1.385–4T	1.385–1, 1.385–3, and 1.385–4.
(j)(2)(v)	1.385–1, 1.385–3, 1.385–3T, and 1.385–4T	1.385–1, 1.385–3, and 1.385–4.

■ 3. Revising paragraphs (b)(3)(vii), (d)(4), (f), and (g)(5) through (8), (15) through (17), (22), and (23).

■ 4. In paragraph (h)(3), designating *Examples 1* through *19* as paragraphs (h)(3)(i) through (xix), respectively.

■ 5. In newly designated paragraphs (h)(3)(i) through (xi), redesignating the paragraphs in the first column as the paragraphs in the second column:

Old paragraphs	New paragraphs
(h)(3)(i)(i) and (ii)	(h)(3)(i)(A) and (B).
(h)(3)(ii)(i) and (ii)	(h)(3)(ii)(A) and (B).
(h)(3)(iii)(i) and (ii)	(h)(3)(iii)(A) and (B).
(h)(3)(iv)(i) and (ii)	(h)(3)(iv)(A) and (B).
(h)(3)(v)(i) and (ii)	(h)(3)(v)(A) and (B).
(h)(3)(vi)(i) and (ii)	(h)(3)(vi)(A) and (B).
(h)(3)(vii)(i) and (ii)	(h)(3)(vii)(A) and (B).
(h)(3)(viii)(i) and (ii)	(h)(3)(viii)(A) and (B).
(h)(3)(ix)(i) and (ii)	(h)(3)(ix)(A) and (B).
(h)(3)(x)(i) and (ii)	(h)(3)(x)(A) and (B).
(h)(3)(xi)(i) and (ii)	(h)(3)(xi)(A) and (B).

■ 6. In newly designated paragraphs (h)(3)(ii)(B), (h)(3)(iii)(B), (h)(3)(vi)(B), (h)(3)(vii)(B), (h)(3)(viii)(B), (h)(3)(ix)(B), and (h)(3)(x)(B), redesignating the paragraphs in the first column as the paragraphs in the second column:

Old paragraphs	New paragraphs
(h)(3)(ii)(B)(A) and (B)	(h)(3)(ii)(B)(*1*) and (*2*).
(h)(3)(iii)(B)(A) and (B)	(h)(3)(iii)(B)(*1*) and (*2*).
(h)(3)(vi)(B)(A) and (B)	(h)(3)(vi)(B)(*1*) and (*2*).
(h)(3)(vii)(B)(A) and (B)	(h)(3)(vii)(B)(*1*) and (*2*).
(h)(3)(viii)(B)(A) though (F).	(h)(3)(viii)(B)(*1*) though (*6*).
(h)(3)(ix)(B)(A) and (B)	(h)(3)(ix)(B)(*1*) and (*2*).
(h)(3)(x)(B)(A) though (C)	(h)(3)(x)(B)(*1*) through (*3*).

■ 7. For each newly designated paragraph listed in the table, remove the language in the ''Remove'' column wherever it appears and add in its place the language in the ''Add'' column as set forth below:

Paragraph	Remove	Add
(h)(3)(v)(A)	*Example 4* of this paragraph (h)(3)	paragraph (h)(3)(iv)(A) of this section (*Example 4*).
(h)(3)(v)(B)	*Example 4* of this paragraph (h)(3)	paragraph (h)(3)(iv)(B) of this section (*Example 4*).
(h)(3)(vii)(A)	*Example 6* of this paragraph (h)(3)	paragraph (h)(3)(vi)(A) of this section (*Example 6*).

■ 8. Revising newly designated paragraphs (h)(3)(xii) through (xix) and paragraph (j)(1).

■ 9. Adding paragraphs (j)(3) and (k).

The revisions and additions read as follows:

§ 1.385–3 Certain distributions of debt instruments and similar transactions.

* * * * *

(b) * * *

(3) * * *

(vii) *Qualified short-term debt instrument.* The term qualified short-term debt instrument means a covered debt instrument that is described in paragraphs (b)(3)(vii)(A) though (D) of this section.

(A) *Short-term funding arrangement.* A covered debt instrument is described in this paragraph (b)(3)(vii)(A) if the requirements of the specified current assets test described in paragraph (b)(3)(vii)(A)(*1*) of this section or the 270-day test described in paragraph (b)(3)(vii)(A)(*2*) of this section (the alternative tests) are satisfied, provided that an issuer may only claim the benefit of one of the alternative tests with respect to covered debt instruments issued by the issuer in the same taxable year.

(*1*) *Specified current assets test*—(*i*) *In general.* The requirements of this paragraph (b)(3)(vii)(A)(*1*) are satisfied with respect to a covered debt instrument if the requirement of paragraph (b)(3)(vii)(A)(*1*)(*ii*) of this section is satisfied, but only to the extent the requirement of paragraph (b)(3)(vii)(A)(*1*)(*iii*) of this section is satisfied.

(*ii*) *Maximum interest rate.* The rate of interest charged with respect to the covered debt instrument does not exceed an arm's length interest rate, as determined under section 482 and §§ 1.482–1 through 1.482–9, that would be charged with respect to a comparable

debt instrument of the issuer with a term that does not exceed the longer of 90 days and the issuer's normal operating cycle.

(*iii*) *Maximum outstanding balance.* The amount owed by the issuer under covered debt instruments issued to members of the issuer's expanded group that satisfy the requirements of paragraph (b)(3)(vii)(A)(*1*)(*ii*), (b)(3)(vii)(A)(*2*) (if the covered debt instrument was issued in a prior taxable year), or (b)(3)(vii)(B) or (C) of this section immediately after the covered debt instrument is issued does not exceed the maximum of the amounts of specified current assets reasonably expected to be reflected, under applicable accounting principles, on the issuer's balance sheet as a result of transactions in the ordinary course of business during the subsequent 90–day period or the issuer's normal operating cycle, whichever is longer. For purposes of the preceding sentence, in the case of an issuer that is a qualified cash pool header, the amount owed by the issuer shall not take into account deposits described in paragraph (b)(3)(vii)(D) of this section. Additionally, the amount owed by any issuer shall be reduced by the amount of the issuer's deposits with a qualified cash pool header, but only to the extent of amounts borrowed from the same qualified cash pool header that satisfy the requirements of paragraph (b)(3)(vii)(A)(*2*) (if the covered debt instrument was issued in a prior taxable year) or (b)(3)(vii)(A)(*1*)(*ii*) of this section.

(*iv*) *Specified current assets.* For purposes of paragraph (b)(3)(vii)(A)(*1*)(*iii*) of this section, the term *specified current assets* means assets that are reasonably expected to be realized in cash or sold (including by being incorporated into inventory that is sold) during the normal operating cycle of the issuer, other than cash, cash equivalents, and assets that are reflected on the books and records of a qualified cash pool header.

(*v*) *Normal operating cycle.* For purposes of paragraph (b)(3)(vii)(A)(*1*) of this section, the term *normal operating cycle* means the issuer's normal operating cycle as determined under applicable accounting principles, except that if the issuer has no single clearly defined normal operating cycle, then the normal operating cycle is determined based on a reasonable analysis of the length of the operating cycles of the multiple businesses and their sizes relative to the overall size of the issuer.

(*vi*) *Applicable accounting principles.* For purposes of paragraph (b)(3)(vii)(A)(*1*) of this section, the term *applicable accounting principles* means the financial accounting principles generally accepted in the United States, or an international financial accounting standard, that is applicable to the issuer in preparing its financial statements, computed on a consistent basis.

(*2*) *270-day test*—(*i*) *In general.* A covered debt instrument is described in this paragraph (b)(3)(vii)(A)(*2*) if the requirements of paragraphs (b)(3)(vii)(A)(*2*)(*ii*) through (*iv*) of this section are satisfied.

(*ii*) *Maximum term and interest rate.* The covered debt instrument must have a term of 270 days or less or be an advance under a revolving credit agreement or similar arrangement and must bear a rate of interest that does not exceed an arm's length interest rate, as determined under section 482 and §§ 1.482–1 through 1.482–9, that would be charged with respect to a comparable debt instrument of the issuer with a term that does not exceed 270 days.

(*iii*) *Lender-specific indebtedness limit.* The issuer is a net borrower from the lender for no more than 270 days during the taxable year of the issuer, and in the case of a covered debt instrument outstanding during consecutive tax years, the issuer is a net borrower from the lender for no more than 270 consecutive days, in both cases taking into account only covered debt instruments that satisfy the requirement of paragraph (b)(3)(vii)(A)(*2*)(*ii*) of this section other than covered debt instruments described in paragraph (b)(3)(vii)(B) or (C) of this section.

(*iv*) *Overall indebtedness limit.* The issuer is a net borrower under all covered debt instruments issued to members of the issuer's expanded group that satisfy the requirements of paragraphs (b)(3)(vii)(A)(*2*)(*ii*) and (*iii*) of this section, other than covered debt instruments described in paragraph (b)(3)(vii)(B) or (C) of this section, for no more than 270 days during the taxable year of the issuer, determined without regard to the identity of the lender under such covered debt instruments.

(*v*) *Inadvertent error.* An issuer's failure to satisfy the 270-day test will be disregarded if the failure is reasonable in light of all the facts and circumstances and the failure is promptly cured upon discovery. A failure to satisfy the 270-day test will be considered reasonable if the taxpayer maintains due diligence procedures to prevent such failures, as evidenced by having written policies and operational procedures in place to monitor compliance with the 270-day test and management-level employees of the expanded group having undertaken reasonable efforts to establish, follow, and enforce such policies and procedures.

(B) *Ordinary course loans.* A covered debt instrument is described in this paragraph (b)(3)(vii)(B) if the covered debt instrument is issued as consideration for the acquisition of property other than money in the ordinary course of the issuer's trade or business, provided that the obligation is reasonably expected to be repaid within 120 days of issuance.

(C) *Interest-free loans.* A covered debt instrument is described in this paragraph (b)(3)(vii)(C) if the instrument does not provide for stated interest or no interest is charged on the instrument, the instrument does not have original issue discount (as defined in section 1273 and §§ 1.1273–1 and 1.1273–2), interest is not imputed under section 483 or section 7872 and §§ 1.483–1 through 1.483–4 or §§ 1.7872–1 through 1.7872–16, respectively, and interest is not required to be charged under section 482 and §§ 1.482–1 through 1.482–9.

(D) *Deposits with a qualified cash pool header*—(*1*) *In general.* A covered debt instrument is described in this paragraph (b)(3)(vii)(D) if it is a demand deposit received by a qualified cash pool header described in paragraph (b)(3)(vii)(D)(*2*) of this section pursuant to a cash-management arrangement described in paragraph (b)(3)(vii)(D)(*3*) of this section. This paragraph (b)(3)(vii)(D) does not apply if a purpose for making the demand deposit is to facilitate the avoidance of the purposes of this section with respect to a qualified business unit (as defined in section 989(a) and § 1.989(a)-1) (QBU) that is not a qualified cash pool header.

(*2*) *Qualified cash pool header.* The term *qualified cash pool header* means an expanded group member, controlled partnership, or QBU described in § 1.989(a)-1(b)(2)(ii), that has as its principal purpose managing a cash-management arrangement for participating expanded group members, provided that the excess (if any) of funds on deposit with such expanded group member, controlled partnership, or QBU (header) over the outstanding balance of loans made by the header is maintained on the books and records of the header in the form of cash or cash equivalents, or invested through deposits with, or the acquisition of obligations or portfolio securities of, persons that do not have a relationship to the header (or, in the case of a header that is a QBU described in § 1.989(a)-1(b)(2)(ii), its owner) described in section 267(b) or section 707(b).

(*3*) *Cash-management arrangement.* The term cash-management arrangement means an arrangement the principal

purpose of which is to manage cash for participating expanded group members. For purposes of the preceding sentence, managing cash means borrowing excess funds from participating expanded group members and lending funds to participating expanded group members, and may also include foreign exchange management, clearing payments, investing excess cash with an unrelated person, depositing excess cash with another qualified cash pool header, and settling intercompany accounts, for example through netting centers and pay-on-behalf-of programs.

* * * * *

(d) * * *

(4) *Treatment of disregarded entities.* This paragraph (d)(4) applies to the extent that a covered debt instrument issued by a disregarded entity, the regarded owner of which is a covered member, would, absent the application of this paragraph (d)(4), be treated as stock under this section. In this case, rather than the covered debt instrument being treated as stock to such extent (applicable portion), the covered member that is the regarded owner of the disregarded entity is deemed to issue its stock in the manner described in this paragraph (d)(4). If the applicable portion otherwise would have been treated as stock under paragraph (b)(2) of this section, then the covered member is deemed to issue its stock to the expanded group member to which the covered debt instrument was, in form, issued (or transferred) in the transaction described in paragraph (b)(2) of this section. If the applicable portion otherwise would have been treated as stock under paragraph (b)(3)(i) of this section, then the covered member is deemed to issue its stock to the holder of the covered debt instrument in exchange for a portion of the covered debt instrument equal to the applicable portion. In each case, the covered member that is the regarded owner of the disregarded entity is treated as the holder of the applicable portion of the debt instrument issued by the disregarded entity, and the actual holder is treated as the holder of the remaining portion of the covered debt instrument and the stock deemed to be issued by the regarded owner. Under Federal tax principles, the applicable portion of the debt instrument issued by the disregarded entity generally is disregarded. This paragraph (d)(4) must be applied in a manner that is consistent with the principles of paragraph (f)(4) of this section. Thus, for example, stock deemed issued is deemed to have the same terms as the covered debt instrument issued by the disregarded entity, other than the identity of the issuer, and payments on the stock are determined by reference to payments made on the covered debt instrument issued by the disregarded entity. See § 1.385–4(b)(3) for additional rules that apply if the regarded owner of the disregarded entity is a member of a consolidated group. If the regarded owner of a disregarded entity is a controlled partnership, then paragraph (f) of this section applies as though the controlled partnership were the issuer in form of the debt instrument.

* * * * *

(f) *Treatment of controlled partnerships*—(1) *In general.* For purposes of this section and § 1.385–4, a controlled partnership is treated as an aggregate of its partners in the manner described in this paragraph (f). Paragraph (f)(2) of this section sets forth rules concerning the aggregate treatment when a controlled partnership acquires property from a member of the expanded group. Paragraph (f)(3) of this section sets forth rules concerning the aggregate treatment when a controlled partnership issues a debt instrument. Paragraph (f)(4) of this section deems a debt instrument issued by a controlled partnership to be held by an expanded group partner rather than the holder-in-form in certain cases. Paragraph (f)(5) of this section sets forth the rules concerning events that cause the deemed results described in paragraph (f)(4) of this section to cease. Paragraph (f)(6) of this section exempts certain issuances of a controlled partnership's debt to a partner and a partner's debt to a controlled partnership from the application of this section. For definitions applicable for this section, see paragraph (g) of this section. For examples illustrating the application of this section, see paragraph (h) of this section.

(2) *Acquisitions of property by a controlled partnership*—(i) *Acquisitions of property when a member of the expanded group is a partner on the date of the acquisition*—(A) *Aggregate treatment.* Except as otherwise provided in paragraphs (f)(2)(i)(C) and (f)(6) of this section, if a controlled partnership, with respect to an expanded group, acquires property from a member of the expanded group (transferor member), then, for purposes of this section, a member of the expanded group that is an expanded group partner on the date of the acquisition is treated as acquiring its share (as determined under paragraph (f)(2)(i)(B) of this section) of the property. The expanded group partner is treated as acquiring its share of the property from the transferor member in the manner (for example, in a distribution, in an exchange for property, or in an issuance), and on the date on which, the property is actually acquired by the controlled partnership from the transferor member. Accordingly, this section applies to a member's acquisition of property described in this paragraph (f)(2)(i)(A) in the same manner as if the member actually acquired the property from the transferor member, unless explicitly provided otherwise.

(B) *Expanded group partner's share of property.* For purposes of paragraph (f)(2)(i)(A) of this section, a partner's share of property acquired by a controlled partnership is determined in accordance with the partner's liquidation value percentage (as defined in paragraph (g)(17) of this section) with respect to the controlled partnership. The liquidation value percentage is determined on the date on which the controlled partnership acquires the property.

(C) *Exception if transferor member is an expanded group partner.* If a transferor member is an expanded group partner in the controlled partnership, paragraph (f)(2)(i)(A) of this section does not apply to such partner.

(ii) *Acquisitions of expanded group stock when a member of the expanded group becomes a partner after the acquisition*—(A) *Aggregate treatment.* Except as otherwise provided in paragraph (f)(2)(ii)(C) of this section, if a controlled partnership, with respect to an expanded group, owns expanded group stock, and a member of the expanded group becomes an expanded group partner in the controlled partnership, then, for purposes of this section, the member is treated as acquiring its share (as determined under paragraph (f)(2)(ii)(B) of this section) of the expanded group stock owned by the controlled partnership. The member is treated as acquiring its share of the expanded group stock on the date on which the member becomes an expanded group partner. Furthermore, the member is treated as if it acquires its share of the expanded group stock from a member of the expanded group in exchange for property other than expanded group stock, regardless of the manner in which the partnership acquired the stock and in which the member acquires its partnership interest. Accordingly, this section applies to a member's acquisition of expanded group stock described in this paragraph (f)(2)(ii)(A) in the same manner as if the member actually acquired the stock from a member of the expanded group in exchange for property other than expanded group

stock, unless explicitly provided otherwise.

(B) *Expanded group partner's share of expanded group stock.* For purposes of paragraph (f)(2)(ii)(A) of this section, a partner's share of expanded group stock owned by a controlled partnership is determined in accordance with the partner's liquidation value percentage with respect to the controlled partnership. The liquidation value percentage is determined on the date on which a member of the expanded group becomes an expanded group partner in the controlled partnership.

(C) *Exception if an expanded group partner acquires its interest in a controlled partnership in exchange for expanded group stock.* Paragraph (f)(2)(ii)(A) of this section does not apply to a member of an expanded group that acquires its interest in a controlled partnership either from another partner in exchange solely for expanded group stock or upon a partnership contribution to the controlled partnership comprised solely of expanded group stock.

(3) *Issuances of debt instruments by a controlled partnership to a member of an expanded group*—(i) *Aggregate treatment.* If a controlled partnership, with respect to an expanded group, issues a debt instrument to a member of the expanded group, then, for purposes of this section, a covered member that is an expanded group partner is treated as the issuer with respect to its share (as determined under paragraph (f)(3)(ii) of this section) of the debt instrument issued by the controlled partnership. This section applies to the portion of the debt instrument treated as issued by the covered member as described in this paragraph (f)(3)(i) in the same manner as if the covered member actually issued the debt instrument to the holder-in-form, unless otherwise provided. See paragraph (f)(4) of this section, which deems a debt instrument issued by a controlled partnership to be held by an expanded group partner rather than the holder-in-form in certain cases.

(ii) *Expanded group partner's share of a debt instrument issued by a controlled partnership*—(A) *General rule.* An expanded group partner's share of a debt instrument issued by a controlled partnership is determined on each date on which the partner makes a distribution or acquisition described in paragraph (b)(2) or (b)(3)(i) of this section (testing date). An expanded group partner's share of a debt instrument issued by a controlled partnership to a member of the expanded group is determined in accordance with the partner's issuance percentage (as defined in paragraph (g)(16) of this section) on the testing date. A partner's share determined under this paragraph (f)(3)(ii)(A) is adjusted as described in paragraph (f)(3)(ii)(B) of this section.

(B) *Additional rules if there is a specified portion with respect to a debt instrument*—(*1*) An expanded group partner's share (as determined under paragraph (f)(3)(ii)(A) of this section) of a debt instrument issued by a controlled partnership is reduced, but not below zero, by the sum of all of the specified portions (as defined in paragraph (g)(23) of this section), if any, with respect to the debt instrument that correspond to one or more deemed transferred receivables (as defined in paragraph (g)(8) of this section) that are deemed to be held by the partner.

(*2*) If the aggregate of all of the expanded group partners' shares (as determined under paragraph (f)(3)(ii)(A) of this section and reduced under paragraph (f)(3)(ii)(B)(*1*) of this section) of the debt instrument exceeds the adjusted issue price of the debt, reduced by the sum of all of the specified portions with respect to the debt instrument that correspond to one or more deemed transferred receivables that are deemed to be held by one or more expanded group partners (excess amount), then each expanded group partner's share (as determined under paragraph (f)(3)(ii)(A) of this section and reduced under paragraph (f)(3)(ii)(B)(*1*) of this section) of the debt instrument is reduced. The amount of an expanded group partner's reduction is the excess amount multiplied by a fraction, the numerator of which is the partner's share, and the denominator of which is the aggregate of all of the expanded group partners' shares.

(iii) *Qualified short-term debt instrument.* The determination of whether a debt instrument is a qualified short-term debt instrument for purposes of paragraph (b)(3)(vii) of this section is made at the partnership-level without regard to paragraph (f)(3)(i) of this section.

(4) *Recharacterization when there is a specified portion with respect to a debt instrument issued by a controlled partnership*—(i) *General rule.* A specified portion, with respect to a debt instrument issued by a controlled partnership and an expanded group partner, is not treated as stock under paragraph (b)(2) or (b)(3)(i) of this section. Except as otherwise provided in paragraphs (f)(4)(ii) and (iii) of this section, the holder-in-form (as defined in paragraph (g)(15) of this section) of the debt instrument is deemed to transfer a portion of the debt instrument (a deemed transferred receivable, as defined in paragraph (g)(8) of this section) with a principal amount equal to the adjusted issue price of the specified portion to the expanded group partner in exchange for stock in the expanded group partner (deemed partner stock, as defined in paragraph (g)(6) of this section) with a fair market value equal to the principal amount of the deemed transferred receivable. Except as otherwise provided in paragraph (f)(4)(vi) of this section (concerning the treatment of a deemed transferred receivable for purposes of section 752) and paragraph (f)(5) of this section (concerning specified events subsequent to the deemed transfer), the deemed transfer described in this paragraph (f)(4)(i) is deemed to occur for all Federal tax purposes.

(ii) *Expanded group partner is the holder-in-form of a debt instrument.* If the specified portion described in paragraph (f)(4)(i) of this section is with respect to an expanded group partner that is the holder-in-form of the debt instrument, then paragraph (f)(4)(i) of this section will not apply with respect to that specified portion except that only the first sentence of paragraph (f)(4)(i) of this section is applicable.

(iii) *Expanded group partner is a consolidated group member.* This paragraph (f)(4)(iii) applies when one or more expanded group partners is a member of a consolidated group that files (or is required to file) a consolidated U.S. Federal income tax return. In this case, notwithstanding § 1.385–4(b)(1) (which generally treats members of a consolidated group as one corporation for purposes of this section), the holder-in-form of the debt instrument issued by the controlled partnership is deemed to transfer the deemed transferred receivable or receivables to the expanded group partner or partners that are members of a consolidated group that make, or are treated as making under paragraph (f)(2) of this section, the regarded distributions or acquisitions (within the meaning of § 1.385–4(e)(5)) described in paragraph (b)(2) or (b)(3)(i) of this section in exchange for deemed partner stock in such partner or partners. To the extent those regarded distributions or acquisitions are made by a member of the consolidated group that is not an expanded group partner (excess amount), the holder-in-form is deemed to transfer a portion of the deemed transferred receivable or receivables to each member of the consolidated group that is an expanded group partner in exchange for deemed partner stock in the expanded group partner. The portion is the excess amount multiplied by a fraction, the numerator of which is

the portion of the consolidated group's share (as determined under paragraph (f)(3)(ii) of this section) of the debt instrument issued by the controlled partnership that would have been the expanded group partner's share if the partner was not a member of a consolidated group, and the denominator of which is the consolidated group's share of the debt instrument issued by the controlled partnership.

(iv) *Rules regarding deemed transferred receivables and deemed partner stock*—(A) *Terms of deemed partner stock.* Deemed partner stock has the same terms as the deemed transferred receivable with respect to the deemed transfer, other than the identity of the issuer.

(B) *Treatment of payments with respect to a debt instrument for which there is one or more deemed transferred receivables.* When a payment is made with respect to a debt instrument issued by a controlled partnership for which there is one or more deemed transferred receivables, then, if the amount of the retained receivable (as defined in paragraph (g)(22) of this section) held by the holder-in-form is zero and a single deemed holder is deemed to hold all of the deemed transferred receivables, the entire payment is allocated to the deemed transferred receivables held by the single deemed holder. If the amount of the retained receivable held by the holder-in-form is greater than zero or there are multiple deemed holders of deemed transferred receivables, or both, the payment is apportioned among the retained receivable, if any, and each deemed transferred receivable in proportion to the principal amount of all the receivables. The portion of a payment allocated or apportioned to a retained receivable or a deemed transferred receivable reduces the principal amount of, or accrued interest with respect to, as applicable depending on the payment, the retained receivable or deemed transferred receivable. When a payment allocated or apportioned to a deemed transferred receivable reduces the principal amount of the receivable, the expanded group partner that is the deemed holder with respect to the deemed transferred receivable is deemed to redeem the same amount of deemed partner stock, and the specified portion with respect to the debt instrument is reduced by the same amount. When a payment allocated or apportioned to a deemed transferred receivable reduces accrued interest with respect to the receivable, the expanded group partner that is the deemed holder with respect to the deemed transferred receivable is deemed to make a matching distribution in the same amount with respect to the deemed partner stock. The controlled partnership is treated as the paying agent with respect to the deemed partner stock.

(v) *Holder-in-form transfers debt instrument in a transaction that is not a specified event.* If the holder-in-form transfers the debt instrument (which is disregarded for Federal tax purposes) to a member of the expanded group or a controlled partnership (and therefore the transfer is not a specified event described in paragraph (f)(5)(iii)(F) of this section), then, for Federal tax purposes, the holder-in-form is deemed to transfer the retained receivable and the deemed partner stock to the transferee.

(vi) *Allocation of deemed transferred receivable under section 752.* A partnership liability that is a debt instrument with respect to which there is one or more deemed transferred receivables is allocated for purposes of section 752 without regard to any deemed transfer.

(5) *Specified events affecting ownership following a deemed transfer*—(i) *General rule.* If a specified event (within the meaning of paragraph (f)(5)(iii) of this section) occurs with respect to a deemed transfer, then, immediately before the specified event, the expanded group partner that is both the issuer of the deemed partner stock and the deemed holder of the deemed transferred receivable is deemed to distribute the deemed transferred receivable (or portion thereof, as determined under paragraph (f)(5)(iv) of this section) to the holder-in-form in redemption of the deemed partner stock (or portion thereof, as determined under paragraph (f)(5)(iv) of this section) deemed to be held by the holder-in-form. The deemed distribution is deemed to occur for all Federal tax purposes, except that the distribution is disregarded for purposes of paragraph (b) of this section. Except when the deemed transferred receivable (or portion thereof, as determined under paragraph (f)(5)(iv) of this section) is deemed to be retransferred under paragraph (f)(5)(ii) of this section, the principal amount of the retained receivable held by the holder-in-form is increased by the principal amount of the deemed transferred receivable, the deemed transferred receivable ceases to exist for Federal tax purposes, and the specified portion (or portion thereof) that corresponds to the deemed transferred receivable (or portion thereof) ceases to be treated as a specified portion for purposes of this section.

(ii) *New deemed transfer when a specified event involves a transferee that is a covered member that is an expanded group partner.* If the specified event is described in paragraph (f)(5)(iii)(E) of this section, the holder-in-form of the debt instrument is deemed to retransfer the deemed transferred receivable (or portion thereof, as determined under paragraph (f)(5)(iv) of this section) that the holder-in-form is deemed to have received pursuant to paragraph (f)(5)(i) of this section, to the transferee expanded group partner in exchange for deemed partner stock issued by the transferee expanded group partner with a fair market value equal to the principal amount of the deemed transferred receivable (or portion thereof) that is retransferred. For purposes of this section, this deemed transfer is treated in the same manner as a deemed transfer described in paragraph (f)(4)(i) of this section.

(iii) *Specified events.* A specified event, with respect to a deemed transfer, occurs when, immediately after the transaction and taking into account all related transactions:

(A) The controlled partnership that is the issuer of the debt instrument either ceases to be a controlled partnership or ceases to have an expanded group partner that is a covered member.

(B) The holder-in-form is a member of the expanded group immediately before the transaction, and the holder-in-form and the deemed holder cease to be members of the same expanded group for the reasons described in paragraph (d)(2) of this section.

(C) The holder-in-form is a controlled partnership immediately before the transaction, and the holder-in-form ceases to be a controlled partnership.

(D) The expanded group partner that is both the issuer of deemed partner stock and the deemed holder transfers (directly or indirectly through one or more partnerships) all or a portion of its interest in the controlled partnership to a person that neither is a covered member nor a controlled partnership with an expanded group partner that is a covered member. If there is a transfer of only a portion of the interest, see paragraph (f)(5)(iv) of this section.

(E) The expanded group partner that is both the issuer of deemed partner stock and the deemed holder transfers (directly or indirectly through one or more partnerships) all or a portion of its interest in the controlled partnership to a covered member or a controlled partnership with an expanded group partner that is a covered member. If there is a transfer of only a portion of

the interest, see paragraph (f)(5)(iv) of this section.

(F) The holder-in-form transfers the debt instrument (which is disregarded for Federal tax purposes) to a person that is neither a member of the expanded group nor a controlled partnership. See paragraph (f)(4)(v) of this section if the holder-in-form transfers the debt instrument to a member of the expanded group or a controlled partnership.

(iv) *Specified event involving a transfer of only a portion of an interest in a controlled partnership.* If, with respect to a specified event described in paragraph (f)(5)(iii)(D) or (E) of this section, an expanded group partner transfers only a portion of its interest in a controlled partnership, then, only a portion of the deemed transferred receivable that is deemed to be held by the expanded group partner is deemed to be distributed in redemption of an equal portion of the deemed partner stock. The portion of the deemed transferred receivable referred to in the preceding sentence is equal to the product of the entire principal amount of the deemed transferred receivable deemed to be held by the expanded group partner multiplied by a fraction, the numerator of which is the portion of the expanded group partner's capital account attributable to the interest that is transferred, and the denominator of which is the expanded group partner's capital account with respect to its entire interest, determined immediately before the specified event.

(6) *Issuance of a partnership's debt instrument to a partner and a partner's debt instrument to a partnership.* If a controlled partnership, with respect to an expanded group, issues a debt instrument to an expanded group partner, or if a covered member that is an expanded group partner issues a covered debt instrument to a controlled partnership, and in each case, no partner deducts or receives an allocation of expense with respect to the debt instrument, then this section does not apply to the debt instrument.

(g) * * *

(5) *Deemed holder.* The term *deemed holder* means, with respect to a deemed transfer, the expanded group partner that is deemed to hold a deemed transferred receivable by reason of the deemed transfer.

(6) *Deemed partner stock.* The term *deemed partner stock* means, with respect to a deemed transfer, the stock deemed issued by an expanded group partner as described in paragraphs (f)(4)(i) and (iii) and (f)(5)(ii) of this section. The amount of deemed partner stock is reduced as described in paragraphs (f)(4)(iv)(B) and (f)(5)(i) of this section.

(7) *Deemed transfer.* The term *deemed transfer* means, with respect to a specified portion, the transfer described in paragraph (f)(4)(i) or (iii) or (f)(5)(ii) of this section.

(8) *Deemed transferred receivable.* The term *deemed transferred receivable* means, with respect to a deemed transfer, the portion of the debt instrument described in paragraph (f)(4)(i) or (iii) or (f)(5)(ii) of this section. The deemed transferred receivable is reduced as described in paragraphs (f)(4)(iv)(B) and (f)(5)(i) of this section.

* * * * *

(15) *Holder-in-form.* The term *holder-in-form* means, with respect to a debt instrument issued by a controlled partnership, the person that, absent the application of paragraph (f)(4) of this section, would be the holder of the debt instrument for Federal tax purposes. Therefore, the term holder-in-form does not include a deemed holder (as defined in paragraph (g)(5) of this section).

(16) *Issuance percentage.* The term *issuance percentage* means, with respect to a controlled partnership and an expanded group partner, the ratio (expressed as a percentage) of the partner's reasonably anticipated distributive share of all the partnership's interest expense over a reasonable period, divided by all of the partnership's reasonably anticipated interest expense over that same period, taking into account any and all relevant facts and circumstances. The relevant facts and circumstances include, without limitation, the term of the debt instrument; whether the partnership anticipates issuing other debt instruments; and the partnership's anticipated section 704(b) income and expense, and the partners' respective anticipated allocation percentages, taking into account anticipated changes to those allocation percentages over time resulting, for example, from anticipated contributions, distributions, recapitalizations, or provisions in the controlled partnership agreement.

(17) *Liquidation value percentage.* The term *liquidation value percentage* means, with respect to a controlled partnership and an expanded group partner, the ratio (expressed as a percentage) of the liquidation value of the expanded group partner's interest in the partnership divided by the aggregate liquidation value of all the partners' interests in the partnership. The liquidation value of an expanded group partner's interest in a controlled partnership is the amount of cash the partner would receive with respect to the interest if the partnership (and any partnership through which the partner indirectly owns an interest in the controlled partnership) sold all of its property for an amount of cash equal to the fair market value of the property (taking into account section 7701(g)), satisfied all of its liabilities (other than those described in § 1.752–7), paid an unrelated third party to assume all of its § 1.752–7 liabilities in a fully taxable transaction, and then the partnership (and any partnership through which the partner indirectly owns an interest in the controlled partnership) liquidated.

* * * * *

(22) *Retained receivable.* The term *retained receivable* means, with respect to a debt instrument issued by a controlled partnership, the portion of the debt instrument that is not transferred by the holder-in-form pursuant to one or more deemed transfers. The retained receivable is adjusted for decreases described in paragraph (f)(4)(iv)(B) of this section and increases described in paragraph (f)(5)(i) of this section.

(23) *Specified portion.* The term *specified portion* means, with respect to a debt instrument issued by a controlled partnership and a covered member that is an expanded group partner, the portion of the debt instrument that is treated under paragraph (f)(3)(i) of this section as issued on a testing date (within the meaning of paragraph (f)(3)(ii) of this section) by the covered member and that, absent the application of paragraph (f)(4)(i) of this section, would be treated as stock under paragraph (b)(2) or (b)(3)(i) of this section on the testing date. A specified portion is reduced as described in paragraphs (f)(4)(iv)(B) and (f)(5)(i) of this section.

* * * * *

(h) * * *

(3) * * *

(xii) *Example 12: Distribution of a covered debt instrument to a controlled partnership*—(A) *Facts.* CFC and FS are equal partners in PRS. PRS owns 100% of the stock in X Corp, a domestic corporation. On Date A in Year 1, X Corp issues X Note to PRS in a distribution.

(B) *Analysis.* (*1*) Under § 1.385–1(c)(4), in determining whether X Corp is a member of the FP expanded group that includes CFC and FS, CFC and FS are each treated as owning 50% of the X Corp stock held by PRS. Accordingly, 100% of X Corp's stock is treated as owned by CFC and FS, and X Corp is a member of the FP expanded group.

(*2*) Together CFC and FS own 100% of the interests in PRS capital and profits, such that PRS is a controlled partnership under § 1.385–1(c)(1). CFC and FS are both expanded group partners on the date on which PRS acquired X Note. Therefore,

pursuant to paragraph (f)(2)(i)(A) of this section, each of CFC and FS is treated as acquiring its share of X Note in the same manner (in this case, by a distribution of X Note), and on the date on which, PRS acquired X Note. Likewise, X Corp is treated as issuing to each of CFC and FS its share of X Note. Under paragraph (f)(2)(i)(B) of this section, each of CFC's and FS's share of X Note, respectively, is determined in accordance with its liquidation value percentage determined on Date A in Year 1, the date X Corp distributed X Note to PRS. On Date A in Year 1, pursuant to paragraph (g)(17) of this section, each of CFC's and FS's liquidation value percentages is 50%. Accordingly, on Date A in Year 1, under paragraph (f)(2)(i)(A) of this section, for purposes of this section, CFC and FS are each treated as acquiring 50% of X Note in a distribution.

(*3*) Under paragraphs (b)(2)(i) and (d)(1)(i) of this section, X Note is treated as stock on the date of issuance, which is Date A in Year 1. Under paragraph (f)(2)(i)(A) of this section, each of CFC and FS are treated as acquiring 50% of X Note in a distribution for purposes of this section. Therefore, X Corp is treated as distributing its stock to PRS in a distribution described in section 305.

(xiii) *Example 13: Loan to a controlled partnership; proportionate distributions by expanded group partners*—(A) *Facts.* DS, USS2, and USP are partners in PRS. USP is a domestic corporation that is not a member of the FP expanded group. Each of DS and USS2 own 45% of the interests in PRS profits and capital, and USP owns 10% of the interests in PRS profits and capital. The PRS partnership agreement provides that all items of PRS income, gain, loss, deduction, and credit are allocated in accordance with the percentages in the preceding sentence. On Date A in Year 1, FP lends $200x to PRS in exchange for PRS Note with stated principal amount of $200x, which is payable at maturity. PRS Note also provides for annual payments of interest that are qualified stated interest. PRS uses all $200x in its business and does not distribute any money or other property to a partner. Subsequently, on Date B in Year 1, DS distributes $90x to USS1, USS2 distributes $90x to FP, and USP distributes $20x to its shareholder. Each of DS's and USS2's issuance percentage is 45% on Date B in Year 1, the date of the distributions and therefore a testing date under paragraph (f)(3)(ii)(A) of this section.

(B) *Analysis.* (*1*) DS and USS2 together own 90% of the interests in PRS profits and capital and therefore PRS is a controlled partnership under § 1.385–1(c)(1). Under § 1.385–1(c)(2), each of DS and USS2 is a covered member.

(*2*) Under paragraph (f)(3)(i) of this section, each of DS and USS2 is treated as issuing its share of PRS Note, and under paragraph (f)(3)(ii)(A) of this section, DS's and USS2's share is each $90x (45% of $200x). USP is not an expanded group partner and therefore has no issuance percentage and is not treated as issuing any portion of PRS Note.

(*3*) The $90x distributions made by DS to USS1 and by USS2 to FP are described in paragraph (b)(3)(i)(A) of this section. Under paragraph (b)(3)(iii)(A) of this section, the portions of PRS Note treated as issued by each of DS and USS2 are treated as funding the distribution made by DS and USS2 because the distributions occurred within the per se period with respect to PRS Note. Under paragraph (b)(3)(i) of this section, the portions of PRS Note treated as issued by each of DS and USS2 would, absent the application of paragraph (f)(4)(i) of this section, be treated as stock of DS and USS2 on Date B in Year 1, the date of the distributions. See paragraph (d)(1)(ii) of this section. Under paragraph (g)(23) of this section, each of the $90x portions is a specified portion.

(*4*) Under paragraph (f)(4)(i) of this section, the specified portions are not treated as stock under paragraph (b)(3)(i) of this section. Instead, FP is deemed to transfer a portion of PRS Note with a principal amount equal to $90x (the adjusted issue price of the specified portion with respect to DS) to DS in exchange for deemed partner stock in DS with a fair market value of $90x. Similarly, FP is deemed to transfer a portion of PRS Note with a principal amount equal to $90x (the adjusted issue price of the specified portion with respect to USS2) to USS2 in exchange for deemed partner stock in USS2 with a fair market value of $90x. The principal amount of the retained receivable held by FP is $20x ($200x − $90x − $90x).

(xiv) *Example 14: Loan to a controlled partnership; disproportionate distributions by expanded group partners*—(A) *Facts.* The facts are the same as in paragraph (h)(3)(xiii)(A) of this section (*Example 13*), except that on Date B in Year 1, DS distributes $45x to USS1 and USS2 distributes $135x to FP.

(B) *Analysis.* (*1*) The analysis is the same as in paragraph (h)(3)(xiii)(B)(*1*) of this section (*Example 13*).

(*2*) The analysis is the same as in paragraph (h)(3)(xiii)(B)(*2*) of this section (*Example 13*).

(*3*) The $45x and $135x distributions made by DS to USS1 and by USS2 to FP, respectively, are described in paragraph (b)(3)(i)(A) of this section. Under paragraph (b)(3)(iii)(A) of this section, the portion of PRS Note treated as issued by DS is treated as funding the distribution made by DS because the distribution occurred within the per se period with respect to PRS Note, but under paragraph (b)(3)(i) of this section, only to the extent of DS's $45x distribution. USS2 is treated as issuing $90x of PRS Note, all of which is treated as funding $90x of USS2's $135x distribution under paragraph (b)(3)(iii)(A) of this section. Under paragraph (b)(3)(i) of this section, absent the application of paragraph (f)(4)(i) of this section, $45x of PRS Note would be treated as stock of DS and $90x of PRS Note would be treated as stock of USS2 on Date B in Year 1, the date of the distributions. See paragraph (d)(1)(ii) of this section. Under paragraph (g)(23) of this section, $45x of PRS Note is a specified portion with respect to DS and $90x of PRS Note is a specified portion with respect to USS2.

(*4*) Under paragraph (f)(4)(i) of this section, the specified portions are not treated as stock under paragraph (b)(3)(i) of this section. Instead, FP is deemed to transfer a portion of PRS Note with a principal amount equal to $45x (the adjusted issue price of the specified portion with respect to DS) to DS in exchange for stock of DS with a fair market value of $90x. Similarly, FP is deemed to transfer a portion of PRS Note with a principal amount equal to $90x (the adjusted issue price of the specified portion with respect to USS2) to USS2 in exchange for stock of USS2 with a fair market value of $90x. The principal amount of the retained receivable held by FP is $65x ($200x − $45x − $90x).

(xv) *Example 15: Loan to partnership; distribution in later year*—(A) *Facts.* The facts are the same as in paragraph (h)(3)(xiii)(A) of this section (*Example 13*), except that USS2 does not distribute $90x to FP until Date C in Year 2, which is less than 36 months after Date A in Year 1. On Date C in Year 2, DS's, USS2's, and USP's issuance percentages under paragraph (g)(16) of this section are unchanged at 45%, 45%, and 10%, respectively.

(B) *Analysis.* (*1*) The analysis is the same as in paragraph (h)(3)(xiii)(B)(*1*) of this section (*Example 13*).

(*2*) The analysis is the same as in paragraph (h)(3)(xiii)(B)(*2*) of this section (*Example 13*).

(*3*) With respect to the distribution made by DS, the analysis is the same as in paragraph (h)(3)(xiii)(B)(*3*) of this section (*Example 13*).

(*4*) With respect to the deemed transfer to DS, the analysis is the same as in paragraph (h)(3)(xiii)(B)(*4*) of this section (*Example 13*). Accordingly, the amount of the retained receivable held by FP as of Date B in Year 1 is $110x ($200x − $90x).

(*5*) Under paragraph (f)(3)(ii)(A) of this section, USS2's share of PRS Note is determined on Date C in Year 2. On Date C in Year 2, DS's, USS2's, and USP's respective shares of PRS Note under paragraph (f)(3)(ii)(A) of this section are $90x, $90x, and $20x. However, because DS is treated as the issuer with respect to a $90x specified portion of PRS Note, DS's share of PRS Note is reduced by $90x to $0 under paragraph (f)(3)(ii)(B)(*1*) of this section. No reduction to either of USS2's or USP's share of PRS Note is required under paragraph (f)(3)(ii)(B)(*2*) of this section because the aggregate of DS's, USS2's, and USP's shares of PRS Note as reduced is $110x (DS has a $0 share, USS2 has a $90x share, and USP has a $20x share), which does not exceed $110x (the $200x adjusted issue price of PRS Note reduced by the $90x specified portion with respect to DS). Under paragraph (f)(3)(i) of this section, USS2 is treated as issuing its share of PRS Note.

(*6*) The $90x distribution made by USS2 to FP is described in paragraph (b)(3)(i)(A) of this section. Under paragraph (b)(3)(iii)(A) of this section, the portion of PRS Note treated as issued by USS2 is treated as funding the distribution made by USS2, because the distribution occurred within the per se period with respect to PRS Note. Accordingly, the portion of PRS Note treated as issued by USS2 would, absent the application of paragraph (f)(4)(i) of this section, be treated as stock of USS2 under paragraph (b)(3)(i) of this section on Date C in Year 2. See paragraph (d)(1)(ii) of this section. Under paragraph (g)(23) of this section, the $90x portion is a specified portion.

(*7*) Under paragraph (f)(4)(i) of this section, the specified portion of PRS Note treated as issued by USS2 is not treated as stock under paragraph (b)(3)(i) of this section. Instead, on Date C in Year 2, FP is deemed to transfer a portion of PRS Note with a principal amount equal to $90x (the adjusted issue price of the specified portion with respect to USS2) to USS2 in exchange for stock in USS2 with a fair market value of $90x. The principal amount of the retained receivable held by FP is reduced from $110x to $20x.

(xvi) *Example 16: Loan to a controlled partnership; partnership ceases to be a controlled partnership*—(A) *Facts.* The facts are the same as in paragraph (h)(3)(xiii)(A) of this section (*Example 13*), except that on Date C in Year 4, USS2 sells its entire interest in PRS to an unrelated person.

(B) *Analysis.* (*1*) On date C in Year 4, PRS ceases to be a controlled partnership with respect to the FP expanded group under § 1.385–1(c)(1). This is the case because DS, the only remaining partner that is a member of the FP expanded group, only owns 45% of the total interest in PRS profits and capital. Because PRS ceases to be a controlled partnership, a specified event (within the meaning of paragraph (f)(5)(iii)(A) of this section) occurs with respect to the deemed transfers with respect to each of DS and USS2.

(*2*) Under paragraph (f)(5)(i) of this section, on Date C in Year 4, immediately before PRS ceases to be a controlled partnership, each of DS and USS2 is deemed to distribute its deemed transferred receivable to FP in redemption of FP's deemed partner stock in DS and USS2. The specified portion that corresponds to each of the deemed transferred receivables ceases to be treated as a specified portion. Furthermore, the deemed transferred receivables cease to exist, and the retained receivable held by FP increases from $20x to $200x.

(xvii) *Example 17: Transfer of an interest in a partnership to a covered member*—(A) *Facts.* The facts are the same as in paragraph (h)(3)(xiii)(A) of this section (*Example 13*), except that on Date C in Year 4, USS2 sells its entire interest in PRS to USS1.

(B) *Analysis.* (*1*) After USS2 sells its interest in PRS to USS1, DS and USS1 together own 90% of the interests in PRS profits and capital and therefore PRS continues to be a controlled partnership under § 1.385–1(c)(1). A specified event (within the meaning of paragraph (f)(5)(iii)(E) of this section) occurs as result of the sale only with respect to the deemed transfer with respect to USS2.

(*2*) Under paragraph (f)(5)(i) of this section, on Date C in Year 4, immediately before USS2 sells its entire interest in PRS to USS1, USS2 is deemed to distribute its deemed transferred receivable to FP in redemption of FP's deemed partner stock in USS2. Because the specified event is described in paragraph (f)(5)(iii)(E) of this section, under paragraph (f)(5)(ii) of this section, FP is deemed to retransfer the deemed transferred receivable deemed received from USS2 to USS1 in exchange for deemed partner stock in USS1 with a fair market value equal to the principal amount of the deemed transferred receivable that is retransferred to USS1.

(xviii) *Example 18: Loan to partnership and all partners are members of a consolidated group*—(A) *Facts.* USS1 and DS are equal partners in PRS. USS1 and DS are members of a consolidated group, as defined in § 1.1502–1(h). The PRS partnership agreement provides that all items of PRS income, gain, loss, deduction, and credit are allocated equally between USS1 and DS. On Date A in Year 1, FP lends $200x to PRS in exchange for PRS Note. PRS uses all $200x in its business and does not distribute any money or other property to any partner. On Date B in Year 1, DS distributes $200x to USS1, and USS1 distributes $200x to FP. If neither of USS1 or DS were a member of the consolidated group, each would have an issuance percentage under paragraph (g)(16) of this section, determined as of Date A in Year 1, of 50%.

(B) *Analysis.* (*1*) Pursuant to § 1.385–4(b)(6), PRS is treated as a partnership for purposes of this section. Under § 1.385–4(b)(1), DS and USS1 are treated as one corporation for purposes of this section, and thus a single covered member under § 1.385–1(c)(2). For purposes of this section, the single covered member owns 100% of the PRS profits and capital and therefore PRS is a controlled partnership under § 1.385–1(c)(1). Under paragraph (f)(3)(i) of this section, the single covered member is treated as issuing all $200x of PRS Note to FP, a member of the same expanded group as the single covered member. DS's distribution to USS1 is a disregarded distribution because it is a distribution between members of a consolidated group that is disregarded under the one-corporation rule described in § 1.385–4(b)(1). However, under paragraph (b)(3)(iii)(A) of this section, PRS Note, treated as issued by the single covered member, is treated as funding the distribution by USS1 to FP, which is described in paragraph (b)(3)(i)(A) of this section and which is a regarded distribution. Accordingly, PRS Note, absent the application of paragraph (f)(4)(i) of this section, would be treated as stock under paragraph (b) of this section on Date B in Year 1. Thus, pursuant to paragraph (g)(23) of this section, the entire PRS Note is a specified portion.

(*2*) Under paragraphs (f)(4)(i) and (iii) of this section, the specified portion is not treated as stock and, instead, FP is deemed to transfer PRS Note with a principal amount equal to $200x to USS1 in exchange for stock of USS1 with a fair market value of $200x. Under paragraph (f)(4)(iii) of this section, FP is deemed to transfer PRS Note to USS1 because only USS1 made a regarded distribution described in paragraph (b)(3)(i) of this section.

(xix) *Example 19: Loan to a disregarded entity*—(A) *Facts.* DS owns DRE, a disregarded entity within the meaning of § 1.385–1(c)(3). On Date A in Year 1, FP lends $200x to DRE in exchange for DRE Note. Subsequently, on Date B in Year 1, DS distributes $100x of cash to USS1.

(B) *Analysis.* Under paragraph (b)(3)(iii)(A) of this section, $100x of DRE Note would be treated as funding the distribution by DS to USS1 because DRE Note is issued to a member of the FP expanded group during the per se period with respect to DS's distribution to USS1. Accordingly, under paragraphs (b)(3)(i)(A) and (d)(1)(ii) of this section, $100x of DRE Note would be treated as stock on Date B in Year 1. However, under paragraph (d)(4) of this section, DS, as the regarded owner, within the meaning of § 1.385–1(c)(5), of DRE is deemed to issue its stock to FP in exchange for a portion of DRE Note equal to the $100x applicable portion (as defined in paragraph (d)(4) of this section). Thus, DS is treated as the holder of $100x of DRE Note, which is disregarded, and FP is treated as the holder of the remaining $100x of DRE Note. The $100x of stock deemed issued by DS to FP has the same terms as DRE Note, other than the issuer, and payments on the stock are determined by reference to payments on DRE Note.

* * * * *

(j) * * * (1) *In general.* Except as provided in paragraph (j)(2) or (3) or (k) of this section, this section applies to taxable years ending on or after January 19, 2017.

* * * * *

(3) *Paragraph (f)(4)(iii) of this section.* Paragraph (f)(4)(iii) of this section applies to taxable years for which the U.S. Federal income tax return is due, without extensions, after May 14, 2020. For taxable years ending on or after January 19, 2017, and for which the U.S. Federal income tax return is due, without extensions, on or before May 14, 2020, see § 1.385–3T(f)(4)(iii), as contained in 26 CFR in part 1 in effect on April 1, 2019. In the case of a taxable year that ends after October 13, 2019, and on or before May 14, 2020, a taxpayer may choose to apply paragraph (f)(4)(iii) of this section to the portion of the taxable year that occurs after the expiration of § 1.385–3T on October 13, 2019, provided that all members of the taxpayer's expanded group apply such paragraph.

(k) *Additional transition rules.* See transition rules in § 1.385–3T(k)(2) as contained in 26 CFR in part 1 in effect on April 1, 2019.

§ § 1.385–3T and 1.385–4T [Removed]

■ **Par. 4.** Sections 1.385–3T and 1.385–4T are removed.

■ **Par. 5.** Section 1.385–4 is added to read as follows:

§ 1.385–4 Treatment of consolidated groups.

(a) *Scope.* This section provides rules for applying § 1.385–3 to members of consolidated groups. Paragraph (b) of this section sets forth rules concerning the extent to which, solely for purposes of applying § 1.385–3, members of a consolidated group that file (or that are required to file) a consolidated U.S. Federal income tax return are treated as one corporation. Paragraph (c) of this

section sets forth rules concerning the treatment of a debt instrument that ceases to be, or becomes, a consolidated group debt instrument. Paragraph (d) of this section provides rules for applying the funding rule of § 1.385–3(b)(3) to members that depart a consolidated group. For definitions applicable to this section, see paragraph (e) of this section and §§ 1.385–1(c) and 1.385–3(g). For examples illustrating the application of this section, see paragraph (f) of this section.

(b) *Treatment of consolidated groups*—(1) *Members treated as one corporation.* For purposes of this section and § 1.385–3, and except as otherwise provided in this section and § 1.385–3, all members of a consolidated group (as defined in § 1.1502–1(h)) that file (or that are required to file) a consolidated U.S. Federal income tax return are treated as one corporation. Thus, for example, when a member of a consolidated group issues a covered debt instrument that is not a consolidated group debt instrument, the consolidated group generally is treated as the issuer of the covered debt instrument for purposes of this section and § 1.385–3. Also, for example, when one member of a consolidated group issues a covered debt instrument that is not a consolidated group debt instrument and therefore is treated as issued by the consolidated group, and another member of the consolidated group makes a distribution or acquisition described in § 1.385–3(b)(3)(i)(A) through (C) with an expanded group member that is not a member of the consolidated group, § 1.385–3(b)(3)(i) may treat the covered debt instrument as funding the distribution or acquisition made by the consolidated group. In addition, except as otherwise provided in this section, acquisitions and distributions described in § 1.385–3(b)(2) and (b)(3)(i) in which all parties to the transaction are members of the same consolidated group both before and after the transaction are disregarded for purposes of this section and § 1.385–3.

(2) *One-corporation rule inapplicable to expanded group member determination.* The one-corporation rule described in paragraph (b)(1) of this section does not apply in determining the members of an expanded group. Notwithstanding the previous sentence, an expanded group does not exist for purposes of this section and § 1.385–3 if it consists only of members of a single consolidated group.

(3) *Application of § 1.385–3 to debt instruments issued by members of a consolidated group*—(i) *Debt instrument treated as stock of the issuing member of a consolidated group.* If a covered debt instrument treated as issued by a consolidated group under the one-corporation rule described in paragraph (b)(1) of this section is treated as stock under § 1.385–3, the covered debt instrument is treated as stock in the member of the consolidated group that would be the issuer of such debt instrument without regard to this section. But see § 1.385–3(d)(7) (providing that a covered debt instrument that is treated as stock under § 1.385–3(b)(2), (3), or (4) and that is not described in section 1504(a)(4) is not treated as stock for purposes of determining whether the issuer is a member of an affiliated group (within the meaning of section 1504(a)).

(ii) *Application of the covered debt instrument exclusions.* For purposes of determining whether a debt instrument issued by a member of a consolidated group is a covered debt instrument, each test described in § 1.385–3(g)(3) is applied on a separate member basis without regard to the one-corporation rule described in paragraph (b)(1) of this section.

(iii) *Qualified short-term debt instrument.* The determination of whether a member of a consolidated group has issued a qualified short-term debt instrument for purposes of § 1.385–3(b)(3)(vii) is made on a separate member basis without regard to the one-corporation rule described in paragraph (b)(1) of this section.

(4) *Application of the reductions of § 1.385–3(c)(3) to members of a consolidated group*—(i) *Application of the reduction for expanded group earnings*—(A) *In general.* A consolidated group maintains one expanded group earnings account with respect to an expanded group period, and only the earnings and profits, determined in accordance with § 1.1502–33 (without regard to the application of § 1.1502–33(b)(2), (e), and (f)), of the common parent (within the meaning of section 1504) of the consolidated group are considered in calculating the expanded group earnings for the expanded group period of the consolidated group. Accordingly, a regarded distribution or acquisition made by a member of a consolidated group is reduced to the extent of the expanded group earnings account of the consolidated group.

(B) *Effect of certain corporate transactions on the calculation of expanded group earnings*—(*1*) *Consolidation.* A consolidated group succeeds to the expanded group earnings account of a joining member under the principles of § 1.385–3(c)(3)(i)(F)(*2*)(*ii*).

(*2*) *Deconsolidation*—(*i*) *In general.* Except as otherwise provided in paragraph (b)(4)(i)(B)(*2*)(*ii*) of this section, no amount of the expanded group earnings account of a consolidated group for an expanded group period, if any, is allocated to a departing member. Accordingly, immediately after leaving the consolidated group, the departing member has no expanded group earnings account with respect to its expanded group period.

(*ii*) *Allocation of expanded group earnings to a departing member in a distribution described in section 355.* If a departing member leaves the consolidated group by reason of an exchange or distribution to which section 355 (or so much of section 356 that relates to section 355) applies, the expanded group earnings account of the consolidated group is allocated between the consolidated group and the departing member in proportion to the earnings and profits of the consolidated group and the earnings and profits of the departing member immediately after the transaction.

(ii) *Application of the reduction for qualified contributions*—(A) *In general.* For purposes of applying § 1.385–3(c)(3)(ii)(A) to a consolidated group—

(*1*) A qualified contribution to any member of a consolidated group that remains a member of the consolidated group immediately after the qualified contribution from a person other than a member of the same consolidated group is treated as made to the one corporation described in paragraph (b)(1) of this section;

(*2*) A qualified contribution that causes a member of a consolidated group to become a departing member of that consolidated group is treated as made to the departing member and not to the consolidated group of which the departing member was a member immediately prior to the qualified contribution; and

(*3*) No contribution of property by a member of a consolidated group to any other member of the consolidated group is a qualified contribution.

(B) *Effect of certain corporate transactions on the calculation of qualified contributions*—(*1*) *Consolidation.* A consolidated group succeeds to the qualified contributions of a joining member under the principles of § 1.385–3(c)(3)(ii)(F)(*2*)(*ii*).

(*2*) *Deconsolidation*—(*i*) *In general.* Except as otherwise provided in paragraph (b)(4)(ii)(B)(*2*)(*ii*) of this section, no amount of the qualified contributions of a consolidated group for an expanded group period, if any, is allocated to a departing member.

Accordingly, immediately after leaving the consolidated group, the departing member has no qualified contributions with respect to its expanded group period.

(*ii*) *Allocation of qualified contributions to a departing member in a distribution described in section 355.* If a departing member leaves the consolidated group by reason of an exchange or distribution to which section 355 (or so much of section 356 that relates to section 355) applies, each qualified contribution of the consolidated group is allocated between the consolidated group and the departing member in proportion to the earnings and profits of the consolidated group and the earnings and profits of the departing member immediately after the transaction.

(5) *Order of operations.* For purposes of this section and § 1.385–3, the consequences of a transaction involving one or more members of a consolidated group are determined as provided in paragraphs (b)(5)(i) and (ii) of this section.

(i) First, determine the characterization of the transaction under Federal tax law without regard to the one-corporation rule described in paragraph (b)(1) of this section.

(ii) Second, apply this section and § 1.385–3 to the transaction as characterized to determine whether to treat a debt instrument as stock, treating the consolidated group as one corporation under paragraph (b)(1) of this section, unless otherwise provided.

(6) *Partnership owned by a consolidated group.* For purposes of this section and § 1.385–3, and notwithstanding the one-corporation rule described in paragraph (b)(1) of this section, a partnership that is wholly owned by members of a consolidated group is treated as a partnership. Thus, for example, if members of a consolidated group own all of the interests in a controlled partnership that issues a debt instrument to a member of the consolidated group, such debt instrument would be treated as a consolidated group debt instrument because, under § 1.385–3(f)(3)(i), for purposes of this section and § 1.385–3, a consolidated group member that is an expanded group partner is treated as the issuer with respect to its share of the debt instrument issued by the partnership.

(7) *Predecessor and successor*—(i) *In general.* Pursuant to paragraph (b)(5) of this section, the determination as to whether a member of an expanded group is a predecessor or successor of another member of the consolidated group is made without regard to paragraph (b)(1) of this section. For purposes of § 1.385–3(b)(3), if a consolidated group member is a predecessor or successor of a member of the same expanded group that is not a member of the same consolidated group, the consolidated group is treated as a predecessor or successor of the expanded group member (or the consolidated group of which that expanded group member is a member). Thus, for example, a departing member that departs a consolidated group in a distribution or exchange to which section 355 applies is a successor to the consolidated group and the consolidated group is a predecessor of the departing member.

(ii) *Joining members.* For purposes of § 1.385–3(b)(3), the term *predecessor* also means, with respect to a consolidated group, a joining member and the term successor also means, with respect to a joining member, a consolidated group.

(c) *Consolidated group debt instruments*—(1) *Debt instrument ceases to be a consolidated group debt instrument but continues to be issued and held by expanded group members*—(i) *Consolidated group member leaves the consolidated group.* For purposes of this section and § 1.385–3, when a debt instrument ceases to be a consolidated group debt instrument as a result of a transaction in which the member of the consolidated group that issued the instrument (the issuer) or the member of the consolidated group holding the instrument (the holder) ceases to be a member of the same consolidated group but both the issuer and the holder continue to be members of the same expanded group, the issuer is treated as issuing a new debt instrument to the holder in exchange for property immediately after the debt instrument ceases to be a consolidated group debt instrument. To the extent the newly-issued debt instrument is a covered debt instrument that is treated as stock under § 1.385–3(b)(3), the covered debt instrument is then immediately deemed to be exchanged for stock of the issuer. For rules regarding the treatment of the deemed exchange, see § 1.385–1(d). For examples illustrating the rule in this paragraph (c)(1)(i), see paragraphs (f)(3)(iv) and (v) of this section (*Examples 4* and *5*).

(ii) *Consolidated group debt instrument that is transferred outside of the consolidated group.* For purposes of this section and § 1.385–3, when a member of a consolidated group that holds a consolidated group debt instrument transfers the debt instrument to an expanded group member that is not a member of the same consolidated group (transferee expanded group member), the debt instrument is treated as issued by the consolidated group to the transferee expanded group member immediately after the debt instrument ceases to be a consolidated group debt instrument. Thus, for example, for purposes of this section and § 1.385–3, the sale of a consolidated group debt instrument to a transferee expanded group member is treated as an issuance of the debt instrument by the consolidated group to the transferee expanded group member in exchange for property. To the extent the newly-issued debt instrument is a covered debt instrument that is treated as stock upon being transferred, the covered debt instrument is deemed to be exchanged for stock of the member of the consolidated group treated as the issuer of the debt instrument (determined under paragraph (b)(3)(i) of this section) immediately after the covered debt instrument is transferred outside of the consolidated group. For rules regarding the treatment of the deemed exchange, see § 1.385–1(d). For examples illustrating the rule in this paragraph (c)(1)(ii), see paragraphs (f)(3)(ii) and (iii) of this section (*Examples 2* and *3*).

(iii) *Overlap transactions.* If a debt instrument ceases to be a consolidated group debt instrument in a transaction to which both paragraphs (c)(1)(i) and (ii) of this section apply, then only the rules of paragraph (c)(1)(ii) of this section apply with respect to such debt instrument.

(iv) *Subgroup exception.* A debt instrument is not treated as ceasing to be a consolidated group debt instrument for purposes of paragraphs (c)(1)(i) and (ii) of this section if both the issuer and the holder of the debt instrument are members of the same consolidated group immediately after the transaction described in paragraph (c)(1)(i) or (ii) of this section.

(2) *Covered debt instrument treated as stock becomes a consolidated group debt instrument.* When a covered debt instrument that is treated as stock under § 1.385–3 becomes a consolidated group debt instrument, then immediately after the covered debt instrument becomes a consolidated group debt instrument, the issuer is deemed to issue a new covered debt instrument to the holder in exchange for the covered debt instrument that was treated as stock. In addition, in a manner consistent with § 1.385–3(d)(2)(ii)(A), when the covered debt instrument that previously was treated as stock becomes a consolidated group debt instrument, other covered debt instruments issued by the issuer of that instrument (including a consolidated group that includes the

issuer) that are not treated as stock when the instrument becomes a consolidated group debt instrument are re-tested to determine whether those other covered debt instruments are treated as funding the regarded distribution or acquisition that previously was treated as funded by the instrument (unless such distribution or acquisition is disregarded under paragraph (b)(1) of this section). Further, also in a manner consistent with § 1.385–3(d)(2)(ii)(A), a covered debt instrument that is issued by the issuer (including a consolidated group that includes the issuer) after the application of this paragraph (c)(2) and within the per se period may also be treated as funding that regarded distribution or acquisition.

(3) *No interaction with the intercompany obligation rules of § 1.1502–13(g).* The rules of this section do not affect the application of the rules of § 1.1502–13(g). Thus, any deemed satisfaction and reissuance of a debt instrument under § 1.1502–13(g) and any deemed issuance and deemed exchange of a debt instrument under this paragraph (c) that arise as part of the same transaction or series of transactions are not integrated. Rather, each deemed satisfaction and reissuance under the rules of § 1.1502–13(g), and each deemed issuance and exchange under the rules of this section, are respected as separate steps and treated as separate transactions.

(d) *Application of the funding rule of § 1.385–3(b)(3) to members departing a consolidated group.* This paragraph (d) provides rules for applying the funding rule of § 1.385–3(b)(3) when a departing member ceases to be a member of a consolidated group, but only if the departing member and the consolidated group are members of the same expanded group immediately after the deconsolidation.

(1) *Continued application of the one-corporation rule.* A disregarded distribution or acquisition by any member of the consolidated group continues to be disregarded when the departing member ceases to be a member of the consolidated group.

(2) *Continued recharacterization of a departing member's covered debt instrument as stock.* A covered debt instrument of a departing member that is treated as stock of the departing member under § 1.385–3(b) continues to be treated as stock when the departing member ceases to be a member of the consolidated group.

(3) *Effect of issuances of covered debt instruments that are not consolidated group debt instruments on the departing member and the consolidated group.* If a departing member has issued a covered debt instrument (determined without regard to the one-corporation rule described in paragraph (b)(1) of this section) that is not a consolidated group debt instrument and that is not treated as stock immediately before the departing member ceases to be a consolidated group member, then the departing member (and not the consolidated group) is treated as issuing the covered debt instrument on the date and in the manner the covered debt instrument was issued. If the departing member is not treated as the issuer of a covered debt instrument pursuant to the preceding sentence, then the consolidated group continues to be treated as issuing the covered debt instrument on the date and in the manner the covered debt instrument was issued.

(4) *Treatment of prior regarded distributions or acquisitions.* This paragraph (d)(4) applies when a departing member ceases to be a consolidated group member in a transaction other than a distribution to which section 355 (or so much of section 356 as relates to section 355) applies, and the consolidated group has made a regarded distribution or acquisition. In this case, to the extent the distribution or acquisition has not caused a covered debt instrument of the consolidated group to be treated as stock under § 1.385–3(b) on or before the date the departing member leaves the consolidated group, then—

(i) If the departing member made the regarded distribution or acquisition (determined without regard to the one-corporation rule described in paragraph (b)(1) of this section), the departing member (and not the consolidated group) is treated as having made the regarded distribution or acquisition.

(ii) If the departing member did not make the regarded distribution or acquisition (determined without regard to the one-corporation rule described in paragraph (b)(1) of this section), then the consolidated group (and not the departing member) continues to be treated as having made the regarded distribution or acquisition.

(e) *Definitions.* The definitions in this paragraph (e) apply for purposes of this section.

(1) *Consolidated group debt instrument.* The term *consolidated group debt instrument* means a covered debt instrument issued by a member of a consolidated group and held by a member of the same consolidated group.

(2) *Departing member.* The term *departing member* means a member of an expanded group that ceases to be a member of a consolidated group but continues to be a member of the same expanded group. In the case of multiple members leaving a consolidated group as a result of a single transaction that continue to be members of the same expanded group, if such members are treated as one corporation under paragraph (b)(1) of this section immediately after the transaction, that one corporation is a departing member with respect to the consolidated group.

(3) *Disregarded distribution or acquisition.* The term *disregarded distribution or acquisition* means a distribution or acquisition described in § 1.385–3(b)(2) or (b)(3)(i) between members of a consolidated group that is disregarded under the one-corporation rule described in paragraph (b)(1) of this section.

(4) *Joining member.* The term *joining member* means a member of an expanded group that becomes a member of a consolidated group and continues to be a member of the same expanded group. In the case of multiple members joining a consolidated group as a result of a single transaction that continue to be members of the same expanded group, if such members were treated as one corporation under paragraph (b)(1) of this section immediately before the transaction, that one corporation is a joining member with respect to the consolidated group.

(5) *Regarded distribution or acquisition.* The term *regarded distribution or acquisition* means a distribution or acquisition described in § 1.385–3(b)(2) or (b)(3)(i) that is not disregarded under the one-corporation rule described in paragraph (b)(1) of this section.

(f) *Examples*—(1) *Assumed facts.* Except as otherwise stated, the following facts are assumed for purposes of the examples in paragraph (f)(3) of this section:

(i) FP is a foreign corporation that owns 100% of the stock of USS1, a covered member, and 100% of the stock of FS, a foreign corporation;

(ii) USS1 owns 100% of the stock of DS1 and DS3, both covered members;

(iii) DS1 owns 100% of the stock of DS2, a covered member;

(iv) FS owns 100% of the stock of UST, a covered member;

(v) At the beginning of Year 1, FP is the common parent of an expanded group comprised solely of FP, USS1, FS, DS1, DS2, DS3, and UST (the FP expanded group);

(vi) USS1, DS1, DS2, and DS3 are members of a consolidated group of which USS1 is the common parent (the USS1 consolidated group);

(vii) The FP expanded group has outstanding more than $50 million of

debt instruments described in § 1.385–3(c)(4) at all times;

(viii) No issuer of a covered debt instrument has a positive expanded group earnings account, within the meaning of § 1.385–3(c)(3)(i)(B), or has received a qualified contribution, within the meaning of § 1.385–3(c)(3)(ii)(B);

(ix) All notes are covered debt instruments, within the meaning of § 1.385–3(g)(3), and are not qualified short-term debt instruments, within the meaning of § 1.385–3(b)(3)(vii);

(x) All notes between members of a consolidated group are intercompany obligations within the meaning of § 1.1502–13(g)(2)(ii);

(xi) Each entity has as its taxable year the calendar year;

(xii) No domestic corporation is a United States real property holding corporation within the meaning of section 897(c)(2);

(xiii) Each note is issued with adequate stated interest (as defined in section 1274(c)(2)); and

(xiv) Each transaction occurs after January 19, 2017.

(2) *No inference.* Except as otherwise provided in this section, it is assumed for purposes of the examples in paragraph (f)(3) of this section that the form of each transaction is respected for Federal tax purposes. No inference is intended, however, as to whether any particular note would be respected as indebtedness or as to whether the form of any particular transaction described in an example in paragraph (f)(3) of this section would be respected for Federal tax purposes.

(3) *Examples.* The following examples illustrate the rules of this section.

(i) *Example 1: Order of operations*—(A) *Facts.* On Date A in Year 1, UST issues UST Note to USS1 in exchange for DS3 stock representing less than 20% of the value and voting power of DS3.

(B) *Analysis.* UST is acquiring the stock of DS3, the non-common parent member of a consolidated group. Pursuant to paragraph (b)(5)(i) of this section, the transaction is first analyzed without regard to the one-corporation rule described in paragraph (b)(1) of this section, and therefore UST is treated as issuing a covered debt instrument in exchange for expanded group stock. The exchange of UST Note for DS3 stock is not an exempt exchange within the meaning of § 1.385–3(g)(11) because UST and USS1 are not parties to an asset reorganization. Pursuant to paragraph (b)(5)(ii) of this section, § 1.385–3 (including § 1.385–3(b)(2)(ii)) is then applied to the transaction, thereby treating UST Note as stock for Federal tax purposes when it is issued by UST to USS1. The UST Note is not treated as property for purposes of section 304(a) because it is not property within the meaning specified in section 317(a). Therefore, UST's acquisition of DS3 stock from USS1 in exchange for UST Note is not an acquisition described in section 304(a)(1).

(ii) *Example 2: Distribution of consolidated group debt instrument*—(A) *Facts.* On Date A in Year 1, DS1 issues DS1 Note to USS1 in a distribution. On Date B in Year 2, USS1 distributes DS1 Note to FP.

(B) *Analysis.* Under paragraph (b)(1) of this section, the USS1 consolidated group is treated as one corporation for purposes of § 1.385–3. Accordingly, when DS1 issues DS1 Note to USS1 in a distribution on Date A in Year 1, DS1 is not treated as issuing a debt instrument to another member of DS1's expanded group in a distribution for purposes of § 1.385–3(b)(2), and DS1 Note is not treated as stock under § 1.385–3. When USS1 distributes DS1 Note to FP, DS1 Note is deemed satisfied and reissued under § 1.1502–13(g)(3)(ii), immediately before DS1 Note ceases to be an intercompany obligation. Under paragraph (c)(1)(ii) of this section, when USS1 distributes DS1 Note to FP, the USS1 consolidated group is treated as issuing DS1 Note to FP in a distribution on Date B in Year 2. Accordingly, DS1 Note is treated as stock under § 1.385–3(b)(2)(i). Under paragraph (c)(1)(ii) of this section, DS1 Note is deemed to be exchanged for stock of the issuing member, DS1, immediately after DS1 Note is transferred outside of the USS1 consolidated group. Under paragraph (c)(3) of this section, the deemed satisfaction and reissuance under § 1.1502–13(g)(3)(ii) and the deemed issuance and exchange under paragraph (c)(1)(ii) of this section, are respected as separate steps and treated as separate transactions.

(iii) *Example 3: Sale of consolidated group debt instrument*—(A) *Facts.* On Date A in Year 1, DS1 lends $200x of cash to USS1 in exchange for USS1 Note. On Date B in Year 2, USS1 distributes $200x of cash to FP. Subsequently, on Date C in Year 2, DS1 sells USS1 Note to FS for $200x.

(B) *Analysis.* Under paragraph (b)(1) of this section, the USS1 consolidated group is treated as one corporation for purposes of § 1.385–3. Accordingly, when USS1 issues USS1 Note to DS1 for property on Date A in Year 1, the USS1 consolidated group is not treated as a funded member, and when USS1 distributes $200x to FP on Date B in Year 2, that distribution is a transaction described in § 1.385–3(b)(3)(i)(A), but does not cause USS1 Note to be recharacterized under § 1.385–3(b)(3). When DS1 sells USS1 Note to FS, USS1 Note is deemed satisfied and reissued under § 1.1502–13(g)(3)(ii), immediately before USS1 Note ceases to be an intercompany obligation. Under paragraph (c)(1)(ii) of this section, when the USS1 Note is transferred to FS for $200x on Date C in Year 2, the USS1 consolidated group is treated as issuing USS1 Note to FS in exchange for $200x on that date. Because USS1 Note is issued by the USS1 consolidated group to FS within the per se period as defined in § 1.385–3(g)(19) with respect to the distribution by the USS1 consolidated group to FP, USS1 Note is treated as funding the distribution under § 1.385–3(b)(3)(iii)(A) and, accordingly, is treated as stock under § 1.385–3(b)(3). Under § 1.385–3(d)(1)(i) and paragraph (c)(1)(ii) of this section, USS1 Note is deemed to be exchanged for stock of the issuing member, USS1, immediately after USS1 Note is transferred outside of the USS1 consolidated group. Under paragraph (c)(3) of this section, the deemed satisfaction and reissuance under § 1.1502–13(g)(3)(ii) and the deemed issuance and exchange under paragraph (c)(1)(ii) of this section are respected as separate steps and treated as separate transactions.

(iv) *Example 4: Treatment of consolidated group debt instrument and departing member's regarded distribution or acquisition when the issuer of the instrument leaves the consolidated group*—(A) *Facts.* The facts are the same as provided in paragraph (f)(1) of this section, except that USS1 and FS own 90% and 10% of the stock of DS1, respectively. On Date A in Year 1, DS1 distributes $80x of cash and newly-issued DS1 Note, which has a value of $10x, to USS1. Also on Date A in Year 1, DS1 distributes $10x of cash to FS. On Date B in Year 2, FS purchases all of USS1's stock in DS1 (90% of the stock of DS1), resulting in DS1 ceasing to be a member of the USS1 consolidated group.

(B) *Analysis.* Under paragraph (b)(1) of this section, the USS1 consolidated group is treated as one corporation for purposes of § 1.385–3. Accordingly, DS1's distribution of $80x of cash to USS1 on Date A in Year 1 is a disregarded distribution or acquisition, and under paragraph (d)(1) of this section, continues to be a disregarded distribution or acquisition when DS1 ceases to be a member of the USS1 consolidated group. In addition, when DS1 issues DS1 Note to USS1 in a distribution on Date A in Year 1, DS1 is not treated as issuing a debt instrument to a member of DS1's expanded group in a distribution for purposes of § 1.385–3(b)(2)(i), and DS1 Note is not treated as stock under § 1.385–3(b)(2)(i). DS1's issuance of DS1 Note to USS1 is also a disregarded distribution or acquisition, and under paragraph (d)(1) of this section, continues to be a disregarded distribution or acquisition when DS1 ceases to be a member of the USS1 consolidated group. The distribution of $10x cash by DS1 to FS on Date A in Year 1 is a regarded distribution or acquisition. When FS purchases 90% of the stock of DS1's from USS1 on Date B in Year 2 and DS1 ceases to be a member of the USS1 consolidated group, DS1 Note is deemed satisfied and reissued under § 1.1502–13(g)(3)(ii), immediately before DS1 Note ceases to be an intercompany obligation. Under paragraph (c)(1)(i) of this section, for purposes of § 1.385–3, DS1 is treated as issuing a new debt instrument to USS1 in exchange for property immediately after DS1 Note ceases to be a consolidated group debt instrument. Under paragraph (d)(4)(i) of this section, the departing member, DS1 (and not the USS1 consolidated group) is treated as having distributed $10x to FS on Date A in Year 1 (a regarded distribution or acquisition) for purposes of applying § 1.385–3(b)(3) after DS1 ceases to be a member of the USS1 consolidated group. Because DS1 Note is reissued by DS1 to USS1 within the per se period (as defined in § 1.385–3(g)(19)) with respect to DS1's regarded distribution to FS, DS1 Note is treated as funding the distribution under § 1.385–3(b)(3)(iii)(A) and,

accordingly, is treated as stock under § 1.385–3(b)(3). Under § 1.385–3(d)(1)(i) and paragraph (c)(1)(i) of this section, DS1 Note is immediately deemed to be exchanged for stock of DS1 on Date B in Year 2. Under paragraph (c)(3) of this section, the deemed satisfaction and reissuance under § 1.1502–13(g)(3)(ii) and the deemed issuance and exchange under paragraph (c)(1)(i) of this section are respected as separate steps and treated as separate transactions. Under § 1.385–3(d)(7)(i), after DS1 Note is treated as stock held by USS1, DS1 Note is not treated as stock for purposes of determining whether DS1 is a member of the USS1 consolidated group.

(v) *Example 5: Treatment of consolidated group debt instrument and consolidated group's regarded distribution or acquisition*—(A) *Facts.* On Date A in Year 1, DS1 issues DS1 Note to USS1. On Date B in Year 2, USS1 distributes $100x of cash to FP. On Date C in Year 3, USS1 sells all of its interest in DS1 to FS, resulting in DS1 ceasing to be a member of the USS1 consolidated group.

(B) *Analysis.* Under paragraph (b)(1) of this section, the USS1 consolidated group is treated as one corporation for purposes of § 1.385–3. Accordingly, when DS1 issues DS1 Note to USS1 in a distribution on Date A in Year 1, DS1 is not treated as issuing a debt instrument to a member of DS1's expanded group in a distribution for purposes of § 1.385–3(b)(2)(i), and DS1 Note is not treated as stock under § 1.385–3(b)(2)(i). DS1's issuance of DS1 Note to USS1 is also a disregarded distribution or acquisition, and under paragraph (d)(1) of this section, continues to be a disregarded distribution or acquisition when DS1 ceases to be a member of the USS1 consolidated group. The distribution of $100x cash by DS1 to USS1 on Date B in Year 2 is a regarded distribution or acquisition. When FS purchases all of the stock of DS1 from USS1 on Date C in Year 3 and DS1 ceases to be a member of the USS1 consolidated group, DS1 Note is deemed satisfied and reissued under § 1.1502–13(g)(3)(ii), immediately before DS1 Note ceases to be an intercompany obligation. Under paragraph (c)(1)(i) of this section, for purposes of § 1.385–3, DS1 is treated as issuing a new debt instrument to USS1 in exchange for property immediately after DS1 Note ceases to be a consolidated group debt instrument. Under paragraph (d)(4)(ii) of this section, the USS1 consolidated group (and not DS1) is treated as having distributed $100x to FP on Date B in Year 2 (a regarded distribution or acquisition) for purposes of applying § 1.385–3(b)(3) after DS1 ceases to be a member of the USS1 consolidated group. Because DS1 has not engaged in a regarded distribution or acquisition that would have been treated as funded by the reissued DS1 Note, the reissued DS1 Note is not treated as stock.

(vi) *Example 6: Treatment of departing member's issuance of a covered debt instrument*—(A) *Facts.* On Date A in Year 1, FS lends $100x of cash to DS1 in exchange for DS1 Note. On Date B in Year 2, USS1 distributes $30x of cash to FP. On Date C in Year 2, USS1 sells all of its DS1 stock to FP, resulting in DS1 ceasing to be a member of the USS1 consolidated group.

(B) *Analysis.* Under paragraph (b)(1) of this section, the USS1 consolidated group is treated as one corporation for purposes of § 1.385–3. Accordingly, on Date A in Year 1, the USS1 consolidated group is treated as issuing DS1 Note to FS, and on Date B in Year 2, the USS1 consolidated group is treated as distributing $30x of cash to FP. Because DS1 Note is issued by the USS1 consolidated group to FS within the per se period as defined in § 1.385–3(g)(19) with respect to the distribution by the USS1consoldiated group of $30x cash to FP, $30x of DS1 Note is treated as funding the distribution under § 1.385–3(b)(3)(iii)(A), and, accordingly, is treated as stock on Date B in Year 2 under § 1.385–3(b)(3) and § 1.385–3(d)(1)(ii). Under paragraph (d)(3) of this section, DS1 (and not the USS1 consolidated group) is treated as the issuer of the remaining portion of DS1 Note for purposes of applying § 1.385–3(b)(3) after DS1 ceases to be a member of the USS1 consolidated group.

(g) *Applicability date.* This section applies to taxable years for which the U.S. Federal income tax return is due, without extensions, after May 14, 2020. For taxable years ending on or after January 19, 2017, and for which the U.S. Federal income tax return is due, without extensions, on or before May 14, 2020, see § 1.385–4T, as contained in 26 CFR in part 1 in effect on April 1, 2019. In the case of a taxable year that ends after October 13, 2019, and on or before May 14, 2020, a taxpayer may choose to apply this section to the portion of the taxable year that occurs after the expiration of § 1.385–4T on October 13, 2019, provided that all members of the taxpayer's expanded group apply this section in its entirety.

Sunita Lough,

Deputy Commissioner for Services and Enforcement.

Approved: April 2, 2020.

David J. Kautter,

Assistant Secretary of the Treasury (Tax Policy).

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R02–OAR–2018–0681; FRL–10007–39–Region 2]

Approval and Air Quality Implementation Plans; New Jersey; Infrastructure SIP for Interstate Transport Requirements for the Requirements for the 2006 PM_{10}, 2008 Lead, 2010 Nitrogen Dioxide, and the 2011 Carbon Monoxide National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving the portions of New Jersey's State Implementation Plan (SIP) revision submittal regarding infrastructure requirements for interstate transport of pollution with respect to the 2006 particulate matter of 10 microns (μm) or less (PM_{10}), 2008 lead, 2010 nitrogen dioxide (NO_2), and 2011 carbon monoxide (CO) National Ambient Air Quality Standards (NAAQS).

DATES: This final rule is effective June 15, 2020.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R02–OAR–2018–0681. All documents in the docket are listed on the *http://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Kenneth Fradkin, Air Programs Branch, Environmental Protection Agency, Region 2 Office, 290 Broadway, 25th Floor, New York, New York 10007–1866, (212) 637–3702, or by email at *fradkin.kenneth@epa.gov.*

SUPPLEMENTARY INFORMATION:

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I. What is the background for this action?

Under sections 110(a)(1) and (2) of the Clean Air Act (CAA), each state is required to submit a State Implementation Plan (SIP) that provides for the implementation, maintenance, and enforcement of a revised primary or secondary NAAQS or standard. CAA sections 110(a)(1) and (2) require each state to make a new SIP submission within three years after the EPA promulgates a new or revised NAAQS for approval into the existing federally approved SIP to assure that the SIP meets the applicable requirements for such new and revised NAAQS. This particular type of SIP submission is commonly referred to as an ''infrastructure SIP.''

Section 110(a)(2)(D)(i)(I) of the CAA requires a state's SIP to include adequate provisions prohibiting any emissions activity in one state that contributes significantly to nonattainment, or interferes with maintenance, of the NAAQS in any downwind state. The EPA sometimes refers to these requirements as prong 1 (significant contribution to nonattainment) and prong 2 (interference with maintenance), or jointly as the ''good neighbor'' provision of the CAA.

On December 13, 2019 (84 FR 68097), the EPA published a Notice of Proposed Rulemaking (NPR) in the **Federal Register** for the State of New Jersey. The NPR proposed to approve elements of the State of New Jersey's Infrastructure SIP submission, dated October 17, 2014, which were submitted to address CAA section 110(a) infrastructure requirements for the following NAAQS: 2006 PM_{10}, 2008 lead, 2010 NO_2, and 2011 CO. Specifically, the EPA proposed in the December 13, 2019 action to approve the portion of the submission addressing the good neighbor provision with respect to the 2006 PM_{10}, 2008 lead, 2010 NO_2, and 2011 CO NAAQS under CAA section 110(a)(2)(D)(i)(I).

Other detailed information relevant to this action on New Jersey's infrastructure SIP submission, including infrastructure requirements concerning the good neighbor provision, and the rationale for EPA's proposed action are explained in the NPR and the associated Technical Support Document (TSD) in the docket and are not restated here.

II. What comments were received in response to the EPA's proposed action?

The EPA received three comments from two commenters in response to the December 13, 2019 NPR. The EPA has evaluated the comments, as discussed below, and has determined that New Jersey's SIP revision addressing the 2006 PM_{10}, 2008 lead, 2010 NO_2, and 2011 CO NAAQS is consistent with the CAA and, therefore, the EPA is approving New Jersey's SIP revision. Following is a summary of the comments and the EPA's response. The full text of the comments may also be viewed under Docket ID Number EPA–R02–OAR–2018–0681 on the *http://www.regulations.gov* website.

Comment: The commenter states that the EPA should consider mandating the use of renewable energy as NO_2, CO, CO_2, and other gases are byproducts of fossil fuel combustion, and New Jersey uses mostly natural gas to generate electricity. The commenter asserts that a federal mandate similar to California's for renewable energy would better serve the EPA's long-term goals for better air quality.

Response: This comment is outside the scope of our proposed action and is not relevant to the approval of New Jersey's interstate transport provisions for the 2006 PM_{10}, 2008 lead, 2010 NO_2, and 2011 CO NAAQS under CAA section 110(a)(2)(D)(i)(I). The EPA's review of New Jersey's SIP revision under CAA section 110(k)(3) is limited to evaluating whether the submission meets the applicable requirements of CAA section 110(a)(2)(D)(i)(I), as detailed further in the NPR and associated TSD. The EPA is not authorized to issue any sort of federal mandate regarding renewable energy in reviewing a state's SIP revision under these provisions.[1] As the commenter has not raised any issues regarding whether New Jersey's SIP revision meets the applicable requirements of section 110(a)(2)(D)(i)(I), the comment is outside the scope of the EPA's proposed action.

Comment: The commenter questioned how the EPA can rely on data for the PM_{10} NAAQS which uses monitors with incomplete or no air monitoring data for PM_{10} for almost 5 years. The commenter further stated that the data in Table 3 in the TSD is at best inconclusive, and the EPA should use only monitors that have complete quality assured data to show whether monitors are violating the NAAQS. The commenter indicates that the monitors with the incomplete data are closest to the state borders, Camden, New Jersey (NJ)—1 kilometer (km); New York, New York (NY)—3 km; Bronx, NY—6 km; and Queens, NY—17 km. The commenter also states that with four out of the seven monitors closest to the New Jersey border showing incomplete data over the past five years (and a fifth monitor considering 2013–2015 data), the EPA must gather more data or show that this data is not needed before proceeding with approval.

Response: In our evaluation of New Jersey's SIP revision, the EPA considered both recent PM_{10} design values (Table 3 of the TSD), as well as maximum annual 24-hour PM_{10} concentrations (Table 4 of the TSD) for active monitoring sites within 50 kilometers of New Jersey borders, as well as the absence of nearby nonattainment and maintenance areas for the 24-hour PM_{10} NAAQS and downward emission trends. The EPA finds this weight-of-evidence analysis is sufficient to conclude that New Jersey has met its interstate transport obligations pursuant to CAA section 110(a)(2)(D)(i)(I), and that no additional air monitoring data is necessary as suggested by the commenter.

The EPA agrees with the commenter that there are limited complete, quality assured PM_{10} design values shown in Table 3 of the TSD, PM_{10} Design Values Within 50 kilometers of New Jersey Borders. There are seven air monitoring sites located within 50 kilometers of the State's borders. Four of the seven air monitoring locations (*i.e.,* Camden, NJ; New York, NY; Bronx, NY and Queens, NY had incomplete design values as shown in Table 3 for the two most recent three-year periods available[2] (2016–2018, and 2015–2017). Additionally, the New York, Bronx and Queens air monitoring sites began operation in January 2017 and, therefore, ''No data'' is shown in Table 3 for the three-year monitoring periods in 2014–2016, and 2013–2015. The EPA, however, disagrees with the commenter that the design values listed are at best inconclusive. The design values shown in Table 3 show the average number of exceedances at each air monitoring site,

[1] Although EPA cannot impose renewable energy requirements in New Jersey in the context of reviewing a SIP revision under CAA section 110(k)(3), the EPA notes that the Governor of New Jersey approved, on May 23, 2018, a State Renewable Energy bill (A–3723), requiring 21 percent of the energy sold in the state to be from renewable energy sources by 2020; 35 percent by 2025, and 50 percent by 2030 (see *https://www.nj.gov/governor/news/news/562018/approved/20180523a_cleanEnergy.shtml*). On January 27, 2020 New Jersey released its Energy Master Plan. *https://nj.gov/emp/docs/pdf/2020_NJBPU_EMP.pdf; https://www.nj.gov/governor/news/news/562020/approved/20200127a.shtml.*

[2] Design values are computed and published annually by the EPA's Office of Air Quality Planning and Standards and reviewed in conjunction with the EPA Regional Offices. At the time of the proposed rulemaking, the latest design values available from the EPA based on air quality data reported and certified by New Jersey was from 2016–2018. Design values are available at *https://www.epa.gov/air-trends/air-quality-design-values.*

deemed valid based on the completeness criteria found in 40 CFR part 50, appendix K. PM_{10} design values, which are used by the EPA to determine attainment of the PM_{10} NAAQS, require three years of representative monitoring data that meets 75 percent data capture,[3] if available.[4] The design values in Table 3 are shown as incomplete if they do not meet minimum completeness criteria.

At air monitoring locations in Lehigh County, Pennsylvania (PA); Hudson County, NJ; and Essex County, NJ, there were zero exceedances for the three most recent three-year periods 2016–2018, 2015–2017, and 2014–2016. These monitor locations are within 50 km of New Jersey's borders with other states: Hudson, NJ—2 km; Essex County, NJ—8 km and Lehigh, PA—20 km. When considered with other data included in the EPA's weight-of-evidence analysis, the absence of violating design values at those locations is an indication that New Jersey is not contributing significantly to nonattainment or interfering with maintenance in those areas since no violations or exceedances have occurred.

The commenter indicated that the Agency should consider only quality assured air monitoring data to show violations of the 24-Hour PM_{10} NAAQS. The commenter further notes the significance of incomplete data from the Camden, NJ, New York, NY, Bronx, NY, and Queens, NY sites since they are closest (*i.e.,* 1 to 17 km away) to State borders. The EPA agrees that the four locations would yield useful information regarding New Jersey's interstate transport contribution provisions based on their close proximity to New Jersey borders. However, the EPA does not conclude that only design values that meet completeness requirements may be considered as part of the weight of evidence analysis used to support approving New Jersey's SIP revision. When determining whether an area has met the NAAQS, the EPA relies only on complete quality assured monitoring data; however, in this rulemaking, the EPA is not making a determination of attainment. There is no regulation, statute, or other requirement that an interstate transport analysis rely only on complete data for determining whether a state has met its interstate transport obligations under 110(a)(2)(D)(i)(I). Rather, the EPA finds it is reasonable to consider any available and relevant data that assists with its consideration regarding whether there may be an air quality problem in downwind states that is impacted by emissions from an upwind state.

Due to the limited number of ''valid'' design values available at active monitoring sites with incomplete data located within 50 kilometers of New Jersey borders, the EPA also considered maximum annual 24-Hour PM_{10} concentrations (Table 4 of the TSD) at the same active monitoring locations for 2013 through 2018. Most of the data considered was well above 75 percent data capture, which means the data was above the level for completeness when considered on an annual basis.[5] The air monitoring data considered was quality-assured and certified using the Federal Reference Method or equivalent data, and was reported by states, tribes or local agencies into EPA's Air Quality System (AQS).

Maximum 24-Hour PM_{10} concentrations at all seven monitoring sites located within 50 kilometers of the State's borders continue to be well below the level of the 150 micrograms per cubic meter ($\mu g/m^3$) NAAQS. As shown in Table 4 of the TSD, the most recent data available (2017 through 2018) shows that maximum PM_{10} concentrations were 30 percent or less of the level of the 24-Hour PM_{10} NAAQS. In 2017, the highest maximum 24-Hour PM_{10} concentrations was 45 $\mu g/m^3$ (Camden County, NJ). In 2018, the highest maximum 24-Hour PM_{10} concentration was 44 $\mu g/m^3$ (Hudson County, NJ).

The EPA continues to determine, based on the information in the NPR and TSD, that there is sufficient PM_{10} air monitoring data, when considered with the other information evaluated as part of the EPA's weight-of evidence interstate transport analysis, to conclude that New Jersey has met its interstate transport obligations under 110(a)(2)(D)(i)(I). For the 24-Hour PM_{10} NAAQS, there are no current or recent violating design values within 50 kilometers of New Jersey's borders. Further, our review of air monitoring data for New Jersey, and the neighboring states of Pennsylvania, New York, and Delaware, shows no violating design values in any of the air monitors located throughout all areas of those states for the most recently available period (2016–2018). Additionally, maximum 24-Hour PM_{10} concentrations are currently all well below the level of the 150 $\mu g/m^3$ NAAQS. The lack of exceedances or violations in any of the air quality monitoring data indicates that there are no areas located within 50 km of New Jersey's border that are likely to be in nonattainment of the PM_{10} NAAQS or to struggle to maintain the standards.

Comment: The commenter asked what specific measures were adopted by the State that control NO_2 and CO on a 1-hour and 8-hour basis. The commenter states that none of the measures listed in the EPA's NPR or TSD or New Jersey's submission discuss control measures which control NO_2 or CO emissions on a short-term basis. The commenter indicates that the EPA should only approve transport elements for NO_2 and CO if control measures control emissions on a short-term basis. The commenter claims that just because annual emissions have decreased as the EPA has shown in Table 7 and 9 (of the TSD) doesn't mean these measures are able to control NO_2 at the 1-hour interval or CO at the 8-hour interval. The commenter further asks the EPA to explain how these control measures control 1-hour NO_2 emissions or 8-hour CO emissions.

Response: The EPA disagrees with the commenter that the EPA should only approve transport elements for NO_2 and CO if New Jersey control measures control emissions on a short-term basis, such as on a 1-hour or 8-hour basis. Additionally, because the EPA did not rely on New Jersey control methods to support approval of New Jersey's interstate transport SIP, these comments regarding whether or how New Jersey measures control NO_2 or CO emissions on a short-term basis (or 1-hour and 8-hour basis or interval) are not relevant to this action.

Although New Jersey included a list of relevant control measures in its October 2014 SIP submittal, the EPA did not rely on specific control measures to support the EPA's conclusion that New Jersey's SIP adequately addresses the good neighbor provision for the CO and NO_2 NAAQS. In our evaluation of the New Jersey's interstate transport SIP, the EPA considered ambient air quality data, the lack of nearby nonattainment and maintenance areas, and downward emission trends to determine that New Jersey did not contribute significantly to

[3] For PM_{10} a complete set of data includes a minimum of 75 percent of the scheduled PM_{10} samples per quarter. See 40 CFR part 50, appendix K, section 2.3(a).

[4] Data not meeting the criteria in 40 CFR part 50 may also suffice to show attainment; however such exceptions must be approved by the appropriate Regional Administrator in accordance with EPA guidance. See 40 CFR part 50, appendix K, section 2.3.

[5] The EPA has added to the docket of this rulemaking annual data completeness data for each of the air monitoring sites considered in our analysis. See AQS data completeness reports (AMP430), and AQS Quick Look Reports (AMP450). Data completeness for all sites in 2017 and 2018 were well above 75 percent data capture, except for the Camden site, which had 74 percent data capture in 2018. The previous year (2017) at the Camden site had 92% data capture.

potential downwind nonattainment and maintenance in another state and, therefore, New Jersey has met its obligations pursuant to 110(a)(2)(D)(i)(I) with respect to the 2010 NO_2 and 2011 CO NAAQS.

Because there are no indications that there are current or potential air quality problems in other states to which emissions from New Jersey would contribute, the EPA has concluded that New Jersey is not required to ''prohibit'' any particular amount of emissions. Rather, the EPA interprets the statute to only require a SIP to include enforceable control measures prohibiting emissions where the EPA has first concluded that emissions from the upwind state will significant contribute to downwind nonattainment or interfere with downwind maintenance of the NAAQS. *See, e.g.,* 83 FR 65866–888; 84 FR 56077–078. Accordingly, the EPA does not agree with the commenter that New Jersey's SIP must include measures specifically designed to control any particular level of NO_2 or CO emissions in order to satisfy the requirements of CAA section 110(a)(2)(D)(i)(I).

The commenter has not raised any concerns with the adequacy of the EPA's analysis of potential downwind air quality problems in other states, nor has the commenter offered any data or evidence suggesting that New Jersey is contributing significantly to nonattainment or interfering with maintenance in another state, or that control of short-term emissions of NO_2 or CO is necessary to address any alleged nonattainment or maintenance concerns in neighboring states.

The EPA finds that the ambient air quality data, the lack of nearby nonattainment and maintenance areas, and emission trends are sufficient to conclude that there are no current or potential air quality problems in other states and, therefore, New Jersey's SIP is adequate to prohibit emissions that significantly contribute to nonattainment or interfere with maintenance of the 2010 NO_2 and 2011 CO NAAQS.

III. What action is the EPA taking?

The EPA is approving the portions of New Jersey's SIP revision submittal dated October 17, 2014, addressing interstate transport for the 2006 PM_{10}, 2008 lead, 2010 NO_2, and 2011 CO NAAQS as these portions meet the infrastructure SIP requirements in section 110(a)(2)(D)(i)(I) of the CAA.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rulemaking action, pertaining to New Jersey's section 110(a)(2) infrastructure requirements for the 2006 PM_{10}, 2008 lead, 2010 NO_2, and 2011 CO NAAQS is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 13, 2020. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: April 19, 2020.

Peter Lopez,

Regional Administrator, Region 2.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart FF—New Jersey

■ 2. In § 52.1570, the table in paragraph (e) is amended by adding the entry ''NJ Infrastructure SIP for the 2006 PM_{10}, 2008 Lead, 2010 Nitrogen Dioxide, and the 2011 Carbon Monoxide NAAQS; Interstate Transport Provisions'' at the end of the table to read as follows:

§ 52.1570 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED NEW JERSEY NONREGULATORY AND QUASI-REGULATORY PROVISIONS

SIP element	Applicable geographic or nonattainment area	New Jersey submittal date	EPA approval date	Explanation
*	*	*	*	*
NJ Infrastructure SIP for the 2006 PM_{10}, 2008 Lead, 2010 Nitrogen Dioxide, and the 2011 Carbon Monoxide NAAQS; Interstate Transport Provisions.	State-wide	October 17, 2014	May 14, 2020, [insert **Federal Register** citation].	This action addresses the following CAA elements: 110(a)(2)(D)(i)(I) prongs 1 and 2.

■ 3. In § 52.1586, paragraph (b)(1) is amended by adding a sentence at the end of the paragraph to read as follows:

§ 52.1586 Section 110(a)(2) infrastructure requirements.

* * * * *

(b) * * *

(1) * * * Submittal from New Jersey dated October 17, 2014 to address the CAA infrastructure requirements of section 110(a)(2) for the 2006 PM_{10}, 2008 Lead, 2010 Nitrogen Dioxide, and the 2011 Carbon Monoxide NAAQS is approved for (D)(i)(I).

* * * * *

[FR Doc. 2020–08646 Filed 5–13–20; 8:45 am]

BILLING CODE 6560–50–P

Proposed Rules

Federal Register
Vol. 85, No. 94
Thursday, May 14, 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–2020–0471; Project Identifier MCAI–2019–00126–E]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Canada Corp. Turboshaft Engines

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 Pratt & Whitney Canada Corp. (P&WC) PT6B–37A model turboshaft engines with engine serial number PCE–PU0289 and earlier. This proposed AD was prompted by a report of contamination from galvanic corrosion between the fuel control unit (FCU) aluminum body and the steel union fitting causing the loss of engine control, resulting in an engine over-speed condition and subsequent in-flight shutdown (IFSD). This proposed AD would require replacing the FCU with a part eligible for installation. 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 June 29, 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 Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; website: *https://www.pwc.ca/en/.* 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.

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–2020–0471; 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, the mandatory continuing airworthiness information (MCAI), 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: 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:

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–2020–0471; Project Identifier MCAI–2019–00126–E'' 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.

Except for Confidential Business Information as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, 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 NPRM.

Confidential Business Information

Confidential Business Information (CBI) is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Mehdi Lamnyi, Aerospace Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA, 01803. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Discussion

Transport Canada Civil Aviation (Transport Canada), which is the aviation authority for Canada, has issued Transport Canada AD CF–2019–05, dated February 19, 2019 (referred to after this as ''the MCAI''), to address the unsafe condition on these products. The MCAI states:

> There has been one reported incident on a PT6B–37A engine, where the contamination from galvanic corrosion between the FCU aluminum body and the steel union fitting has caused the loss of engine control, resulting in an engine over-speed condition and subsequently leading to an engine inflight shutdown (IFSD). This condition, if not corrected, could lead to additional cases of IFSDs, which on a single engine helicopter may result in an emergency autorotation landing. To address the subject galvanic corrosion problem in the FCU, P&WC has issued Service Bulletin (SB) 39107 to replace the affected FCUs with a modified FCU that is not susceptible to the subject galvanic corrosion problem. This [Transport Canada] AD mandates compliance with P&WC SB 39107, requiring the replacement of the

affected FCUs to mitigate the potential unsafe condition.

You may obtain further information by examining the MCAI in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0471.

Related Service Information Under 1 CFR Part 51

The FAA reviewed P&WC Service Bulletin (SB) No. PT6B–72–39107, Revision No. 1, dated December 13, 2017. The SB describes procedures for replacing the FCU. 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

This product has been approved by the aviation authority of Canada and is approved for operation in the United States. Pursuant to our bilateral agreement with Canada, Transport Canada, its technical representative has notified us of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because it evaluated all the relevant information provided by Transport Canada and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require replacing the FCU with a part eligible for installation.

Differences Between This Proposed AD and the Service Information

P&WC SB No. PT6B–72–39107, Revision No. 1, dated December 13, 2017, directs the replacement of both the FCU and the bypass valve cover. This proposed AD requires only the replacement of the FCU.

Costs of Compliance

The FAA estimates that this proposed AD affects 75 engines installed on helicopters of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Replace the FCU	1 work-hour × $85 per hour = $85	$37,000	$37,085	$2,781,375

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 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 this 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):

Pratt & Whitney Canada Corp: Docket No. FAA–2020–0471; Project Identifier MCAI–2019–00126–E.

(a) Comments Due Date

The FAA must receive comments by June 29, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Pratt & Whitney Canada Corp. (P&WC) PT6B–37A model turboshaft engines with engine serial number PCE–PU0289 and earlier, which do not have an installed fuel control unit (FCU) that incorporates a stainless steel air adapter using P&WC Service Bulletin (SB) No. PT6B–72–39107, Revision No. 1, dated December 13, 2017.

(d) Subject

Joint Aircraft System Component (JASC) Code 7321, Fuel Control/Turbine Engines.

(e) Unsafe Condition

This AD was prompted by a report of contamination from galvanic corrosion between the FCU aluminum body and the steel union fitting causing the loss of engine control, resulting in an engine over-speed condition and subsequent in-flight shutdown (IFSD). The FAA is issuing this AD to prevent failure of the FCU due to contamination from galvanic corrosion. The unsafe condition, if not addressed, could result in loss of engine control, failure of the engine, IFSD, and loss of the helicopter.

(f) Compliance

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

(g) Required Actions

Within the compliance time identified in Table 1 to paragraph (g) of this AD, replace the FCU with an FCU that incorporates the stainless steel air adapter using the Accomplishment Instruments, paragraphs 3.A. and 3.C., of P&WC SB No. PT6B–72–

39107, Revision No. 1, dated December 13, 2017.

TABLE 1 TO PARAGRAPH (g)—COMPLIANCE TIME REQUIREMENTS

	Compliance time [A or B, whichever occurs later after the effective date of this AD]
A	Before the FCU accumulates 1,500 flight hours, or before the FCU accumulates six years since new or last overhaul, whichever occurs first.
B	Within six months.

(h) Credit for Previous Actions

You may take credit for the replacement of the FCU that is required by paragraph (g) of this AD if you replaced the FCU with an FCU that incorporates a stainless steel air adapter before the effective date of this AD using P&WC SB No. PT6B–72–39107, Original Issue, dated December 15, 2016.

(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 ECO Branch, send it to the attention of the person identified in paragraph (j)(1) 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

(1) 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.*

(2) Refer to Transport Canada Civil Aviation (Transport Canada) AD CF–2019–05, dated February 19, 2019, for more information. You may examine the Transport Canada AD in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating it in Docket No. FAA–2020–0471.

(3) For service information identified in this AD, contact Pratt & Whitney Canada Corp., 1000 Marie-Victorin, Longueuil, Quebec, Canada, J4G 1A1; phone: 800–268–8000; fax: 450–647–2888; website: *https://www.pwc.ca/en/.* You may view this referenced 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.

Issued on May 5, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–09944 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0472; Product Identifier 2018–CE–060–AD]

RIN 2120–AA64

Airworthiness Directives; Textron Aviation Inc. 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 Textron Aviation Inc. (Textron) Models 180, 180A, 180B, 180C, 180D, 180E, 180F, 180G, 180H, 180J, 180K, 182, 182A, 182B, 182C, 182D, 185, 185A, 185B, 185C, 185D, 185E, A185E, and A185F airplanes. This proposed AD was prompted by a report of cracks found in the tailcone and horizontal stabilizer attachment structure. This proposed AD would require inspecting the tailcone and horizontal stabilizer for corrosion and cracks and repairing or replacing damaged parts as necessary. 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 June 29, 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 Textron Aviation Customer Service, P.O. Box 7706, Wichita, Kansas 67277, (316) 517–5800; *customercare@txtav.com; https://txtav.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

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–2020–0472; 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, the regulatory evaluation, 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: Tara Shawn, Aerospace Engineer, Wichita ACO Branch, 1801 Airport Road, Room 100, Wichita, Kansas 67209; telephone: (316) 946–4141; fax: (316) 946–4107; email: *tara.shawn@faa.gov* or *Wichita-COS@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–2020–0472; Product Identifier 2018–CE–060–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 received, 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 NPRM.

Discussion

The FAA received a report of cracks in the tailcone and horizontal stabilizer attachment structure on a Textron (type certificate previously held by Cessna Aircraft Company) Model 185 airplane. It was observed during maintenance that the horizontal stabilizer tail section moved up and down and had excessive play. After a detailed inspection, the tailcone reinforcement braces were found cracked on both sides of the airplane. Upon further investigation, the FAA discovered similar conditions on 29 additional Textron 180 and 185 series airplanes. The FAA determined that the combination of the attachment structure design and high loads during landing contribute to the development of cracks in the tailcone and horizontal stabilizer attachment structure. This condition, if unaddressed, could result in failure of the horizontal stabilizer to tailcone attachment and lead to tail separation with consequent loss of control of the airplane.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Textron Aviation Single Engine Mandatory Service Letter SEL–55–01, dated December 7, 2017. The service information contains procedures for inspecting the stabilizer hinge brackets, tailcone reinforcement angles, corner reinforcements, stabilizer hinge reinforcement channel, stabilizer hinge assemblies, stabilizer aft spar reinforcement, and the lower half of the stabilizer aft spar from station (STA) 16 on the left side of the stabilizer aft spar to STA 16 on the right side for cracks and corrosion. 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 it 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.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously.

Differences Between This Proposed AD and the Service Information

The service information applies to airplanes with more than 3,000 total hours time-in-service or 10 years in service, while this proposed AD would apply regardless of the airplane's time-in-service. This proposed AD would require inspecting for and replacing loose or sheared rivets, which is not specified in the service information.

Costs of Compliance

The FAA estimates that this proposed AD would affect 6,586 airplanes of U.S. registry.

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

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	2 work-hours × $85 per hour = $170	Not applicable	$170	$1,119,620

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. The FAA has no way of determining the number of aircraft that might need these actions:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace left-hand (LH) stabilizer hinge bracket	4 work-hours × $85 per workhour = $340	$551	$891
Replace right-hand (RH) stabilizer hinge bracket	4 work-hours × $85 per workhour = $340	530	870
Replace LH tailcone reinforcement angle	12 work-hours × $85 per workhour = $1,020	2,291	3,311
Replace RH tailcone reinforcement angle	12 work-hours × $85 per workhour = $1,020	3,006	4,026
Replace LH corner reinforcement	6 work-hours × $85 per workhour = $510	169	679
Replace RH corner reinforcement	6 work-hours × $85 per workhour = $510	390	900
Replace LH stabilizer hinge reinforcement channel	6 work-hours × $85 per workhour = $510	99	609
Replace RH stabilizer hinge reinforcement channel	6 work-hours × $85 per workhour = $510	99	609
Replace LH stabilizer hinge assembly	1 work-hours × $85 per workhour = $85	570	655
Replace RH stabilizer hinge assembly	1 work-hours × $85 per workhour = $85	694	779
Replace LH stabilizer aft spar reinforcement	*	825	825
Replace RH stabilizer aft spar reinforcement	*	466	466
Replace stabilizer aft spar (* includes work-hour cost for replacing stabilizer aft spar reinforcement parts).	28* work-hours × $85 per workhour = $2,380	563	2,943
Remove and replace horizontal and vertical stabilizers and rig flight controls.	8 work-hours × $85 per workhour = $680	(*)	680

* Not applicable.

Since corrosion may affect any or all of the parts subject to the inspection in this proposed AD differently and the severity of the corrosion on each part would affect the time necessary to correct the condition, the FAA has no way to determine an overall cost per product for removing the corrosion. Similarly, loose or sheared rivets may also affect any or all of the parts subject to the inspection in this proposed AD differently, and the time necessary to correct the condition on each product would be different. Therefore, the FAA has no way to determine an overall cost

per product for replacing loose or sheared rivets.

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 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 this 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):

Textron Aviation Inc.: Docket No. FAA–2020–0472; Product Identifier 2018–CE–060–AD.

(a) Comments Due Date

The FAA must receive comments by June 29, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Textron Aviation Inc. (type certificate previously held by Cessna Aircraft Company) Models 180, 180A, 180B, 180C, 180D, 180E, 180F, 180G, 180H, 180J, 180K, 182, 182A, 182B, 182C, 182D, 185, 185A, 185B, 185C, 185D, 185E, A185E, and A185F airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 53, Fuselage; 55, Stabilizers.

(e) Unsafe Condition

This AD was prompted by a report of cracks found in the tailcone and horizontal stabilizer attachment structure. The FAA is issuing this AD to detect and correct corrosion and cracks in the tailcone and horizontal stabilizer attachment structure. The unsafe condition, if not addressed, could result in failure of the horizontal stabilizer to tailcone attachment, which could lead to tail separation with consequent loss of control of the airplane.

(f) Compliance

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

(g) Inspect, Repair, and Replace

Within the next 100 hours time-in-service (TIS) after the effective date of this AD or within the next 12 months after the effective date of this AD, whichever occurs later, and thereafter every 500 hours TIS or 5 years, whichever occurs first, visually inspect each stabilizer hinge bracket, tailcone reinforcement angle, corner reinforcement, stabilizer hinge reinforcement channel, stabilizer hinge assembly, stabilizer aft spar reinforcement, and the lower half of the stabilizer aft spar from station (STA) 16 on the left side to STA 16 on the right side for corrosion and cracks; remove any corrosion; and replace any part with a crack by following the Accomplishment Instructions, paragraphs 9 through 11 and 13, of Textron Aviation Single Engine Mandatory Service Letter SEL–55–01, dated December 7, 2017. Also inspect for loose rivets and sheared rivets. If there is a loose or sheared rivet, before further flight, replace the rivet.

(h) Credit for Previous Actions

Actions accomplished before the effective date of this AD within the previous 5 years or 500 hours TIS, whichever was the most recent, in accordance with the procedures specified in the documents listed in paragraphs (h)(i) through (viii) of this AD as applicable to your airplane are considered acceptable for compliance with the corresponding actions in paragraph (g) of this AD. The time between any inspection for which credit is allowed by this paragraph and the next inspection accomplished in accordance with paragraph (g) of this AD must not exceed 500 hours TIS or 5 years, whichever occurs first.

(i) Cessna Aircraft Company Model 100 Series (1953–1962) Service Manual, Supplemental Inspection Number: 53–10–01, D138–1–13 Temporary Revision Number 8, dated May 18, 2015.

(ii) Cessna Aircraft Company Model 100 Series (1963–1968) Service Manual, Supplemental Inspection Number: 53–10–01, D637–1–13 Temporary Revision Number 10, dated May 18, 2015;

(iii) Cessna Aircraft Company Model 180/185 Series (1969–1980) Service Manual, Supplemental Inspection Number: 53–10–01, D2000–9–13 Temporary Revision Number 9, dated May 18, 2015.

(iv) Cessna Aircraft Company Model 180/185 Series (1981–1985) Service Manual, Supplemental Inspection Number: 53–10–01, D2067–1TR9 Temporary Revision Number 9, dated May 1, 2016.

(v) Cessna Aircraft Company Model 100 Series (1953–1962) Service Manual, Supplemental Inspection Number: 55–10–01, D138–1–13 Temporary Revision Number 7, dated December 1, 2011.

(vi) Cessna Aircraft Company Model 100 Series (1963–1968) Service Manual, Supplemental Inspection Number: 55–10–01, D637–1–13 Temporary Revision Number 9, dated December 1, 2011.

(vii) Cessna Aircraft Company Model 180/185 Series (1969–1980) Service Manual, Supplemental Inspection Number: 55–10–01, D2000–9–13 Temporary Revision Number 7, dated December 1, 2011.

(viii) Cessna Aircraft Company Model 180/185 Series (1981–1985) Service Manual, Supplemental Inspection Number: 55–10–01, D2067–1–13 Temporary Revision Number 7, dated December 1, 2011.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Wichita 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) of this AD.

(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

(1) For more information about this AD, contact Tara Shawn, Aerospace Engineer, Wichita ACO Branch, 1801 Airport Road,

Room 100, Wichita, Kansas 67209; telephone: (316) 946–4141; fax: (316) 946–4107; email: *tara.shawn@faa.gov* or *Wichita-COS@faa.gov.*

(2) For service information identified in this AD, contact Textron Aviation Customer Service, P.O. Box 7706, Wichita, Kansas 67277, (316) 517–5800; *customercare@txtav.com; https://txtav.com.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on May 8, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–10316 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0473; Product Identifier 2018–CE–058–AD]

RIN 2120–AA64

Airworthiness Directives; Polskie Zaklady Lotnicze Sp. z o.o. Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Polskie Zaklady Lotnicze Sp. z o.o. Model PZL M28 05 airplanes. This proposed AD results from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as defective thermo-shrinkable tubes installed on the electrical harnesses located in the fuel tanks. 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 June 29, 2020.

ADDRESSES: You may send comments 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:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Polskie Zaklady Lotnicze Sp. z o.o., Wojska Polskiego 3, 39–300 Mielec, Poland, +48 17 743 1901, email: *pzl.lm@lmco.com,* internet: *www.pzlmielec.pl.* You may review this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

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–2020–0473; 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 proposed AD, the regulatory evaluation, 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: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2020–0473; Product Identifier 2018–CE–058–AD'' at the beginning of your comments. The FAA specifically invites comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. The FAA will consider all comments received by the closing date and may amend this proposed AD because of those comments.

The FAA will post all comments we receive, without change, to *https://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 European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued AD No. 2018–0242, dated October 8, 2018 (referred to after this as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> During accomplishment of maintenance on an M28 05 military version airplane, torn pieces of thermo-shrinkable tubes were found in the header section of the main fuel tank. These tubes are installed on electrical harnesses located in the fuel tanks and serve as marking and protection devices against mechanical damage during manufacturing and servicing. Pieces of these tubes may travel with the fuel flow and may block the jet pump or reduce its performance, particularly in the centre-wing fuel tank, in which the jet pump is the only way of further transfer of fuel to the engine. Subsequent investigation determined that degradation of the tube material was caused by a manufacturing deficiency, leading to insufficient material resistance against mechanical damage when a tube is located in a fuel.
>
> This condition, if not detected and corrected, could lead to reduced fuel supply to the engines, inability to use all the fuel in fuel tanks and reduced available engine power, resulting in reduced aeroplane performance.
>
> To address this potentially unsafe condition, PZL identified the batch of aeroplanes that are potentially equipped with thermo-shrinkable tubes having this manufacturing defect, and issued the [service bulletin] SB providing inspection and replacement instructions.
>
> For the reasons described above, this [EASA] AD requires a one-time inspection of the electrical harnesses located in the fuel tanks and, depending on findings, replacement of the affected harness.

Polskie Zaklady Lotnicze Sp. z o.o. informed us the potential for damage to the thermo-shrinkable tubes does not progress with time. Therefore, we determined repetitive inspections are not required. You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0473.

Related Service Information Under 1 CFR Part 51

Polskie Zaklady Lotnicze Sp. z o.o. has issued Service Bulletin No. E/12.141/2018, dated May 15, 2018. The service information contains procedures for inspecting the thermo-shrinkable tubes on the electrical harnesses in the center and outer wing fuel tanks for damage and replacing any electrical harness with damaged thermo-shrinkable tubes. 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 and Requirements of the Proposed AD

This product has been approved by the aviation authority of another country, and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is proposing this AD because it evaluated all information and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design.

Costs of Compliance

The FAA estimates that this proposed AD would affect 15 products of U.S. registry. The FAA also estimates that it would take about 3 work-hours per product to comply with the basic inspection requirement of this proposed AD. The average labor rate is $85 per work-hour.

Based on these figures, the FAA estimates the cost of the proposed AD on U.S. operators to be $3,825, or $255 per product.

In addition, the FAA estimates that any necessary follow-on replacement action would take about 60 work-hours and require parts costing $5,000, for a cost of $10,100 per electrical harness. The FAA has no way of determining the number of products that may need these actions.

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 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 this 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):

Polskie Zaklady Lotnicze Sp. z o.o.: Docket No. FAA–2020–0473; Product Identifier 2018–CE–058–AD.

(a) Comments Due Date

The FAA must receive comments by June 29, 2020.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Polskie Zaklady Lotnicze Sp. z o.o. Model PZL M28 05 airplanes, serial numbers AJE00301 through AJE00343, and AJE00345 through AJE00347, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 28: Fuel Tank.

(e) Reason

This AD was prompted by mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as defective thermo-shrinkable tubes installed on the electrical harnesses located in the fuel tanks. The FAA is issuing this AD to prevent broken pieces of the thermo-shrinkable tubes from blocking the jet pump, reducing fuel supply to the engines, and resulting in the inability to use all the fuel in the fuel tanks. This condition could lead to reduced engine power and airplane performance.

(f) Actions and Compliance

Unless already done, do the following actions in paragraphs (f)(1) and (2) of this AD:

(1) Within the next 200 hours time-in-service (TIS) after the effective date of this AD or within the next 8 months after the effective date of this AD, whichever occurs first:

(i) Inspect each electrical wire harness in the center wing and the left-hand and right-hand outer wing fuel tanks for cracking, tears, and seizing of the thermo-shrinkable tubes in accordance with paragraphs II.1 through 2 a) of the Procedure for Bulletin Execution section in Polskie Zaklady Lotnicze Sp. z o.o. Service Bulletin No. E/12.141/2018, dated May 15, 2018.

(ii) If there is a tear or any cracking in or any seizing of an electrical wire harness thermo-shrinkable tube, before further flight, replace the harness in accordance with section II. a) Replacement of harness KL8 (KP), II. b) Replacement of Harness KL9 (KP9), or II. c) Replacement of harness KL10 (KP10), as applicable, of the Procedure for Bulletin Execution in Polskie Zaklady Lotnicze Sp. z o.o. Service Bulletin No. E/12.141/2018, dated May 15, 2018.

(2) As of the effective date of this AD, do not install any electrical wire harness part number 28.14.7205.073.000, 28.14.7205.074.000, 28.14.7205.075.000, 28.14.7205.076.000, 28.14.7205.077.000, or 28.14.7205.078.000, that has more than zero hours TIS on any airplane, unless it has passed the inspection required by paragraph (f)(1)(i) of this AD.

(g) Alternative Methods of Compliance (AMOCs)

The Manager, Small Airplane Standards Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Doug Rudolph, Aerospace Engineer, FAA, Small Airplane Standards Branch, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329–4059; fax: (816) 329–4090; email: *doug.rudolph@faa.gov*. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No. 2018–0242, dated October 8, 2018, for related information. You may examine the MCAI on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–0473.

For service information related to this AD, contact Polskie Zaklady Lotnicze Sp. z o.o., Wojska Polskiego 3, 39–300 Mielec, Poland, +48 17 743 1901, email: *pzl.lm@lmco.com,* internet: *www.pzlmielec.pl.* You may review this referenced service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on May 6, 2020.

Gaetano A. Sciortino,

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

[FR Doc. 2020–10015 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–0483; Product Identifier 2016–SW–066–AD]

RIN 2120–AA64

Airworthiness Directives; MD Helicopters Inc. (MDHI), Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain MD Helicopters Inc. (MDHI), Model 369A, 369D, 369E, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters. This proposed AD would require tap inspecting each main rotor (MR) blade leading edge abrasion strip and is prompted by reports of abrasion strips departing the MR blade in-flight. The proposed actions are intended to prevent an unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by July 13, 2020.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *https://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

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–2020–0483; 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 proposed AD, 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 service information identified in this proposed rule, contact Helicopter Technology Company, LLC, address 12902 South Broadway, Los Angeles, CA 90061; telephone (310) 523–2750; email *gburdorf@helicoptertech.com;* or at *http://www.helicoptertech.com.* You may view the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy, Room 6N–321, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Payman Soltani, Aviation Safety Engineer, Los Angeles ACO Branch, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5313; email *payman.soltani@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to participate in this rulemaking by submitting written comments, data, or views. The FAA also invites comments relating to the economic, environmental, energy, or federalism impacts that might result from adopting the proposals in this document. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit only one time.

The FAA will file in the docket all comments received, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments received on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments received.

Discussion

The FAA proposes to adopt a new AD for MDHI Model 369A, 369D, 369E, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters with an MR blade part number (P/N) 500P2100–105, P/N 500P2100–305, P/N 500P2300–505, P/N 369D21120–505, P/N 369D21121–505, or P/N 369D21123–505, with a 1.25-inch chord length nickel abrasion strip (abrasion strip) manufactured or installed by Helicopter Technology Company (HTC) or where the manufacturer of the abrasion strip is unknown. This proposed AD would require tap inspecting the abrasion strip within 10 hours time-in-service (TIS) and thereafter before the first flight of each day until the abrasion strip has accumulated 700 hours TIS since installation.

This proposed AD is prompted by reports that leading edge abrasion strips manufactured by HTC are departing the MR blades during flight. An investigation determined that the abrasion strips were manufactured from electroformed nickel, have a chord length of 1.25 inch, and are delaminating from the MR blade before departing from the helicopter. HTC has determined that a repetitive tap inspection of the abrasion strips should be performed on all blades with abrasion strips that have less than 700 hours TIS to detect any voids, including blistering, bubbling, or lifting of the abrasion strip. Identical looking electroformed nickel abrasion strips with a chord length of 1.25 inch manufactured by other repair stations have not departed in flight and therefore are not the subject of this proposed AD. If the manufacturer of the installed abrasion strip is unknown, this proposed AD would apply to the strip.

FAA's Determination

The FAA is proposing this AD because the agency evaluated all known relevant information and determined that an unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information Under 1 CFR Part 51

The FAA reviewed HTC Mandatory Service Bulletin Notice No. 2100–8R4, dated June 1, 2017, which specifies a daily tap inspection of the MR blade abrasion strip to detect voids. If there are any voids, the SB specifies repairing or replacing the MR blade, depending on the size, quantity, and location of any damage.

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.

Proposed AD Requirements

This proposed AD would require, within 10 hours TIS and thereafter before the first flight of each day until the abrasion strip reaches 700 hours TIS, tap inspecting the leading edge abrasion strip for a void. If there is a void within 0.5 inch (12.7 mm) of the edge of the abrasion strip, the proposed AD would require replacing the blade with an airworthy blade before further flight. If there is a void that is not within 0.5 inch (12.7 mm) from the edge of the abrasion strip and is larger than 0.5 square inch (322.6 square mm) or if there is more than one void of any size, the proposed AD would require replacing the blade with an airworthy blade before further flight.

Costs of Compliance

The FAA estimates that this proposed AD would affect 50 helicopters of U.S. Registry.

The FAA estimates that operators may incur the following costs in order to comply with this AD. At an average labor rate of $85 per hour, tap-testing the MR blades will require about 0.25 work-hour, for a cost per helicopter of $22 per inspection cycle.

If required, replacing an MR blade would require 1 work-hour, and required parts would cost up to $24,130, for a cost per helicopter of $24,215.

According to HTC's service information some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. The FAA does not control warranty coverage by HTC. Accordingly, the FAA has included all costs in our cost estimate.

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 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, I certify this proposed regulation:

1. Is not a ''significant regulatory action'' under Executive Order 12866;
2. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; 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):

MD Helicopters Inc. (MDHI): Docket No. FAA–2020–0483; Product Identifier 2016–SW–066–AD.

(a) Applicability

This AD applies to MD Helicopters Inc. (MDHI), Model 369A, 369D, 369E, 369FF, 369H, 369HE, 369HM, 369HS, 500N, and 600N helicopters, certificated in any category, with a main rotor (MR) blade part number (P/N) 500P2100–105, P/N 500P2100–305, P/N 500P2300–505, P/N 369D21120–505, P/N 369D21121–505, or P/N 369D21123–505 with a 1.25 inch chord length nickel abrasion strip (abrasion strip) manufactured or installed by Helicopter Technology Company (HTC) or where the manufacturer of the abrasion strip is unknown. This AD does not apply if the abrasion strip has accumulated 700 or more hours time-in-service (TIS).

(b) Unsafe Condition

This AD defines the unsafe condition as failure of the bond between the leading edge abrasion strip and an MR blade. This condition could result in the abrasion strip departing the MR blade in-flight, subsequent imbalance of the rotor system, and loss of control of the helicopter.

(c) Comments Due Date

The FAA must receive comments by July 13, 2020.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 10 hours TIS and thereafter before the first flight of each day, tap inspect each MR blade leading edge abrasion strip for a void in accordance with Part 1—Inspection, paragraphs 2 through 4, of HTC Mandatory Service Bulletin Notice No. 2100–8R4, dated June 1, 2017.

(1) If there is a void within 0.5 inch (12.7 mm) of the edge of the abrasion strip, before further flight, replace the MR blade.

(2) If there is a void larger than 0.5 square inch (322.6 square mm) or if there is more than one void of any size, before further flight, replace the MR blade.

(f) Alternative Methods of Compliance (AMOC)

(1) The Manager, Los Angeles ACO Branch, FAA, may approve AMOCs for this AD. Send your proposal to: Payman Soltani, Aviation Safety Engineer, Los Angeles ACO Branch, FAA, 3960 Paramount Blvd., Lakewood, California 90712; telephone (562) 627–5313; email *9-ANM-LAACO-AMOC-REQUESTS@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, the FAA suggests that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

(g) Subject

Joint Aircraft Service Component (JASC) Code: 6210, Main Rotor Blade.

Issued on May 8, 2020.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2020–10246 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2020–0426; Airspace Docket No. 20–AGL–22]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Coshocton, OH

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend the Class E airspace extending upward from 700 feet above the surface at Richard Downing Airport, Coshocton, OH. The FAA is proposing this action as the result of an airspace review caused by the development of new instrument procedures at this airport.

DATES: Comments must be received on or before June 29, 2020.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590; telephone (202) 366–9826, or (800) 647–5527. You must identify FAA Docket No. FAA–2020–0426/Airspace Docket No. 20–AGL–22, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.* You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays.

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 Airspace Policy 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: Jeffrey Claypool, Federal Aviation Administration, Operations Support Group, Central Service Center, 10101 Hillwood Parkway, Fort Worth, TX 76177; telephone (817) 222–5711.

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 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 amend the Class E airspace extending upward from 700 feet above the surface at Richard Downing Airport, Coshocton, OH, to support instrument flight rule operations at this airport.

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 and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. FAA–2020–0426/Airspace Docket No. 20–AGL–22.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of the comments received. 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 the **ADDRESSES** section for the 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 Federal Aviation Administration, Air Traffic Organization, Central Service Center, Operations Support Group, 10101 Hillwood Parkway, Fort Worth, TX 76177.

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.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by amending the Class E airspace extending upward from 700 feet above the surface by adding an extension 2 miles each side of the 217° bearing from the Richard Downing Airport, Coshocton, OH, extending from the 6.5-mile radius of the airport to 9.3 miles southwest of the airport.

This action is the result of an airspace review caused by the development of new instrument procedures at this airport.

Class E airspace designations are published in paragraph 6005 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 Class E airspace designations listed in this document will be published subsequently 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 regulation only involves an established body of technical regulations for which

frequent and routine amendments are necessary to keep them operationally current, is non-controversial and unlikely to result in adverse or negative comments. It, therefore: (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 will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, would 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

Accordingly, pursuant to the authority delegated to me, 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 14 CFR 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 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

AGL OH E5 Coshocton, OH [Amended]

Richard Downing Airport, OH
(Lat. 40°18′37″ N, long. 81°51′09″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Richard Downing Airport, and within 2 miles each side of the 037° bearing from the airport extending from the 6.5-mile radius to 8.6 miles northeast of the airport, and within 2 miles each side of the 217° bearing from the airport extending from the 6.5-mile radius to 9.3 miles southwest of the airport.

Issued in Fort Worth, Texas, on April 11, 2020.

Steven T. Phillips,

Acting Manager, Operations Support Group, ATO Central Service Center.

[FR Doc. 2020–10356 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2017–F–0969]

Food Additives Permitted in Feed and Drinking Water of Animals; Spent Bleaching Clay

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; petition for rulemaking; amendment.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending a notice of petition announcing that the Canadian Oilseed Processors Association has filed a petition proposing that the food additive regulations be amended to provide for the safe use of spent bleaching clay as a flow agent in canola meal for all livestock and poultry species. Additionally, the petition proposes that the regulations be amended to provide for the safe use of silicon dioxide and diatomaceous earth as components of spent bleaching clay. At our request, a revised environmental assessment (EA) has been placed in the docket for public review and comment.

DATES: Submit either electronic or written comments on the petitioner's environmental assessment by June 15, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 15, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 15, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–F–0969 for ''Food Additives Permitted in Feed and Drinking Water of Animals; Spent Bleaching Clay.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the

information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-02015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Cerrito, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl. (HFV–224), Rockville, MD 20855, 240–402–6729, *Chelsea.Cerrito@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under section 409(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348(b)(5)), notice was given in the **Federal Register** of April 18, 2017 (82 FR 18268), that a food additive petition (FAP 2299) has been filed by the Canadian Oilseed Processors Association, 404–167 Lombard Ave., Winnipeg MB R3B 0T6, Canada. The petition proposes to amend Title 21 of the Code of Federal Regulations (CFR) in part 573 *Food Additives Permitted in Feed and Drinking Water of Animals* (21 CFR part 573) to provide for the safe use of spent bleaching clay as a flow agent in canola meal for all livestock and poultry species. Additionally, the submission proposes that the existing regulations be amended to provide for the safe use of silicon dioxide (21 CFR 573.940) and diatomaceous earth (21 CFR 573.340) for use as components of spent bleaching clay.

In a **Federal Register** notice published on March 19, 2019 (84 FR 9989), an amendment was made to the petition to include an environmental assessment. Based on a review of that assessment, we have asked the petitioner to make revisions.

To encourage public participation consistent with regulations issued under the National Environmental Policy Act (40 CFR 1501.4(b)), we are placing the revised EA submitted with FAP 2299 on public display at the Dockets Management Staff (see **DATES** and **ADDRESSES**) for public review and comment.

We will also place on public display, at the Dockets Management Staff and at *https://www.regulations.gov,* any amendments to, or comments on, the petitioner's EA without further announcement in the **Federal Register**. If, based on our review, we find that an environmental impact statement is not required, and this petition results in a regulation, we will publish the notice of availability of our finding of no significant impact and the evidence supporting that finding with the regulation in the **Federal Register** in accordance with 21 CFR 25.51(b).

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10035 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–477]

Schedules of Controlled Substances: Placement of Zipeprol in Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Drug Enforcement Administration (DEA) proposes placing the substance zipeprol (Chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers and salts is possible, in schedule I of the Controlled Substances Act. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess), or propose to handle zipeprol.

DATES: Comments must be submitted electronically or postmarked on or before July 13, 2020.

Interested persons may file a request for hearing or waiver of hearing pursuant to 21 Code of Federal Regulations (CFR) 1308.44 and in accordance with 21 CFR 1316.45 and/or 1316.47, as applicable. Requests for hearing and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before June 15, 2020.

ADDRESSES: Interested persons may file written comments on this proposal in accordance with 21 CFR 1308.43(g). Commenters should be aware that the electronic Federal Docket Management System will not accept comments after 11:59 p.m. Eastern Time on the last day of the comment period. To ensure proper handling of comments, please reference ''Docket No. DEA–477'' on all electronic and written correspondence, including any attachments.

- *Electronic comments:* DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *http://www.regulations.gov* and follow the on-line instructions at that site for submitting comments. Upon completion of your submission you will receive a Comment Tracking Number for your comment. Please be aware that submitted comments are not instantaneously available for public view on *regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.
- *Paper comments:* Paper comments that duplicate electronic submissions are not necessary and are discouraged. Should you wish to mail a paper comment in lieu of an electronic comment, it should be sent via regular or express mail to: Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

• *Hearing requests:* All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for hearing and waivers of participation should also be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

FOR FURTHER INFORMATION CONTACT:

Scott A. Brinks, Regulatory Drafting and Policy Support Section, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (571) 362–3261.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record. They will, unless reasonable cause is given, be made available by the Drug Enforcement Administration (DEA) for public inspection online at *http://www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter. The Freedom of Information Act applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase ''PERSONAL IDENTIFYING INFORMATION'' in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase ''CONFIDENTIAL BUSINESS INFORMATION'' in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment.

Comments containing personal identifying information and confidential business information identified as directed above will generally be made publicly available in redacted form. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments posted to *http://www.regulations.gov* may include any personal identifying information (such as name, address, and phone number) included in the text of your electronic submission that is not identified as directed above as confidential.

An electronic copy of this document and supplemental information to this proposed rule are available at *http://www.regulations.gov* for easy reference.

Request for Hearing or Waiver of Participation in Hearing

Pursuant to 21 United States Code (U.S.C.) 811(a), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act, 5 U.S.C. 551–559. 21 CFR 1308.41–1308.45; 21 CFR part 1316, subpart D. Interested persons may file requests for a hearing or notices of intent to participate in a hearing in conformity with the requirements of 21 CFR 1308.44(a) or (b), and include a statement of interest in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any interested person may file a waiver of an opportunity for a hearing or to participate in a hearing together with a written statement regarding the interested person's position on the matters of fact and law involved in any hearing as set forth in 21 CFR 1308.44(c).

All requests for hearing and waivers of participation must be sent to DEA using the address information provided above.

Legal Authority

The United States is a party to the 1971 United Nations Convention on Psychotropic Substances (1971 Convention), February 21, 1971, 32 U.S.T. 543, 1019 U.N.T.S. 175, as amended. Procedures respecting changes in drug schedules under the 1971 Convention are governed domestically by 21 U.S.C. 811(d). When the United States receives notification of a scheduling decision pursuant to Article 2 of the 1971 Convention indicating that a drug or other substance has been added or transferred to a schedule specified in the notification, the Secretary of the Department of Health and Human Services (HHS),[1] after consultation with the Attorney General, shall first determine whether existing legal controls under subchapter I of the Controlled Substances Act (CSA) and the Federal Food, Drug, and Cosmetic Act (FDCA) meet the requirements of the schedule specified in the notification with respect to the specific drug or substance. 21 U.S.C. 811(d)(3). If such requirements are not met by existing controls and the Secretary of the HHS concurs in the scheduling decision, the Secretary shall recommend to the Attorney General that he initiate proceedings for scheduling the drug or substance under the appropriate schedule pursuant to 21 U.S.C. 811(a) and (b). 21 U.S.C. 811(d)(3)(B). Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, add to such a schedule or transfer between such schedules any drug or other substance, if he finds that such drug or other substance has a potential for abuse, and makes with respect to such drug or other substance the findings prescribed by 21 U.S.C. 812(b) for the schedule in which such drug is to be placed. The Attorney General has delegated this scheduling authority to the Administrator of the DEA (Administrator). 28 CFR 0.100.

Background

Zipeprol, known chemically as 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol, is pharmacologically an opioid drug with some hallucinogenic properties that has no approved medical use in the United States.

In June 1994 and January 1995, the Food and Drug Administration (FDA), on behalf of the Secretary of the HHS, published notices in the **Federal Register** regarding zipeprol to comply with 21 U.S.C. 811(d)(2). The 1994 notice requested information to be considered by the World Health Organization (WHO) in preparing its scientific and medical evaluation for zipeprol.[2] The 1995 notice solicited public comment regarding a recommendation by the WHO to impose international controls on zipeprol.[3] In

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within HHS in carrying out the Secretary's scheduling responsibilities under the Controlled Substances Act, with the concurrence of NIDA. 50 FR 9518 (March 8, 1985). The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460 (July 1, 1993).

[2] FDA notice, International Drug Scheduling; Convention on Psychotropic Substances; Certain Stimulant/Hallucinogenic Drugs and Certain Nonbarbiturate Sedative Drugs, 59 FR 31639 (June 20, 1994).

[3] FDA notice, International Drug Scheduling; Convention on Psychotropic Substances; World Health Organization Scheduling Recommendations

March 1995, the United Nations Commission on Narcotic Drugs (CND), on the advice of the Director-General of the WHO, placed zipeprol in Schedule II of the 1971 Convention.[4]

As a party to the 1971 Convention, the United States is taking action to place appropriate controls on zipeprol by scheduling it under the CSA after determining that no existing legal controls under subchapter I of the CSA and the FDCA meet the requirements of the scheduling decision with respect to zipeprol. 21 U.S.C. 811(d)(3). Specifically, DEA is proposing to place zipeprol in schedule I of the CSA. Placing zipeprol in schedule I of the CSA would satisfy the United States' international obligations as set forth in Article 2, paragraph 7(b) of the 1971 Convention, and as implemented by the CSA. 21 U.S.C. 811(d)(3).

Article 2, paragraph 7(b), of the 1971 Convention sets forth the minimum requirements that the United States must meet when a substance has been added to Schedule II of the 1971 Convention. Pursuant to the 1971 Convention, the United States must require licenses for the manufacture, export and import, and distribution of zipeprol. This license requirement is accomplished by the CSA's registration requirement as set forth in 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. In addition, the United States must adhere to specific export and import provisions set forth in the 1971 Convention. This requirement is accomplished by the CSA's export and import provisions established in 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312. Likewise, under Article 13, paragraphs 1 and 2, of the 1971 Convention, a party to the 1971 Convention may notify another party, through the Secretary-General of the United Nations, that it prohibits the importation of a substance in Schedule II, III, or IV of the Convention. If such notice is presented to the United States, the United States shall take measures to ensure that the named substance is not exported to the notifying country. This requirement is also accomplished by the CSA's export provisions mentioned above. Under Article 16, paragraph 4, of the 1971 Convention, the United States is required to provide annual statistical reports to the International Narcotics Control Board (INCB). Using INCB Form P, the United States shall provide the following information: (1) In regard to each substance in Schedule I and II of the 1971 Convention, quantities manufactured, exported to and imported from each country or region as well as stocks held by manufacturers; (2) in regard to each substance in Schedule II and III of the 1971 Convention, quantities used in the manufacture of exempt preparations; and (3) in regard to each substance in Schedule II—IV of the 1971 Convention, quantities used for the manufacture of non-psychotropic substances or products. Lastly, under Article 2 of the 1971 Convention, the United States must adopt measures in accordance with Article 22 to address violations of any statutes or regulations that are adopted pursuant to its obligations under the 1971 Convention. The United States complies with this provision as persons acting outside the legal framework established by the CSA are subject to administrative, civil, and/or criminal action.

Proposed Determination To Schedule Zipeprol

Pursuant to 21 U.S.C. 811(b), DEA gathered the necessary data on zipeprol and on April 3, 2009, submitted it to the Assistant Secretary for Health of the HHS with a request for a scientific and medical evaluation of available information and a scheduling recommendation for zipeprol. On May 20, 2013, HHS provided to DEA a written scientific and medical evaluation and scheduling recommendation entitled, ''Basis for the Recommendation for Control of Zipeprol and Its Salts in Schedule I of the Controlled Substances Act.'' Pursuant to 21 U.S.C. 811(b), this document contained HHS' eight-factor analysis of zipeprol, along with its recommendation that zipeprol be placed in schedule I of the CSA.

In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS and all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). Since receiving the HHS recommendation, no additional studies have been published in the scientific literature. Included below is a brief summary of each factor as analyzed by HHS and DEA in their respective eight-factor analyses, and as considered by DEA in its proposed scheduling determination. Please note that both DEA and HHS analyses are available in their entirety under ''Supporting Documents'' of the public docket for this proposed rule at *http://www.regulations.gov* under docket number ''DEA–477.''

1. *The Drug's Actual or Relative Potential for Abuse:* As reported by HHS, there are numerous reports indicating that abuse of zipeprol resulted in seizures, comas, amnesia, hallucinations, and death in countries where zipeprol has been marketed as an antitussive. The pharmacological effects of zipeprol are similar to opioids in schedule II of the CSA such as morphine; however, zipeprol is a weak opioid relative to morphine. Hallucinations, convulsions, and opioid-like tolerance and dependence are observed in humans following zipeprol intake. Zipeprol abuse is associated with psychological and physical dependence. Abuse liability studies suggest that the primary motivation for zipeprol abuse was reaching the opioid-like, hypnotic sedative effects and euphoria associated with this drug.

2. *Scientific Evidence of the Drug's Pharmacological Effects, if Known:* Zipeprol binds with low to moderate affinity to mu and kappa opioid receptors, has a moderate affinity for sigma 1 receptors, and has a strong affinity for sigma 2 receptors. Animal testing data in monkeys, rats and mice show that zipeprol is self-administered. Acute cardiovascular and respiratory toxicity was observed in animals continuously infused with zipeprol. Published clinical reports have indicated that euphoric effects are observed at doses ranging from 3- to 10-fold higher than the therapeutic daily dose range (75–150 mg/day). Generalized seizures were reported at relatively low doses (375 mg) but still higher than the therapeutic dose range.

3. *The State of Current Scientific Knowledge Regarding the Drug or Other Substance:* Zipeprol, also known as 1-methoxy-3-[4-(2-methoxy-2-phenylethyl) piperazin-1-yl]-1-phenylpropan-2-ol, has a molecular weight of 322.37 g/mol. Zipeprol is extensively metabolized in humans into four major metabolites. Zipeprol is not expected to be detected in urine with a normal pH. When urine pH rises above 6.2, unchanged zipeprol is reabsorbed whereas under acidic urine conditions (pH < 5.0), approximately 1–5 percent of zipeprol is excreted unchanged. There is no currently accepted medical use of zipeprol in the United States. In other countries, zipeprol was used as a cough suppressant (antitussive), but there is no longer any reported manufacture of, consumption of, stocks or trade of zipeprol.

4. *Its History and Current Pattern of Abuse:* There have been numerous

for Seven Drug Substances, 60 FR 4169, 4173 (January 20, 1995).

[4] United Nations Office on Drugs and Crime, CND. Decision 2 (XXXVIII). Inclusion of zipeprol in Schedule II of the Convention on Psychotropic Substances of 1971. *https://www.unodc.org/pdf/decisions/decision2_38.pdf* (last retrieved October 3, 2018).

reports of zipeprol abuse from Brazil, Chile, France, Italy, Mexico, the Republic of Korea, Switzerland, and the former Yugoslavia during the 1980s and 1990s. These reports suggest the sedative, hallucinogenic, and euphorigenic effects of zipeprol, and its ability to suppress some signs of opioid withdrawal at high doses, may be the reasons for its abuse. It is important to note that the ability of one opioid to suppress withdrawal from a different opioid does not represent a beneficial effect. Ease of obtaining zipeprol by over-the-counter access may have contributed to its widespread abuse in some countries. Following these reports, many countries in Asia, Europe, and South America discontinued medical use of zipeprol. Incidences of zipeprol abuse were not reported after placement of zipeprol in Schedule II of the 1971 Convention on Psychotropic Substances in 1995 (CND Dec. 38/2). Queries of DEA's System to Retrieve Information from Drug Evidence (STRIDE)/STARLiMS [5] and the National Forensic Laboratory Information System (NFLIS) [6] databases on October 3, 2018, did not generate any reports of zipeprol, suggesting that it is not trafficked in the United States.

5. *The Scope, Duration, and Significance of Abuse:* The lack of abuse and overdose associated with zipeprol is most likely due to its lack of availability for medical use in the United States.

6. *What, if any, Risk There is to the Public Health:* Currently in the United States, zipeprol is not an FDA-approved drug, and there have been no reports or epidemiological studies submitted to FDA regarding its abuse. In countries where it was available for medical use, zipeprol became a significant health problem. Based on the available clinical data, zipeprol has the same risks to public health as schedule I or schedule II substances. Such risks include deaths due to voluntary or accidental acute intoxications and the potential for psychological and physical dependence.

7. *Its Psychic or Physiological Dependence Liability:* Psychological and physiological dependence is associated with zipeprol. Several clinical studies examined and described physical dependence and withdrawal effects associated with zipeprol abuse. Main signs of zipeprol withdrawal include sweating, diarrhea, anxiety, insomnia, dyspnea, yawning, and pain. The euphoric and hallucinogenic effects associated with zipeprol and other opioid-like drugs serve as reinforcers and can result in psychological dependence and are supported by case studies with zipeprol abusers.

8. *Whether the Substance is an Immediate Precursor of a Substance Already Controlled Under the CSA:* DEA and HHS find that zipeprol is not an immediate precursor of a substance already controlled under the CSA.

Conclusion: Based on consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and based on DEA's consideration of its own eight-factor analysis, DEA finds that these facts and all relevant data constitute substantial evidence of potential for abuse of zipeprol. As such, DEA hereby proposes to schedule zipeprol as a controlled substance under the CSA.

Proposed Determination of Appropriate Schedule

The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also outlines the findings required to place a drug or other substance in any particular schedule. 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of the HHS and review of all available data, the Acting Administrator of the DEA (Acting Administrator), pursuant to 21 U.S.C. 812(b)(1), finds that:

(1) Zipeprol has a high potential for abuse. Widespread reports of zipeprol abuse have occurred in countries that have marketed zipeprol. Zipeprol is self-administered in animals and clinical studies reported that zipeprol abuse is related to its opioid, sedative, hallucinogenic, and euphorigenic effects. Epidemiological reports on zipeprol, worldwide, have indicated that adverse reactions (primarily seizures) are caused by zipeprol abuse and dependence.

(2) There are no approved New Drug Applications for zipeprol and no known therapeutic applications for zipeprol in the United States.[7] Therefore, zipeprol has no currently accepted medical use in treatment in the United States.

(3) There is a lack of accepted safety for use of zipeprol under medical supervision. Zipeprol was first approved and introduced as an antitussive in France and Italy during the late 1970s. Following several reports of abuse and overdosing from zipeprol, this drug was withdrawn in the early to mid-1990s.

Based on these findings, the Acting Administrator concludes that zipeprol warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1). More precisely, because of its opioid effects, and producing opioid-like tolerance and dependence in humans, DEA is proposing to place zipeprol in 21 CFR 1308.11(b) (the opiates category of schedule I). As such, the proposed control of zipeprol includes the substance as well as its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, whenever the existence of such isomers, esters, ethers and salts is possible within the specific chemical designation.

Requirements for Handling Zipeprol

If this rule is finalized as proposed, zipeprol would be subject to the CSA's schedule I regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, import, export, engagement in research, conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances, including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses) zipeprol, or who desires to handle zipeprol, would need to be registered with DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312 as of the effective date of a final scheduling action. Any person who currently handles zipeprol, and is not registered with DEA, would need to submit an application for registration

[5] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from DEA, other federal agencies, and law enforcement agencies. On October 1, 2014, STARLiMS replaced STRIDE as DEA laboratory drug evidence data system of record.

[6] NFLIS is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by state and local forensic laboratories across the country. The NFLIS participation rate, defined as the percentage of the national drug caseload represented by laboratories that have joined NFLIS, is over 97 percent. NFLIS includes drug chemistry results from completed analyses only.

[7] Although there is no evidence suggesting that zipeprol has a currently accepted medical use in treatment in the United States, it bears noting that a drug cannot be found to have such medical use unless DEA concludes that it satisfies a five-part test. Specifically, with respect to a drug that has not been approved by the FDA, to have a currently accepted medical use in treatment in the United States, all of the following must be demonstrated:

i. the drug's chemistry must be known and reproducible;

ii. there must be adequate safety studies;

iii. there must be adequate and well-controlled studies proving efficacy;

iv. the drug must be accepted by qualified experts; and

v. the scientific evidence must be widely available.

57 FR 10499 (1992).

and may not continue to handle zipeprol after the effective date of a final scheduling action unless DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration would be required to surrender all quantities of currently held zipeprol, or transfer all quantities of currently held zipeprol to a person registered with DEA before the effective date of a final scheduling action in accordance with all applicable federal, state, local, and tribal laws. As of the effective date of a final scheduling action, zipeprol would be required to be disposed of in accordance with 21 CFR part 1317, in addition to all other applicable federal, state, local, and tribal laws.

3. *Security.* Zipeprol would be subject to schedule I security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821 and 823, and in accordance with 21 CFR 1301.71–1301.93 as of the effective date of a final scheduling action.

4. *Labeling and Packaging.* All labels, labeling, and packaging for commercial containers of zipeprol would need to be in compliance with 21 U.S.C. 825 and 958(e), and be in accordance with 21 CFR part 1302 as of the effective date of a final scheduling action.

5. *Quota.* Only registered manufacturers would be permitted to manufacture zipeprol in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of the effective date of a final scheduling action.

6. *Inventory.* Every DEA registrant who possesses any quantity of zipeprol on the effective date of a final scheduling action would be required to take an inventory of zipeprol on hand at that time, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (d).

Any person who becomes registered with DEA on or after the effective date of the final scheduling action would be required to take an initial inventory of all stocks of controlled substances (including zipeprol) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant would be required to take an inventory of all controlled substances (including zipeprol) on hand every two years, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

7. *Records and Reports.* Every DEA registrant would be required to maintain records and submit reports pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, 1312, and 1317 as of the effective date of a final scheduling action. Manufacturers and distributors would be required to submit reports regarding zipeprol to the Automation of Reports and Consolidated Order System pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304 and 1312 as of the effective date of a final scheduling action.

8. *Order Forms.* Every DEA registrant who distributes zipeprol would be required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305 as of the effective date of a final scheduling action.

9. *Importation and Exportation.* All importation and exportation of zipeprol would need to be in compliance with 21 U.S.C. 952, 953, 957, and 958, and in accordance with 21 CFR part 1312 as of the effective date of a final scheduling action.

10. *Liability.* Any activity involving zipeprol not authorized by, or in violation of, the CSA or its implementing regulations, would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866, 13563, and 13771, Regulatory Planning and Review, Improving Regulation and Regulatory Review, and Reducing Regulation and Controlling Regulatory Costs

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed ''on the record after opportunity for a hearing,'' which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

This rulemaking is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 12866.

Executive Order 12988, Civil Justice Reform

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132, Federalism

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects 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.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Regulatory Flexibility Act

The Acting Administrator, in accordance with the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–602, has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities.

DEA proposes placing the substance zipeprol (chemical name: 1-methoxy-3-[4-(2-methoxy-2-phenylethyl)piperazin-1-yl]-1-phenylpropan-2-ol), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers and salts is possible, in schedule I of the CSA. This action is being taken to enable the United States to meet its obligations under the 1971 Convention on Psychotropic Substances. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical

analysis with, or possess), or propose to handle zipeprol.

According to HHS, zipeprol has a high potential for abuse, has no currently accepted medical use in treatment in the United States, and lacks accepted safety for use under medical supervision. DEA's research confirms that there is no commercial market for zipeprol in the United States. Additionally, queries of DEA's STRIDE/STARLiMS and the NFLIS databases on October 3, 2018, did not generate any reports of zipeprol, suggesting that it is not trafficked in the United States. Therefore, DEA estimates that no United States entity currently handles zipeprol and does not expect any United States entity to handle zipeprol in the foreseeable future. DEA concludes that no United States entity would be affected by this rule if finalized. As such, the proposed rule will not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the ''Regulatory Flexibility Act'' section above, DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), that this action would not result in any Federal mandate that may result ''in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year * * *.'' Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), 956(b), unless otherwise noted.

■ 2. In § 1308.11, add paragraph (b)(71) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(b) * * *

(71) Zipeprol 9873

* * * * *

Uttam Dhillon,

Acting Administrator.

[FR Doc. 2020–09592 Filed 5–13–20; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Parts 733, 736, and 842

[Docket ID: OSM–2019–0010; S1D1S SS08011000 SX064A000 201S180110; S2D2S SS08011000 SX064A00 20XS501520]

RIN 1029–AC77

Clarification of Provisions Related to the Issuance of Ten-Day Notices to State Regulatory Authorities and Enhancement of Corrective Action for State Regulatory Program Issues

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Proposed rule.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSMRE) proposes to clarify the regulations about notifying regulatory authorities of possible violations of any requirement of the Surface Mining Control and Reclamation Act of 1977 (SMCRA). This action would streamline the process for OSMRE's coordination with regulatory authorities in order to minimize duplication of inspections, enforcement, and administration of SMCRA. Additionally, the proposed rule would enhance the procedures for early identification of, and implementation of corrective action to address, State regulatory program issues.

DATES: OSMRE will accept comments received or postmarked on or before 11:59 p.m. Eastern Daylight Time (EDT), June 15, 2020 (the closing date). OSMRE must receive comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES** below) by 11:59 p.m. EDT on the closing date.

ADDRESSES: You may submit comments, identified by RIN 1029–AC77, by any of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *https://www.regulations.gov.* In the search box, enter RIN 1029–AC77, which is the docket number for this proposed rulemaking. Then in the search panel on the left side of the screen, under the Document type heading, click on the Proposed Rules link to locate this document. You may submit a comment by clicking on ''Comment Now!''

(2) *By hard copy:* Submit by U.S. mail, other mail delivery service, or hand-delivery to: U.S. Department of the Interior, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Mail Stop 4550, Room 4558, Main Interior Building, Washington, DC 20240, Attention: Division of Regulatory Support.

OSMRE requests that you send comments only by the methods described above. OSMRE will post all comments on *https://www.regulations.gov.* This generally means that OSMRE will post any personal information you provide (see Public Comment Procedures, below, for more information).

FOR FURTHER INFORMATION CONTACT: Kathleen G. Vello, OSMRE, Division of Regulatory Support, 1849 C Street NW, Mail Stop 4550, Room 4558, Washington, DC 20240, telephone number: (202) 208–1908. If you use a telecommunications device for the deaf (TDD), call the Federal Relay Service at: (800) 877–8339.

SUPPLEMENTARY INFORMATION:

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I. Public Comment Procedures
II. Background
III. Discussion of Proposed Rule and Section-by-Section Analysis
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I. Public Comment Procedures

You may submit written comments, identified with the RIN 1029–AC77, by any of the methods described in the **ADDRESSES** section. Written comments submitted on the proposed rule should be specific, confined to issues pertinent to the proposed rule, and should explain the reason for any recommended change. Where possible, your comments should reference the specific section or paragraph of the proposal that you are addressing. The comments and recommendations that will be most useful and likely to influence agency decisions are those: Supported by quantitative information or studies; based on specific, identifiable experience; and that include citations to, and analyses of, the applicable laws and regulations.

Comments received after the close of the comment period (see the **DATES** section) or delivered to addresses other than those listed above (see the **ADDRESSES** section) may not be considered or included in the Administrative Record for the final rule.

Comments, including names and street addresses of respondent commenters, will be available for public review at the address listed under **ADDRESSES** during regular business

hours (7:00 a.m. to 4:00 p.m.), Monday through Friday, except holidays.

Please be advised that OSMRE may make your entire comment—including your personal identifying information such as your name, phone number, or email address—publicly available at any time. While you may ask OSMRE in your comment to withhold your personal identifying information from public view, OSMRE cannot guarantee that your request will be granted.

II. Background

A. Proposed Rule Summary

As set forth in section 201(c)(12) of SMCRA, Congress requires OSMRE to, among other responsibilities, ''cooperate with . . . State regulatory authorities to minimize duplication of inspections, enforcement, and administration of this Act.'' 30 U.S.C. 1211(c)(12). Consistent with this statutory obligation and based on OSMRE's 42 years of experience administering SMCRA, the proposed rule would clarify the regulations found at 30 CFR 842.11 and 842.12 to state that, before issuing a notification to a State regulatory authority when a possible violation exists, OSMRE will consider any information readily available. This proposed modification would reduce inefficiencies by ensuring that OSMRE considers any readily available information, including information that a State regulatory authority may choose to provide, before OSMRE issues a notification to a State regulatory authority. Our consideration of this information is critical because a State regulatory authority has primary enforcement responsibility under a State regulatory program. Thus, the proposed rule would enable OSMRE to eliminate duplication of inspection and enforcement under SMCRA by clarifying that OSMRE would consider all readily available information, including any information provided by the State regulatory authority and other readily available information, before issuing a notification of a possible violation to that State regulatory authority. Furthermore, the proposed rule would clarify the meaning of the statutory terms ''appropriate action'' and ''good cause,'' as used in 30 CFR 842.11, to describe the State regulatory authority's action or inaction after OSMRE notifies the State regulatory authority that a possible violation exists. Examples of what constitutes appropriate action and good cause exist in the existing regulations; however, in OSMRE's experience, the existing, example explanations are not exhaustive and do not fully reflect the array of in-the-field scenarios. Within the context of evaluating whether a State regulatory authority has taken appropriate action with respect to a possible violation, OSMRE has observed that not all State regulatory program issues OSMRE identifies warrant a Federal inspection, but may require further evaluation. To address these issues comprehensively and to ensure more complete and efficient enforcement of SMCRA, the proposed revision of 30 CFR part 733 would add procedures for corrective action of State regulatory program issues, including implementation of action plans. The proposed revisions to 30 CFR part 733 include adding definitions of the terms ''action plan'' and ''State regulatory program issue'' and introducing a mechanism for early identification and corrective action to address State regulatory program issues.

For ease of organization, the preamble describes the proposed changes to Part 842 first, then it describes the proposed changes to Part 733.

In the spirit of cooperative federalism, OSMRE has developed each of the proposed modifications and clarifications in close coordination with State regulatory authorities. The proposed clarifications are also consistent with Executive Order 13777 of February 24, 2017, 82 FR 12285 (March 1, 2017), because the proposed clarifications would modify the existing regulations to alleviate unnecessary regulatory burden.

The proposed changes in this rulemaking are consistent with SMCRA and will add transparency to OSMRE's oversight responsibilities; promote regulatory certainty for State regulatory authorities, regulated entities, and the public; enhance OSMRE's relationship with the State regulatory authorities; reduce redundancy in inspection and enforcement; and streamline the process for notifying State regulatory authorities of possible violations and other issues.

B. Statutory Background

When Congress enacted SMCRA, 30 U.S.C. 1201 *et seq.,* it established a regulatory structure for protecting the environment from the surface effects of coal mining. Specific to this proposed rulemaking, Title V of SMCRA embodies a regulatory relationship between the Federal Government, through OSMRE, and the States and Tribes (collectively referred to as ''State regulatory authority'' throughout this proposed rule because no Tribes currently have regulatory programs) known as cooperative federalism. SMCRA's mandate of cooperative federalism authorizes States (or Tribes)—within limits established by Federal minimum standards—to enact and administer regulatory programs structured to satisfy each State's individual needs. Under section 503(a) of SMCRA, States may submit proposed State regulatory programs to the Secretary of the Interior (Secretary) for approval. 30 U.S.C. 1253(a). The Secretary acts through OSMRE to review and approve or not approve a State's proposed State regulatory program. 30 U.S.C. 1211(c)(1). After approval of a proposed State regulatory program, the State has achieved ''primacy.'' When a State achieves primacy, the State becomes the regulatory authority and has primary jurisdiction over the regulation of surface coal mining and reclamation operations on non-Federal lands within its borders, except as provided in sections 521 and 523 and Title IV of SMCRA. 30 U.S.C. 1271, 1273, and 1231–1244. In general, a State can assume primary jurisdiction if the Secretary, acting through OSMRE, approves a proposed State regulatory program that demonstrates the State's capability to carry out SMCRA's provisions and satisfy its purposes.

One of the exceptions outlined in 30 U.S.C. 1271(a) is the primary subject of this proposed rulemaking. This provision of SMCRA authorizes OSMRE to issue a notification to a State regulatory authority—commonly known as a Ten-Day Notice (TDN)—if OSMRE has reason to believe, based on any information available, that any person is in violation of any requirement of SMCRA or any permit condition required by SMCRA. The State regulatory authority must, within ten days, take appropriate action to cause the violation to be corrected or the State regulatory authority must demonstrate good cause for not correcting the violation. The State regulatory authority is obligated to transmit this response to OSMRE for further evaluation as dictated by OSMRE's regulations (discussed below in section II. *C. Regulatory Background*).

Relevant to the proposed revisions to the regulations at 30 CFR part 733, as discussed below, section 504 of SMCRA, 30 U.S.C. 1254, in general, directs the Secretary to prepare and implement a Federal program if a State regulatory authority, among other reasons, fails to implement, enforce, or maintain its approved program. Furthermore, section 521(b) of SMCRA generally requires OSMRE to enforce the requirements of SMCRA when a State regulatory authority fails to enforce an approved State regulatory program effectively and certain other criteria are satisfied. 30 U.S.C. 1271(b).

C. Regulatory Background

Section 201(c)(2) of SMCRA authorizes OSMRE to ''publish and promulgate such rules and regulations as may be necessary to carry out the purposes and provisions of this Act.'' 30 U.S.C. 1211(c)(2). OSMRE has implemented the statutory requirements discussed above through the existing regulations, including 30 CFR parts 842 and 733.

OSMRE has implemented section 521(a)(1) of SMCRA, in part, through the existing regulations at 30 CFR 842.11(b)(1) and (b)(2). These regulations outline the procedures for an authorized representative of the Secretary to notify a State regulatory authority of a possible violation and possible Federal enforcement. In addition, the existing regulation at § 842.11(b)(2) provides that ''[a]n authorized representative shall have reason to believe that a violation, condition or practice exists if the facts alleged by the informant would, if true, constitute a condition, practice or violation referred to in paragraph (b)(1)(i) of this section.'' As discussed below, in conjunction with the proposed revision to § 842.11(b)(2), the proposed rule would modify that section to recognize that OSMRE considers other readily available information in addition to the facts that a citizen complainant alleges when the authorized representative of the Secretary is determining whether there is reason to believe a violation exists.

An administrative case before the Interior Board of Land Appeals (IBLA) has interpreted SMCRA and these regulations, holding that OSMRE ''retains a significant oversight role to ensure compliance with SMCRA's mandates.'' *Frank Hubbard,* 145 IBLA 49, 52 (1998). In *Hubbard,* the IBLA also stated: ''[w]here pursuant to a citizen's complaint, OSM[RE] has reason to believe that a permittee is in violation of a [S]tate regulatory program, OSM[RE] is required to issue a TDN to the appropriate [S]tate regulatory authority.'' *Id.* at 53. However, neither SMCRA nor the regulations clearly define the phrase ''reason to believe,'' and both are ambiguous as to what information OSMRE may consider when determining whether OSMRE has ''reason to believe'' that a permittee is in violation of applicable requirements.

The proposed rule would clarify areas of the regulations discussed above, which have resulted in disparate application, regulatory uncertainty, redundancy, and duplicative investigation and enforcement by OSMRE and State regulatory authorities.

Moreover, the existing regulations at 30 CFR 842.11(b)(1)(ii)(B)(*2*) through (*4*) further implement the requirements of section 521(a)(1) of SMCRA. 30 U.S.C. 1271(a)(1). The existing regulations are primarily the result of substantial amendments made to the regulations in 1988. Pursuant to the final rule published in the July 14, 1988, **Federal Register** (53 FR 26728), the regulations were amended to ''establish a uniform standard by which OSMRE will evaluate [S]tate responses to [F]ederal notices of possible violations of [SMCRA].'' The regulations established that OSMRE ''will accept a [S]tate regulatory authority's response to a [TDN] as constituting appropriate action to cause a possible violation to be corrected or showing good cause for failure to act unless OSMRE makes a written determination that the [S]tate's response was arbitrary, capricious, or an abuse of discretion under the [S]tate program.'' *Id.* This final rule became effective on August 15, 1988.

In summary, a State regulatory authority must take appropriate action to correct a possible violation identified by OSMRE in a TDN, or the State regulatory authority must show good cause why the violation has not been corrected. Under section 521(a)(1) of SMCRA, if a State regulatory authority does not take appropriate action or show good cause, SMCRA requires us to initiate a Federal inspection of the surface coal mining operation at which the alleged violation is occurring (unless the information OSMRE has is from a previous Federal inspection of the same operation). 30 U.S.C. 1271(a)(1). Thus, OSMRE's interpretations of what the terms ''appropriate action'' and ''good cause'' mean are essential to maintaining the proper balance between Federal enforcement and the primary role of a State regulatory authority in implementing an approved program. Although the existing regulations discuss both ''appropriate action'' and ''good cause,'' the regulations about these integral phrases have not been substantially updated in over 31 years. Based on our experience and feedback from State regulatory authorities, the proposed rule would update and clarify the meaning of the terms ''appropriate action'' and ''good cause.''

OSMRE is also proposing to revise the regulations at 30 CFR part 733 to add new definitions and a new section that would operate in conjunction with the Part 842 regulations, discussed above. To balance the provisions of SMCRA found at sections 503 and 504, 30 U.S.C. 1253 and 1254, and the provisions of section 517(b), 30 U.S.C. 1267(b), regulations found at 30 CFR part 733 were promulgated. *See generally* 44 FR 15323 (March 13, 1979). States with State regulatory programs are required to implement, administer, enforce, and maintain their respective programs in accordance with SMCRA, the implementing regulations, and the provisions of the approved program. 30 CFR 733.11. The regulations at 30 CFR part 733 establish requirements for the maintenance of State regulatory programs and procedures for the rare remedy of substituting Federal enforcement of State regulatory programs and withdrawing approval of State regulatory programs. 30 CFR 733.1. These regulations have not been substantively revised in over 37 years. 47 FR 26366 (June 17, 1982). However, in coordination with State regulatory authorities, OSMRE determined that mechanisms exist for addressing identified State regulatory program issues to avoid reaching a threshold that would require substitution of Federal enforcement of a State regulatory program. OSMRE may identify these State regulatory program issues in the context of reviewing a State regulatory authority's response to a TDN. Therefore, the proposed rule addresses any State regulatory program issue OSMRE may find during State regulatory program reviews by adding provisions to 30 CFR part 733 for early identification and corrective action and to refer to these State regulatory program issues in the proposed revisions to 30 CFR 842.11(b)(1)(ii)(B)(*3*).

III. Discussion of the Proposed Rule and Section-by-Section Analysis

A. Overview

While most States with significant surface coal mining operations have obtained primacy to regulate surface coal mining within their borders, OSMRE still plays a significant oversight role in regulating the coal mining industry. When OSMRE is not the primary agency regulating surface coal mining in a State, OSMRE assumes a direct oversight role. If OSMRE has reason to believe that any person has violated the applicable requirements, section 521(a)(1) of SMCRA requires OSMRE to notify the relevant State regulatory authority of the potential violation. In this context, ''any person'' includes the SMCRA permit holder, an operator contracted to conduct the surface coal mining activity, or certain officials related to these entities who have responsibilities under SMCRA. However, ''any person'' does not include State regulatory authorities, OSMRE, or employees or agents thereof,

unless they are acting as permit holders. A reasonable reading of section 521(a)(1) is that the referenced violations are those that permittees, and related entities or persons, commit in contravention of State regulatory programs. Therefore, within the context of section 521(a) of SMCRA and the TDN regulations, the proposed rule would clarify that OSMRE will not send TDNs to State regulatory authorities based on allegations or other information that indicates that a State regulatory authority may have taken an improper action under the State's regulatory program. OSMRE concludes that this approach is consistent with the plain language of section 521(a). However, if OSMRE becomes aware that there is a State regulatory program issue that calls into question a State regulatory authority's effective administration of its State regulatory program, even with respect to a single operation, OSMRE intends to clarify that OSMRE would address the issue programmatically under the proposed revisions to 30 CFR part 733, rather than through the TDN process. Moreover, as explained below in the discussion of the proposed revisions to 30 CFR part 733, the proposed rule would clarify that even when OSMRE is engaged in a corrective action process with a State regulatory authority, the State regulatory authority may take direct enforcement action under its State regulatory program. Additionally, OSMRE can take appropriate oversight enforcement actions, in the event that there is, or may be, an imminent on-the-ground violation.

One of the instances when OSMRE may issue a TDN is when OSMRE receives a complaint from a citizen about an alleged violation at a surface coal mining operation. When OSMRE receives such a citizen complaint, OSMRE will issue a TDN to the State regulatory authority if OSMRE has reason to believe that any person is in violation of any requirement of SMCRA, the implementing regulations, the applicable State regulatory program, or a permit condition required by SMCRA. Based on 42 years of regulatory and oversight experience, OSMRE finds that unnecessary duplication exists in the current TDN process that can be eliminated by ensuring OSMRE examines all readily available information, including the information the State regulatory authority possesses. This is critical because in some instances in the past, OSMRE has issued a TDN after receipt of a citizen complaint even though the State regulatory authority had received a simultaneous complaint about the same possible violation. This resulted in the State regulatory authority and OSMRE initiating two parallel processes and engaging in duplicative effort without any significant benefit. Further, the relevant State regulatory authority and OSMRE were actively investigating the same issue. If OSMRE issues a TDN when a State regulatory authority is already investigating the same allegation, it can divert the State regulatory authority's efforts away from addressing a potential problem to instead responding to OSMRE's TDN. OSMRE could minimize or avoid redundancy and duplication of time and resources by ensuring that a State regulatory authority is involved early in the process, thus, freeing both OSMRE and the State regulatory authority to redirect time and allocate limited resources more effectively to ensure that potential violations are addressed. Accordingly, the proposed rule would clarify that, if OSMRE's authorized representative, while using his or her best professional judgment, is aware that a State regulatory authority has investigated or is actively investigating the possible violation, the authorized representative would consider the State regulatory authority's action before determining if there is reason to believe a violation exists.

B. Proposed 30 CFR 842.11(b)(1)

Existing 30 CFR 842.11(b)(1) explains the circumstances when OSMRE ''shall'' conduct a Federal inspection, but the paragraph primarily focuses on the process leading up to a Federal inspection, including the process for OSMRE's issuance of a TDN to a State regulatory authority. In general (when there is no imminent danger or harm scenario), consistent with section 521(a) of SMCRA, when OSMRE issues a TDN to a State regulatory authority, OSMRE evaluates the State regulatory authority's response to the TDN before deciding whether to conduct a Federal inspection. Consistent with the existing regulations, OSMRE will issue a TDN to a State regulatory authority when an authorized representative of OSMRE has reason to believe that there is a violation of SMCRA, the implementing regulations, the applicable State regulatory program, or any condition of a permit or an exploration approval. In general, OSMRE may also issue a TDN when there is any condition, practice, or violation that creates an imminent danger to the health or safety of the public or is causing, or that OSMRE reasonably expect to cause, a significant, imminent, environmental harm to land, air, or water resources. In the latter situation, OSMRE will bypass the TDN process, and proceed directly to a Federal inspection, if the person supplying the information provides adequate proof that there is an imminent danger to the public health and safety or a significant, imminent environmental harm.

In the introductory sentence at 30 CFR 842.11(b)(1), the proposed rule would replace the word ''shall'' with the word ''will'' because it explains an action that OSMRE will take under the specified circumstances.[1] In the context of the existing provision at § 842.11(b)(1), OSMRE already treats ''shall'' as ''will.'' Consequently, because other revisions are proposed to this section, the proposed rule would change ''shall'' to ''will'' to remove any possible ambiguity.

The proposed rule would also modify existing 30 CFR 842.11(b)(1)(i) to clarify that when an authorized representative assesses whether he or she has reason to believe a violation exists, the authorized representative would consider any information that is accessible without unreasonable delay. The proposed rule would achieve this clarification by inserting the word ''readily'' between the existing words ''information'' and ''available.''

OSMRE finds that these proposed revisions would be consistent with section 521(a)(1) of SMCRA, which sets forth that OSMRE can form reason to believe ''on the basis of any information available to [the Secretary], including receipt of information from any person.'' 30 U.S.C. 1271(a)(1). Based on SMCRA's plain language, such information is not restricted to information OSMRE receives from a citizen complainant. Rather, the information includes any information OSMRE receives from a citizen or the applicable State regulatory authority, or any other information OSMRE is aware exists. Also, the proposed rule would clarify that such information must be readily available, so that the process will proceed as quickly as possible and will not become open-ended.

In addition, the House of Representatives discussion of proposed section 521(a)(1) attempted to illustrate one way to establish ''reason to believe'' in the context of TDNs:

> In addition to normally programmed inspections, section 521(a)(1) of the bill also provides for special inspections when the Secretary receives information giving him reason to believe that violations of the act or

[1] The U.S. Government Publishing Office recommends against using the word ''shall'' because it can mean may, will, or must depending on the context and can create ambiguity.

permit have occurred. It is anticipated that ''reasonable belief'' could be established by a snapshot of an operation in violation or other simple and effective documentation of a violation.

By mandating primary enforcement authority to field inspectors, this bill recognizes that inspectors are in the best position to recognize and control compliance problems.

H. Rept. No. 95–218, at 129 (April 22, 1977) (emphasis added). *See also* H. Rept. No. 94–1445, at 74–75; H. Rep. No. 94–896, at 76–77; and H. Rept. No. 94–45, at 118–119. The proposed revision to § 842.11(b)(1)(i) is consistent with this reference to the Secretary's consideration of ''other simple and effective documentation of a violation'' in determining whether there is reason to believe that a violation exists. While this language from the legislative history relates to the information that a citizen provides, it is reasonable to apply the same principle to section 521, as enacted. In addition, in practice, citizen complaints do not always include simple and effective documentation of a violation. Instead, citizen complaints sometimes present a combination of documentation and bare allegations. Under the existing regulations, in cases where OSMRE has determined ''reason to believe'' that a violation exists at a particular operation, it was often because OSMRE only accepted the alleged facts. To ensure OSMRE obtains effective documentation, the proposed rule would expand our consideration to include a broader array of readily available information.

As mentioned above, section 521(a)(1) allows OSMRE to consider ''any information available . . ., including receipt of any information from any person'' when OSMRE is determining whether it has reason to believe that a violation exists. Congress provided that when States achieve primacy, they are the primary SMCRA regulatory authorities; therefore, it is important for OSMRE to be able to consider any readily available information that OSMRE receives from a State regulatory authority when OSMRE is determining whether OSMRE has reason to believe that a violation exists. Indeed, the above quoted passage from the House Report notes inspectors, based on on-the-ground observations, are ''in the best position to recognize'' violations. In the overall context of SMCRA, any information OSMRE receives from a State regulatory authority is often integral to the assessment of whether a violation exists. During the course of OSMRE oversight enforcement history, the knowledge and information provided by a State regulatory authority has been critical to OSME's understanding of a possible violation.

Moreover, OSMRE's consideration of information that it receives from the State regulatory authority promotes efficiency and avoids duplication and redundancy of investigatory and enforcement activity between OSMRE and a State regulatory authority. As discussed above in the *Overview,* the TDN process is time-consuming for both State regulatory authorities and OSMRE. OSMRE has spent considerable time preparing TDNs and analyzing State regulatory authority TDN responses. Similarly, State regulatory authorities have spent considerable time preparing responses to TDNs issued by OSMRE, and some State regulatory authorities have reported increases in the time spent investigating and responding to TDNs. Accordingly, the proposed rule would clarify that, if OSMRE's authorized representative, while using his or her best professional judgment, is aware that a State regulatory authority has investigated or is actively investigating the possible violation, the authorized representative would consider the State regulatory authority's action before determining if there is reason to believe a violation exists.

In addition, clarification of the existing regulations is warranted because State regulatory authorities have reported varying levels of communication and approaches from our various field offices relative to consideration of a State regulatory authority's actions when assessing whether the OSMRE authorized representative has reason to believe that a violation exists. Clarifying the regulation in the manner described above will promote regulatory certainty for State regulatory authorities and permittees, as well as the public, and should foster better relationships between OSMRE and State regulatory authority personnel. Increased cooperation between OSMRE and the State regulatory authorities promotes both the common mission of effective SMCRA implementation and collaboration between Federal and State agencies. Additionally, relying on information OSMRE receives from a State regulatory authority, along with the information in a citizen complaint and other readily available information, will promote more efficient and informed decision making on our part. Thus, by making a more informed decision, the TDNs that OSMRE issues will be focused on situations with a higher likelihood of a violation, which is a better use of OSMRE and the State regulatory authority's resources. Armed with more time, the State regulatory authorities and OSMRE could devote more resources to effective regulation of potential environmental effects of surface coal mining.

Finally, the existing regulations at § 842.12(a) require that a person requesting a Federal inspection must demonstrate that he or she has notified the applicable State regulatory authority. In the context of this rulemaking, OSMRE reiterates that, in general, OSMRE would not consider a citizen complaint until the citizen has complied with this regulation and properly notified the relevant State regulatory authority. Therefore, the provisions of existing § 842.12(a) work in conjunction with the addition of the provisions of proposed § 842.11(b) that would require an authorized representative to determine whether he or she has reason to believe that a violation exists based on ''any information readily available.'' The ''information readily available'' would include information from a State regulatory authority, which a citizen complainant has notified—consistent with the existing regulations. However, if an imminent harm is present, OSMRE will take any action it deems necessary under 30 U.S.C. 1271(a) and the implementing regulations.

C. Proposed 30 CFR 842.11(b)(1)(ii)(A)

Existing 30 CFR 842.11(b)(1)(ii)(A) reads as follows: ''[t]here is no State regulatory authority or the Office is enforcing the State regulatory program under section 504(b) or 521(b) of the Act and part 733 of this chapter.'' In this section, the proposed rule would only capitalize the ''p'' in the word ''Part'' and add the word ''regulatory'' between the words ''State'' and ''program'' to promote consistency throughout this rulemaking and clarify that OSMRE is referring to State regulatory programs.

D. Proposed 30 CFR 842.11(b)(1)(ii)(B)(1)–(4)

The proposed rule would make non-substantive changes to existing 30 CFR 842.11(b)(1)(ii)(B)(*1*) for readability. The existing language is set forth above under section *II.C. Regulatory Background.* The proposed revision would read,

The authorized representative has notified the State regulatory authority of the possible violation and more than ten days have passed since notification, and the State regulatory authority has not taken appropriate action to cause the violation to be corrected or to show good cause for not doing so, or the State regulatory authority has not provided the authorized representative with a response. After receiving a response from the State regulatory authority, but before a Federal inspection, the authorized representative will

determine in writing whether the standards for appropriate action or good cause have been satisfied. A State regulatory authority's failure to respond within ten days does not prevent the authorized representative from making a determination, and will constitute a waiver of the State regulatory authority's right to request review under paragraph (b)(1)(iii) of this section.

Although there is no proposed change to the existing regulation at 30 CFR 842.11(b)(1)(ii)(B)(*2*), it is discussed here for context related to the proposed clarifications in 30 CFR 842.11(b)(1)(ii)(B)(*3*), which describes the term ''appropriate action,'' and 30 CFR 842.11(b)(1)(ii)(B)(*4*), which describes the term ''good cause.'' Consistent with § 842.11(b)(1)(ii)(B)(*2*), when OSMRE receives a State regulatory authority's response to a TDN, OSMRE determines whether or not the State regulatory authority's action or response constitutes appropriate action to cause any violation to be corrected or good cause for not taking action. The existing regulation requires OSMRE to determine that the State regulatory authority's action or response constitutes appropriate action or good cause if it is not arbitrary, capricious, or an abuse of discretion under the approved State regulatory program. In this context, the arbitrary and capricious standard is appropriately deferential to State regulatory authorities and is consistent with SMCRA's cooperative federalism model.

As it currently exists, 30 CFR 842.11(b)(1)(ii)(B)(*3*) explains that ''[a]ppropriate action includes enforcement or other action authorized under the State program to cause the violation to be corrected.'' The proposed rule would add to this requirement a second sentence that reads, ''[a]ppropriate action may include OSMRE and the State regulatory authority immediately and jointly initiating steps to implement corrective action to resolve any issue that the authorized representative and applicable Field Office Director identify as a State regulatory program issue, as defined in 30 CFR part 733.'' The proposed rule gives the responsibility for identification of State regulatory program issues to the applicable Field Office Director and authorized representative, as these officials possess unique knowledge of the specific requirements of and responsibilities under the applicable State regulatory program. Although OSMRE has historically allowed programmatic resolution of State regulatory program issues, such as implementation of remedies under 30 CFR part 732, to constitute ''appropriate action'' in a given situation, the existing regulations do not specifically explain resolution of State regulatory program issues through corrective actions. This approach has created regulatory uncertainty. In order to avoid confusion for the regulated community, State regulatory authorities, and the public at large, the proposed rule would remove any ambiguity and definitively state that ''appropriate action'' may include corrective action to resolve State regulatory program issues. However, proposed § 733.12(a)(2) reaffirms that if OSMRE concludes that the State regulatory authority is not effectively implementing, administering, enforcing, or maintaining all or a portion of its State regulatory program, OSMRE may substitute Federal enforcement of the State regulatory program or withdraw approval. Additionally, in accordance with proposed § 733.12(d), OSMRE reserves the right to reinstitute oversight enforcement if, subsequent to a finding of appropriate action based upon a corrective action consistent with proposed 30 CFR part 733, an on-the-ground violation occurs or may imminently occur.

As it currently exists, 30 CFR 842.11(b)(1)(ii)(B)(*4*) identifies circumstances that constitute good cause for a State regulatory authority not to have corrected a violation. In general, pursuant to the existing regulations, good cause for a State regulatory authority's failure to take action includes: (1) A finding that the possible violation does not exist under the State regulatory program; (2) the State regulatory authority requires additional time to determine whether a violation exists; (3) the State regulatory authority lacks jurisdiction over the possible violation under the State regulatory program; (4) the State regulatory authority is precluded by an administrative or judicial order from acting on the possible violation; or (5) specific to abandoned mine sites, the State regulatory authority is diligently pursuing or has exhausted all appropriate enforcement provisions.

The proposed rule would make minor clarifications to the examples of what constitutes good cause. First, proposed § 842.11(b)(1)(ii)(B)(*4*)(*i*) would make a non-substantive change for readability and consistency that would simply add the word ''regulatory'' between ''State'' and ''program'' and switch the position of two phrases in the provision. The existing provision reads, ''[u]nder the State program, the possible violation does not exist,'' and the revised provision would read, ''[t]he possible violation does not exist under the State regulatory program.'' Second, the proposed rule would revise § 842.11(b)(1)(ii)(B)(*4*)(*ii*) to provide that good cause includes: ''[t]he State regulatory authority has initiated an investigation into a possible violation and as a result has determined that it requires a reasonable, specified additional amount of time to determine whether a violation exists.'' The proposed revision would explain that the authorized representative would have discretion to determine how long the State regulatory authority should reasonably be given to complete its investigation of the possible violation. Also, the authorized representative would communicate to the State regulatory authority the date by which its investigation must be completed. This proposed revision would promote prompt identification and resolution of possible violations. OSMRE cautions that investigations should not be open-ended, the State regulatory authority would be required to perform the investigations efficiently and effectively, and the State regulatory authority should focus the investigation on satisfying the objective of the TDN process—achieving compliance with the State regulatory program. A State regulatory authority must demonstrate that, when engaging in an investigation, its inquiry focuses on investigating a possible violation. In no circumstance should a State regulatory authority use an investigation to delay Federal oversight or enforcement or delay our evaluation of a State regulatory authority's response to a TDN.

The proposed rule would make a minor revision to § 842.11(b)(1)(ii)(B)(*4*)(*iii*). This proposed change would also require that a State regulatory authority would need to demonstrate that it lacks jurisdiction over the possible violation to qualify for this good cause showing. The existing language reads, ''[t]he State regulatory authority lacks jurisdiction under the State program over the possible violation or operation . . . .'' The proposed language would read, ''[t]he State regulatory authority demonstrates that it lacks jurisdiction over the possible violation under the State regulatory program . . . .''

Similarly, the proposed rule would make minor, non-substantive modifications to § 842.11(b)(1)(ii)(B)(*4*)(*iv)* for readability and to clarify that, in order to show good cause, the State regulatory authority would need to demonstrate that an order from an administrative review body or court of competent jurisdiction precludes it from taking action on the possible violation. The

existing language reads, ''[t]he State regulatory authority is precluded by an administrative or judicial order from an administrative body or court of competent jurisdiction from acting on the possible violation, where that order is based on the violation not existing or where the temporary relief standards of section 525(c) or 526(c) of the Act have been met . . . .'' The proposed language would read, ''[t]he State regulatory authority demonstrates that it is precluded from taking action on the possible violation because an administrative review body or court of competent jurisdiction has issued an order concluding that the possible violation does not exist or that the temporary relief standards of the State regulatory program counterparts to section 525(c) or 526(c) of the Act have been satisfied . . . .''

Finally, the proposed rule would make minor, non-substantive modifications to § 841.11(b)(1)(ii)(B)(*4*)(*v*) to enhance readability and clarity. The existing language reads,

> [w]ith regard to abandoned sites as defined in § 840.11(g) of this chapter, the State regulatory authority is diligently pursuing or has exhausted all appropriate enforcement provisions of the State program.

The proposed rule would read,

> [r]egarding abandoned sites, as defined in 30 CFR 840.11(g), the State regulatory authority is diligently pursuing or has exhausted all appropriate enforcement provisions of the State regulatory program.

In addition to the specific clarifications of the terms ''appropriate action'' and ''good cause'' noted above, the proposed rule would reaffirm the process OSMRE currently employs in relationship to conclusions about State regulatory authority TDN responses. Pursuant to existing § 842.11(b)(1)(B)(*2*), the authorized representative may make a finding that the State regulatory authority has taken an appropriate action or has good cause for not taking action, as long as the State regulatory authority has presented a rational basis for its decision, action, or inaction. Additionally, the State regulatory authority's response must not be arbitrary, capricious, or an abuse of discretion under the State regulatory program. When an authorized representative assesses whether a State regulatory authority has taken appropriate action or has good cause for not taking action, the authorized representative focuses on whether the action corrected the violation and not merely the methodology that the State regulatory authority employed to correct the violation. Additionally, OSMRE assesses and determines if the State regulatory authority based its action or response on a reasonable consideration of the relevant facts and if the action or response is an exercise of reasoned discretion that complies with the State regulatory program.

E. Proposed 30 CFR 842.11(b)(2)

As it currently exists, § 842.11(b)(2) offers an interpretation of the phrase ''reason to believe'' that has not been revisited in this section since a 1982 rulemaking. The existing regulation at § 842.11(b)(2) essentially requires an authorized representative to accept the facts in a citizen complaint as true when determining whether he or she has reason to believe that a violation exists. The existing provision reads, ''[a]n authorized representative shall have reason to believe that a violation, condition or practice exists if the facts alleged by the informant would, if true, constitute a condition, practice or violation referred to in paragraph (b)(1)(i) of this section.''

The proposed revision reads,

> [a]n authorized representative will have reason to believe that a violation, condition, or practice referred to in paragraph (b)(1)(i) of this section exists if the facts that a complainant alleges, or facts that are otherwise known to the authorized representative, constitute simple and effective documentation of the alleged violation, condition, or practice. In making this determination, the authorized representative will consider any information readily available to him or her, including any information a citizen complainant or the relevant regulatory authority submits to the authorized representative.

Some might have interpreted the existing regulatory provisions to mean that all OSMRE has to do is determine if the alleged facts would constitute a violation before issuing a TDN. However, the existing regulations at § 842.11(b)(1)(i) provide that the authorized representative can consider ''information available'' when determining whether he or she has reason to believe a violation exists, rather than automatically and only accepting the facts alleged in a citizen complaint as true. Because of its importance to an understanding of the statutory scheme, clarifying the meaning of the phrase ''reason to believe,'' as discussed above in the explanation of proposed 30 CFR 842.11(b)(1), is paramount.

Consistent with this approach, the proposed rule would modify § 842.11(b)(2) to clarify that OSMRE would consider any information readily available and not only the facts alleged in a citizen complaint when determining whether it has reason to believe a violation exists. Nothing in SMCRA requires OSMRE to accept alleged facts as true in a vacuum. Rather, information that a citizen provides is usually only a portion of the readily available information that OSMRE would consider when deciding whether to initiate the TDN process. Moreover, the inclusion of the phrase ''reason to believe'' in section 521(a)(1) of SMCRA indicates that Congress intended for OSMRE to use discretion in determining whether to issue a TDN to a State regulatory authority. With the proposed changes, after OSMRE receives an allegation of a violation and assess all readily available information, OSMRE would apply independent, professional judgment to determine whether OSMRE has reason to believe a violation exists. Congress created OSMRE to be the expert agency that administers SMCRA. Therefore, OSMRE should never be acting as a mere conduit for transmitting a citizen complaint to a State regulatory authority in the form of a TDN.

Proposed § 842.11(b)(2) would complement the provisions of proposed § 842.11(b)(1)(i), discussed above, and, together, the provisions would provide clarification for how an authorized representative would arrive at reason to believe that a violation exists in the context of the TDN process. In short, the clarified provisions propose to adopt language that Congress offered when it was drafting SMCRA. Specifically, Congress anticipated that '''reasonable belief' could be established by a snapshot of an operation in violation or other simple and effective documentation of a violation.'' H. Rept. No. 95–218 at 129 (1977). As explained above, under the discussion of proposed § 842.11(b)(1), OSMRE would apply the principle of considering ''other simple and effective documentation of a violation'' to all information readily available to it, no matter the source. Specifically, the reference to ''any information available'' in section 521(a)(1), 30 U.S.C. 1271(a)(1), would include not only information OSMRE receives from a citizen complainant and information of which it is already aware, but also any information OSMRE receives from the applicable State regulatory authority. The discussion of proposed § 842.11(b)(1)(i), above, discusses in more detail OSMRE's multi-faceted rationale for clarifying the meaning of the phrase ''reason to believe.'' One key point that the proposed rule would be clarifying is that, if the authorized representative, while using his or her best professional

judgment, is aware that the State regulatory authority has investigated or is actively investigating the possible violation, the authorized representative would consider the State regulatory authority's action before determining if there is reason to believe a violation exists.

However, OSMRE remains mindful of the important role that citizens play in effective implementation and enforcement of SMCRA. Therefore, OSMRE would continue to take allegations in a citizen complaint very seriously, and OSMRE encourages citizens to provide as much detail and simple and effective documentation about the alleged violation in their complaints as possible.

In summary, the proposed revision to § 842.11(b)(2) dovetails with existing § 842.11(b)(1)(i), as well as the proposed clarification of that section, discussed above, which would allow OSMRE to consider ''any information readily available'' when making a ''reason to believe'' determination. Being able to read these two provisions in harmony should reduce or eliminate any conflict or confusion that the existing provisions created.

F. Proposed 30 CFR 842.12(a)

As it currently exists, 30 CFR 842.12(a) identifies the process to request a Federal inspection. This existing regulatory provision states that a person may request a Federal inspection by submitting a signed, written statement giving the authorized representative reason to believe that a violation, condition or practice referred to in § 842.11(b)(1)(i) exists and that the State regulatory authority has been notified in writing about the violation. The provision also requires the submitter to include a phone number and address where the person can be contacted. The authorized representative then assesses if he or she has reason to believe that a violation, condition, or practice referred to in § 842.11(b)(1)(i) exists.

The proposed modifications to 30 CFR 842.12(a) complement the proposed clarifications outlined above in the discussion of proposed § 842.11(b)(1)'s ''reason to believe'' standard. Specifically, the proposed rule would modify the existing language in § 842.12(a) to clarify that, when a person requests a Federal inspection, the person's request must include, ''information that, along with any other readily available information, may give the authorized representative reason to believe that a violation, condition, or practice referred to in § 842.11(b)(1)(i) exists.'' The proposed rule would also make minor, non-substantive modifications to the provision at existing § 842.12(a) so that the revised provision would reaffirm that when any person requests a Federal inspection, the person's written statement ''must also set forth the fact that the person has notified the State regulatory authority, if any, in writing, of the existence of the possible violation, condition, or practice . . . .'' Under the proposed rule, the person's statement must also include ''the basis for the person's assertion that the regulatory authority has not taken action with respect to the possible violation.'' The latter provision reflects the fact that, most often, a State regulatory authority will address a potential violation when the State regulatory authority is made aware of the situation.

Under this section of the proposed rule, OSMRE would verify whether the individual requesting the Federal inspection notified the State regulatory authority. As with the ''reason to believe'' standard in § 842.11(b)(1), OSMRE would consider any readily available information, including any information that the citizen or the State regulatory authority provides, in our ''reason to believe'' determination. OSMRE may verify the person's compliance with this section, and the State regulatory authority's action or inaction relative to the alleged violation, using a variety of methods, not limited to the examples that follow. OSMRE may directly communicate with the State regulatory authority to obtain any readily available information, or rely on other readily available information, such as information in permit files, public records, or documentation that the person provides in connection with the request for a Federal inspection. OSMRE may also obtain the status of the situation if the State regulatory authority acknowledges in writing that the requester previously notified the State regulatory authority of the possible violation, and the State regulatory authority sets forth whether it has acted or not with respect to the possible violation. Again, OSMRE does not deem this list of examples to be exhaustive, and OSMRE may select other mechanisms to verify that the requester properly notified the State regulatory authority of the existence of a possible violation, and to ascertain the status of the State regulatory authority's response to the possible violation.

Finally, in order to conform and update the regulations to modern, generally accepted, and efficient mechanisms of communication, the proposed rule would provide that, in addition to providing a phone number and physical address, any person who requests a Federal inspection should include an email address, if one is available, so that OSMRE may contact the requester.

In § 842.12(a), the proposed rule would replace the term ''a person'' with the term ''any person'' to mirror the language of section 521(a) of SMCRA.

Please note that, under the proposed rule change in § 842.12(a), when OSMRE determines whether a violation exists for purposes of issuing a TDN or determining whether to conduct a Federal inspection, a State regulatory program issue would not qualify as a possible violation. Similarly, OSMRE would not consider a State regulatory authority's failure to enforce its State regulatory program as a violation that warrants a TDN or Federal inspection. The TDN and Federal inspection process in section 521(a) applies to oversight enforcement about violations at individual operations. Congress differentiated this type of individual operation oversight from the State regulatory program enforcement provisions of section 521(b). Based on this distinction, the existing 30 CFR part 733 addresses State regulatory program issue enforcement identified in section 521(b). As discussed in the next section of the preamble, the proposed rule would add new provisions to 30 CFR part 733, so that OSMRE may also address potential problems for individual permits under the part 733 regulations. As proposed, the changes to 30 CFR part 733 discussed below would not address the types of issues that qualify as violations under the TDN and Federal inspection process in section 521(a). However, OSMRE could still take appropriate oversight enforcement actions in the event that there is an on-the-ground violation, or such a violation could be imminent. The proposed modifications to 30 CFR part 733 are discussed below.

G. 30 CFR part 733

As it currently exists, this part establishes requirements for the maintenance of State regulatory programs, and procedures for substituting Federal enforcement of State regulatory programs or OSMRE withdrawal of approval of State regulatory programs.

Throughout OSMRE's 42 years of implementing and overseeing SMCRA and State regulatory programs, OSMRE has observed that early identification of and corrective action to address problems is critical to strong enforcement of SMCRA. If problems remain unaddressed, they may result in a State regulatory authority's ineffective

implementation, administration, enforcement, or maintenance of its State regulatory program. To prevent this from occurring and to encourage a more complete and efficient implementation of SMCRA, the proposed rule would enhance the provisions of 30 CFR part 733. Proposed § 733.5 would define the terms ''action plan'' and ''State regulatory program issue.'' Proposed § 733.12 would address how early identification of and corrective action for State regulatory program issues can be achieved. OSMRE considers these additions to the regulations beneficial for early identification, evaluation, and resolution of potential problems that may impact a State regulatory authority's ability to effectively implement, administer, enforce, or maintain its State regulatory program. Further, these proposed mechanisms would avoid unnecessary substitution of Federal enforcement and minimize the number of on-the-ground violations.

Additionally, in the sections that would be added or revised throughout 30 CFR part 733, the proposed rule would add the term ''regulatory'' between the terms ''State'' and ''program.'' Specific wording is discussed in each proposed section, below. OSMRE finds these to be nonsubstantive changes made for the purpose of clarity; if incorporated into a final rule, these changes would clearly differentiate between a regulatory program administered by OSMRE and a State regulatory program that is administered by a State that has achieved primacy after approval by OSMRE.

Proposed § 733.5—Definitions

The proposed rule would add a definition section to 30 CFR part 733. The proposed rule would define the terms ''action plan'' and ''State regulatory program issue.'' In short, under the proposed definition, the term ''action plan'' would mean ''a detailed schedule OSMRE prepares to identify specific requirements a State regulatory authority must achieve in a timely manner to resolve State regulatory program issues identified during oversight of State regulatory programs.'' Historically, OSMRE and State regulatory authorities have used action plans as a compliance strategy and documented their use in the Annual Evaluation Reports that OSMRE compiles to discuss, among other things, the status of State regulatory programs. Therefore, the proposed inclusion of a definition for the term ''action plan'' in the regulations would not place a new burden on State regulatory authorities, but would merely create regulatory certainty and promote uniform application.

Similarly, the proposed rule would define the term ''State regulatory program issue'' to mean:

> an issue we identified during our oversight of a State or Tribal regulatory program that could result in a State regulatory authority not effectively implementing, administering, enforcing, or maintaining all or any portion of its State regulatory program, including instances when a State regulatory authority has not adopted and implemented program amendments that are required under 30 CFR 732.17 and 30 CFR Subchapter T, and issues related to the requirement in section 510(b) of the Act that a regulatory authority must not approve a permit or revision to a permit unless the regulatory authority finds that the application is accurate and complete and that the application is in compliance with all requirements of the Act and the State regulatory program.

Generally, OSMRE identifies State regulatory program issues during oversight of a State regulatory program. In short, State regulatory program issues are those that may result in a State regulatory authority not adhering to its approved, State regulatory program. Other examples of a State regulatory program issue include when a State regulatory authority does not adopt and implement program amendments that are required under 30 CFR 732.17 and 30 CFR Subchapter T. The proposed definition would also include issues related to the requirement in SMCRA section 510(b), 30 U.S.C. 1260(b), that a regulatory authority must not approve a permit or permit revision, unless the regulatory authority finds that the application is accurate and complete and is in compliance with all of SMCRA's requirements and those of the approved program.

As discussed above in relation to the proposed changes to 30 CFR part 842, the TDN and Federal inspection process in section 521(a) of SMCRA and the State regulatory program enforcement provisions in section 521(b) of SMCRA, along with the existing implementing regulations, differentiate between issues related to a State regulatory authority's failure to implement, administer, maintain, and enforce all or a part of a State regulatory program and possible violations that could lead to a TDN or Federal inspection. Most notably, the State regulatory program enforcement provisions of section 521(b) of SMCRA generally address systemic programmatic problems with a State regulatory program, not specific violations exclusive to an individual operation or permit as detailed in section 521(a) of SMCRA. However, citizens sometimes identify State regulatory program issues in citizen complaints under section 521(a) of SMCRA and 30 CFR part 842. OSMRE may also become aware of a State regulatory program issue while overseeing enforcement of specific operations or permits. As discussed above in connection with proposed § 842.11(b)(1)(ii)(B)(*3*), the proposed rule would modify the definition of ''appropriate action'' to further clarify the differences between possible violations, which may warrant issuance of a TDN or a Federal inspection on specific permits, and systemic, programmatic issues, which are not appropriately addressed through the TDN or Federal inspection process. SMCRA and the existing regulations provide a remedy for systemic, programmatic issues at 30 CFR part 733 by identifying procedures for substituting Federal enforcement of State regulatory programs or withdrawing approval of State regulatory programs. The proposed addition of early identification and corrective action to address State regulatory program issues would enhance our ability to ensure prompt resolution of issues, which, if unattended, may result in OSMRE exercising the rare remedy of substituting Federal enforcement. Specifically, if the proposed inclusion of an ''action plan,'' as proposed in § 733.5(a), is finally adopted, an ''appropriate action'' that a State might take, as explained in proposed § 842.11(b)(1)(ii)(B)(*3*), could include OSMRE and the State regulatory authority immediately and jointly initiating steps to implement corrective action to resolve any issue that the authorized representative and applicable Field Office Director identify as a State regulatory program issue. The proposed modification to 30 CFR 842.11(b)(1)(ii)(B)(*3*), coupled with the proposed definition of ''State regulatory program issue,'' is designed to further clarify the differences between the types of violations or issues that would be addressed by the TDN and Federal inspection process in section 521(a) and the State regulatory program enforcement provisions in section 521(b) of SMCRA, respectively.

While OSMRE may sometimes identify State regulatory program issues during the TDN process, as discussed in the preceding paragraph, at other times, as referenced earlier in this preamble, OSMRE may identify and address State regulatory program issues before, and instead of, initiating the TDN process. For example, over the years, various groups, including citizens, State regulatory authorities, and industry,

have raised the issue of how OSMRE deals with alleged problems in a permit that a State regulatory authority has issued to a permittee. This proposed rule would address these types of issues in the proposed additions to the regulations at 30 CFR part 733. As discussed above, SMCRA provides textual support for this approach. However, as previously discussed earlier in this preamble, even when a State regulatory authority and OSMRE are engaged in the proposed Part 733 process, the State regulatory authority could still take direct enforcement action under its State regulatory program. Additionally, OSMRE could still take appropriate oversight enforcement actions, in the event that there is or may be an imminent on-the-ground violation. It should be noted that an imminent on-the-ground violation is different from ''[i]mminent danger to the health and safety of the public,'' as defined at 30 CFR 701.5. Like other changes proposed in this rulemaking, the proposed additions to 30 CFR part 733 should provide greater regulatory stability and certainty in relationship to State regulatory program issues and how these issues will be addressed to all interested parties, including citizens, State regulatory authorities, and permittees. OSMRE has addressed mechanisms for handling State regulatory program issues in various ways outside the context of rulemaking, but uncertainty among the regulated community and State regulatory authorities remain. The proposed rule would resolve the issue in the context of this rulemaking initiative by clearly differentiating between the types of violations or issues that would be addressed by the TDN and Federal inspection process outlined in section 521(a) and the State regulatory program enforcement provisions in section 521(b) of SMCRA.

In sum, these proposed changes would ensure a more complete enforcement of SMCRA, and provide guidance on early detection of potential problems that may, if left unaddressed, escalate to the point that OSMRE considers substituting Federal enforcement procedures as outlined in existing 30 CFR 733.12 through 733.13.

Proposed 733.12—Early Identification and Corrective Action To Address State Regulatory Program Issues

The proposed rule would redesignate certain sections of existing 30 CFR part 733 to accommodate both the proposed new definition section at 30 CFR 733.5, discussed above, and a new proposed § 733.12 entitled, ''Early identification and corrective action to address State regulatory program issues.'' Because this rulemaking proposes to number the new, proposed section as 733.12, the proposed rule would re-designate existing § 733.12 as 733.13 and existing § 733.13 as 733.14. Additionally, the proposed rule would replace references to § 733.12 in the existing regulations with references to § 733.13 in the proposed rule, in accordance with the new section numbering to accommodate the addition of proposed new § 733.12. In particular, in existing § 733.10, the proposed rule would replace the reference to 30 CFR 733.12(a)(2) with a reference to 30 CFR 733.13(a)(2). Similarly, in existing § 736.11(a)(2), the proposed rule would replace the reference to ''§ 733.12'' with a reference to ''§ 733.13.'' Also, in existing § 733.10, the proposed rule would change a reference from ''OSM'' to ''OSMRE'' for consistency.

Proposed § 733.12 would contain the substantive mechanisms and compliance strategies that OSMRE would use to resolve a State regulatory program issue (as defined in proposed 30 CFR 733.5) that OSMRE becomes aware of during oversight of a State regulatory program or from information OSMRE receives from any person. Although OSMRE has historically worked closely with the State regulatory authorities and used similar approaches, incorporating these approaches into the regulations would provide a clear mechanism for early identification and resolution of issues that would enable OSMRE to achieve regulatory certainty and uniform implementation of the procedures among State regulatory authorities. This proposed addition to the regulations would include procedures for developing an action plan (as defined in proposed 30 CFR 733.5) so that OSMRE can ensure that State regulatory program issues are timely resolved.

When OSMRE identifies a State regulatory program issue, proposed § 733.12(a) would provide that the Director should take action to make sure that the issue does not escalate to the point that might give the Director reason to believe that the State regulatory authority is not effectively implementing, administering, enforcing, or maintaining all or a part of its State regulatory program, which could otherwise lead to substituting Federal enforcement of a State regulatory program or withdrawing approval of a State regulatory program as provided in 30 CFR part 733. OSMRE would use the proposed procedures in proposed § 733.12 to attempt to achieve resolution of the issue in a timely and effective manner. It is emphasized that proposed § 733.12 would not, in any manner, diminish the requirements of existing 30 CFR 733.12 (that would be re-designated as 30 CFR 733.13 under this proposed rule) or our responsibilities associated with substituting Federal enforcement of State regulatory programs or withdrawing approval of State regulatory programs under the appropriate circumstances. Instead, this proposed procedure supplements the existing process in order to identify problems before State regulatory program issues rise to the level of warranting the rare remedy of substituting Federal enforcement. In the event OSMRE has reason to believe that the State regulatory authority is not effectively implementing, administering, enforcing, or maintaining its State regulatory program, OSMRE would use existing 30 CFR 733.12 (that would be redesignated as § 733.13) and all other applicable provisions to respond appropriately. In contrast, if the State regulatory program issue does not rise to the level of requiring OSMRE to substitute Federal enforcement, OSMRE may initiate the proposed process for early identification and corrective action found in proposed § 733.12(b). Inherent in the previous statement is the supposition that the State regulatory program issue is a programmatic problem, not a possible violation warranting a TDN or Federal inspection, as contemplated in section 521(a)(1) of SMCRA; if it is a possible violation, OSMRE would use the TDN procedures if OSMRE has reason to believe that a violation exists.

In general, proposed § 733.12(b) would allow the OSMRE Director, or his or her delegate, as set forth in OSMRE's guidance, to ''employ any number of compliance strategies to ensure that the State regulatory authority corrects State regulatory program issues in a timely and effective manner.'' OSMRE suggests that possible compliance strategies might include, but are not limited to:

- OSMRE engaging in informal discussions with the State regulatory authority regarding possible resolutions of the issue;
- OSMRE and the State regulatory authority participating in the program amendment process as outlined in 30 CFR 732.17;
- OSMRE suggesting changes in the State regulatory authority's procedures, use of resources, or training of staff;
- OSMRE providing technical assistance or initiating targeted special studies that our technical experts would conduct;
- OSMRE increasing our number of oversight inspections beyond the statutory minimum or providing more

OSMRE inspection teams to supplement the State regulatory authority's inspection resources;

- OSMRE conducting a formal audit of the State regulatory authority's permitting and compliance activities;
- OSMRE conducting public fact-finding hearings related to the State regulatory program issue; or
- OSMRE devising enhanced tracking procedures to determine if the State regulatory program issue represents a systemic problem.

Although the above list reflects examples of potential corrective actions that a State regulatory authority and OSMRE might jointly employ, the list is not exhaustive. In fact, OSMRE recommends a case-by-case analysis of the State regulatory program issue. This would allow the State regulatory authority and OSMRE to develop a specifically tailored, innovative solution to the State regulatory program issue that is designed to achieve timely resolution.

Generally, OSMRE does not anticipate that resolution of a State regulatory program issue should exceed 180 days. However, the proposed rule at § 733.12(b) would provide that if the OSMRE Director or delegate ''does not expect that the State regulatory authority will resolve the State regulatory program issue within 180 days after identification or that it is likely to result in an on-the-ground violation, then the Director or delegate will develop and institute an action plan [as defined in proposed § 733.5].'' In proposed § 733.12(b)(1), OSMRE would prepare a written action plan with sufficient ''specificity to identify the State regulatory program issue and an effective mechanism for timely correction.'' When OSMRE is preparing the action plan, OSMRE would consider any input it receives from the State regulatory authority. When selecting corrective measures to integrate into the action plan, OSMRE may consider any established or innovative solutions, including the compliance strategies referenced above. Additionally, proposed § 733.12(b)(2) states that ''[a]ction plans will identify any necessary technical or other assistance that the Director or his or her delegate can provide and remedial measures that a State regulatory authority must take immediately.'' It is important for OSMRE to assist the State regulatory authorities in any way to ensure successful implementation of their respective State regulatory programs. This provision also recognizes that OSMRE might identify a State regulatory program issue that requires immediate remedial measures, and the action plan would reflect that fact.

The balance of this proposed section, at § 733.12(b)(3), describes the contents of action plans. To ensure that OSMRE can adequately track actions plans and that the underlying State regulatory program issue is resolved, under the proposed rule each action plan would be required to include: A specific ''action plan identification number''; ''a concise title and description of the State regulatory program issue''; ''explicit criteria for establishing when complete resolution will be achieved''; ''explicit and orderly sequence of actions the State regulatory authority must take to remedy the problem''; ''a schedule for completion of each action in the sequence''; and ''a clear explanation that if the action plan, upon completion, does not result in the correction of the State regulatory program issue, the provisions of 30 CFR 733.13 [existing § 733.12] may be triggered.''

Proposed § 733.12(c) reiterates that OSMRE will track all identified State regulatory program issues. As part of OSMRE oversight responsibilities, each year OSMRE develops a performance agreement and evaluation plan to guide oversight activities within each primacy State. That process includes solicitation and consideration of public input and involves collaboration with the respective State. At the end of the evaluation period, OSMRE prepares an Annual Evaluation report. As proposed, this section would also require OSMRE to report the issues in the applicable State regulatory authority's Annual Evaluation report.

Finally, proposed § 733.12(d) would emphasize that nothing in the proposed new section ''prevents a State regulatory authority from taking direct enforcement action in accordance with its State regulatory program, or [us] from taking appropriate oversight enforcement action, in the event that a previously identified State regulatory program issue results in or may imminently result in an on-the-ground violation.'' In context, ''imminence'' may vary, and OSMRE will rely on our authorized representative to use his or her professional judgment to determine whether an on-the-ground violation is imminent in a given situation.

IV. Procedural Matters

Executive Order 12630—Governmental Actions and Interference With Constitutionally Protected Property Rights

This proposed rule would not affect a taking of private property or otherwise have takings implications under Executive Order 12630. The proposed rule primarily concerns Federal oversight of State regulatory programs and enforcement when permittees and operators are not complying with the law. Therefore, the proposed rule would not result in private property being taken for public use without just compensation. A takings implication assessment is not required.

Executive Order 12866—Regulatory Planning and Review and Executive Order 13563—Improving Regulation and Regulatory Review

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has not deemed this proposed rule significant because it would not have a $100 million annual impact on the economy, raise novel legal issues, or create significant impacts. The proposed rule would primarily clarify the existing regulations to reduce the burden upon the regulated community and preserve resources by allowing for greater cooperation between the Federal Government and the States.

Executive Order 13563 reaffirms the principles of Executive Order 12866 while calling for improvements in the nation's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. The Executive Order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. Executive Order 13563 emphasizes further that agencies must base regulations on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. This proposed rule has been developed in a manner consistent with these requirements.

Executive Order 13771—Reducing Regulation and Controlling Regulatory Costs

This proposed rule describes a proposed deregulatory action. Consistent with Executive Order 13771 and the April 5, 2017, Guidance Implementing Executive Order 13771, the proposed rule, if finalized, will have total costs less than zero.

Executive Order 12988—Civil Justice Reform

This proposed rule complies with the requirements of Executive Order 12988. Among other things, this rule:

(a) Satisfies the criteria of Section 3(a) requiring that all regulations be reviewed to eliminate drafting errors and ambiguity; be written to minimize litigation; and provide clear legal standards for affected conduct; and

(b) satisfies the criteria of Section 3(b) requiring that all regulations be written in clear language and contain clear legal standards.

Executive Order 13132—Federalism

Under the criteria in Section 1 of Executive Order 13132, this proposed rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement. While clarification of the existing regulations would have a direct effect on the States and the Federal Government's relationship with the States, this effect is not significant as it neither imposes substantial unreimbursed compliance costs on States nor preempts State law. Furthermore, this proposed rule would not have a significant effect on the distribution of power and responsibilities among the various levels of government. The proposed rule would reduce burdens on State regulatory authorities and more closely align the regulations to SMCRA. A federalism summary impact statement is not required.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

The Department of the Interior strives to strengthen its government-to-government relationship with Tribes through a commitment to consultation with Tribes and recognition of their right to self-governance and tribal sovereignty. OSMRE has evaluated this proposed rule under the Department's consultation policy and under the criteria in Executive Order 13175 and have determined that it would not have substantial direct effects on federally recognized Tribes and that consultation under the Department's tribal consultation policy is not required. Currently, no Tribes have achieved primacy; therefore, OSMRE regulates all surface coal mining and reclamation operations on Indian lands with tribal input and assistance. Currently, OSMRE works in conjunction with the Crow, Hopi, and Navajo regarding enforcement of surface coal mining and reclamation operations. This proposed rulemaking would not directly impact the Tribes. However, because they have expressed interest in perhaps having their own regulatory programs in the future, OSMRE has coordinated with the Crow, Hopi, and Navajo to inform them of, and to provide updates on the progress of, our proposed rulemaking.

Executive Order 13211—Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

Executive Order 13211 requires agencies to prepare a Statement of Energy Effects for a rule that is: (1) Considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy; or is designated as a significant energy action by the Office of Management and Budget. Because this proposed rule is not deemed significant under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

Executive Order 13045—Protection of Children From Environmental Health Risks and Safety Risks

This proposed rule is not subject to Executive Order 13045 because this is not an economically significant regulatory action as defined by Executive Order 12866; and this action would not concern environmental health or safety risks disproportionately affecting children.

National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 3701 note *et seq.*) directs Federal agencies to use voluntary consensus standards when implementing regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. This proposed rule would not be subject to the requirements of section 12(d) of the NTTAA because application of those requirements would be inconsistent with SMCRA, and the requirements would not be applicable to this proposed rulemaking.

National Environmental Policy Act

OSMRE has made a preliminary determination that the changes to the existing regulations that would be made under this proposed rule are categorically excluded from environmental review under the National Environmental Policy Act (NEPA). 42 U.S.C. 4321 *et seq.* Specifically, OSMRE has determined that the proposed rule is administrative or procedural in nature in accordance with the Department of the Interior's NEPA regulations at 43 CFR 46.210(i). The regulation provides a categorical exclusion for, ''[p]olicies, directives, regulations, and guidelines: that are of an administrative, financial, legal, technical, or procedural nature; or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis . . . .'' The proposed rule primarily seeks to clarify how OSMRE formulates reason to believe in the TDN context and the information OSMRE considers in this analysis. As such, the proposed rule would merely clarify OSMRE's process. Therefore, OSMRE deems the proposed changes to the regulations to be administrative and procedural in nature, as these proposed changes ensure regulatory certainty. These clarifications would result in efficiency and enhanced collaboration among State regulatory authorities and OSMRE. OSMRE has also determined that the proposed rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that would require further analysis under NEPA. OSMRE will continue to review these factors as the proposed rule is evaluated.

Paperwork Reduction Act

This proposed rule would not impose a collection of information burden, as defined by 44 U.S.C. 3502, upon any entity defined in the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

Based on OSMRE's collaboration with State regulatory authorities and years of experience, OSMRE certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The Regulatory Flexibility Act generally requires Federal agencies to prepare a regulatory flexibility analysis for rules that are subject to the notice-and-comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553), if the rule would have a significant economic impact on a substantial number of small entities. *See* 5 U.S.C. 601–612.

Small Business Regulatory Enforcement Fairness Act

This proposed rule is not a major rule under the Small Business Regulatory Enforcement Fairness Act. 5 U.S.C. 804(2). Specifically, the proposed rule: (a) Would not have an annual effect on

the economy of $100 million or more; (b) would not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) would not have 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.

Unfunded Mandates Reform Act

This proposed rule would not impose an unfunded mandate on State, local, or Tribal governments, or the private sector, of $100 million or more in any given year. The proposed rule would not have a significant or unique effect on State, local, or Tribal governments, or the private sector. A statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects

30 CFR Part 733

Intergovernmental relations, Surface mining, Underground mining.

30 CFR Part 736

Coal mining, Intergovernmental relations, Surface mining, Underground mining.

30 CFR Part 842

Law enforcement, Surface mining, Underground mining.

Casey Hammond,

Principal Deputy Assistant Secretary, Exercising the authority of the Assistant Secretary, Land and Minerals Management.

For the reasons set out in the preamble, the Department of the Interior, acting through OSMRE, proposes to amend 30 CFR parts 733, 736 and 842 as follows:

PART 733—EARLY IDENTIFICATION OF CORRECTIVE ACTION, MAINTENANCE OF STATE PROGRAMS, PROCEDURES FOR SUBSTITUTING FEDERAL ENFORCEMENT OF STATE PROGRAMS, AND WITHDRAWING APPROVAL OF STATE PROGRAMS

■ 1. The authority citation for part 733 is revised to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. The heading of part 733 is revised as set forth above.

■ 3. Add § 733.5 to read as follows:

§ 733.5 Definitions.

As used in this part, the following terms have the specified meanings:

Action plan means a detailed schedule OSMRE prepares to identify specific

requirements a regulatory authority must achieve in a timely manner to resolve State regulatory program issues identified during oversight of State regulatory programs.

State regulatory program issue means an issue OSMRE identifies during oversight of a State or Tribal regulatory program that could result in a State regulatory authority not effectively implementing, administering, enforcing, or maintaining all or any portion of its State regulatory program, including instances when a State regulatory authority has not adopted and implemented program amendments that are required under 30 CFR 732.17 and 30 CFR Subchapter T, and issues related to the requirement in section 510(b) of the Act that a State regulatory authority must not approve a permit or revision to a permit unless the State regulatory authority finds that the application is accurate and complete and that the application is in compliance with all requirements of the Act and the State regulatory program.

■ 4. Revise § 733.10 to read as follows:

§ 733.10 Information collection.

The information collection requirement contained in 30 CFR 733.13(a)(2) has been approved by the Office of Management and Budget under 44 U.S.C. 3507 and assigned clearance number 1029–0025. The information required is needed by OSMRE to verify the allegations in a citizen request to evaluate a State program and to determine whether an evaluation should be undertaken.

■ 5. Redesignate §§ 733.12 and 733.13 as §§ 733.13 and 733.14 respectively.

■ 6. Add a new § 733.12 to read as follows:

§ 733.12 Early identification and corrective action to address State regulatory program issues.

(a) When the Director identifies a State regulatory program issue, he or she should take action to make sure the identified State regulatory program issue is corrected as soon as possible in order to ensure that it does not escalate into an issue that would give the Director reason to believe that the State regulatory authority is not effectively implementing, administering, enforcing, or maintaining all or a portion of its State regulatory program.

(1) The Director may become aware of State regulatory program issues through oversight of State regulatory programs or as a result of information received from any person.

(2) If the Director concludes that the State regulatory authority is not effectively implementing, administering, enforcing, or maintaining all or a portion of its State regulatory program, the Director may substitute Federal enforcement of a State regulatory program or withdraw approval of a State regulatory program as provided in part 733.

(b) The Director or his or her delegate may employ any number of compliance strategies to ensure that the State regulatory authority corrects State regulatory program issues in a timely and effective manner. However, if the Director or delegate does not expect that the State regulatory authority will resolve the State regulatory program issue within 180 days after identification or that it is likely to result in an on-the-ground violation, then the Director or delegate will develop and institute an action plan.

(1) Action plans will be written with specificity to identify the State regulatory program issue and an effective mechanism for timely correction.

(2) Action plans will identify any necessary technical or other assistance that the Director or his or her delegate can provide and remedial measures that a State regulatory authority must take immediately.

(3) Action plans must also include:

(i) An action plan identification number;

(ii) A concise title and description of the State regulatory program issue;

(iii) Explicit criteria for establishing when complete resolution will be achieved;

(iv) Explicit and orderly sequence of actions the State regulatory authority must take to remedy the problem;

(v) A schedule for completion of each action in the sequence; and

(vi) A clear explanation that if the action plan, upon completion, does not result in correction of the State regulatory program issue, the provisions of 30 CFR 733.13 may be triggered.

(c) All identified State regulatory program issues must be tracked and reported in the applicable State regulatory authority's Annual Evaluation report. Within each report, benchmarks identifying progress related to resolution of the State regulatory program issue must be documented.

(d) Nothing in this section prevents a State regulatory authority from taking direct enforcement action in accordance with its State regulatory program, or OSMRE from taking appropriate

oversight enforcement action, in the event that a previously identified State regulatory program issue results in or may imminently result in an on-the-ground violation.

PART 736—FEDERAL PROGRAM FOR A STATE

■ 7. The authority citation for part 736 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.,* as amended; and Pub. L. 100–34.

■ 8. Revise § 736.11(a)(2) to read as follows:

§ 736.11 General procedural requirements.

(a) * * *

(2) The Director shall promulgate a complete Federal program for a State upon the withdrawal of approval of an entire State program under § 733.13.

* * * * *

PART 842—FEDERAL INSPECTIONS AND MONITORING

■ 9. The authority citation for part 842 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 10. Amend § 842.11 by revising paragraphs (b)(1) introductory text, (b)(1)(i), (b)(1)(ii)(A), (b)(1)(ii)(B)(*1*), (*3*) and (*4*), and (b)(2) to read as follows:

§ 842.11 Federal inspections and monitoring.

* * * * *

(b)(1) An authorized representative of the Secretary will immediately conduct a Federal inspection:

(i) When the authorized representative has reason to believe on the basis of any information readily available to him or her (other than information resulting from a previous Federal inspection) that there exists a violation of the Act, this chapter, the State regulatory program, or any condition of a permit or an exploration approval, or that there exists any condition, practice, or violation that creates an imminent danger to the health or safety of the public or is causing or could reasonably be expected to cause a significant, imminent environmental harm to land, air, or water resources and—

(ii)(A) There is no State regulatory authority or the Office is enforcing the State regulatory program under section 504(b) or 521(b) of the Act and part 733 of this chapter; or

(B)(*1*) The authorized representative has notified the State regulatory authority of the possible violation and more than ten days have passed since notification, and the State regulatory authority has not taken appropriate action to cause the violation to be corrected or to show good cause for not doing so, or the State regulatory authority has not provided the authorized representative with a response. After receiving a response from the State regulatory authority, but before a Federal inspection, the authorized representative will determine in writing whether the standards for appropriate action or good cause have been satisfied. A State regulatory authority's failure to respond within ten days does not prevent the authorized representative from making a determination, and will constitute a waiver of the State regulatory authority's right to request review under paragraph (b)(1)(iii) of this section.

* * *

(*3*) Appropriate action includes enforcement or other action authorized under the approved State program to cause the violation to be corrected. Appropriate action may include OSMRE and the State regulatory authority immediately and jointly initiating steps to implement corrective action to resolve any issue that the authorized representative and applicable Field Office Director identify as a State regulatory program issue, as defined in 30 CFR part 733.

(*4*) Good cause includes:

(*i*) The possible violation does not exist under the State regulatory program;

(*ii*) The State regulatory authority has initiated an investigation into a possible violation and as a result has determined that it requires a reasonable, specified additional amount of time to determine whether a violation exists. When analyzing the State regulatory authority's response for good cause, the authorized representative has discretion to determine how long the State regulatory authority should reasonably be given to complete its investigation of the possible violation and will communicate to the State regulatory authority the date by which the investigation must be completed. At the conclusion of the specified additional time, the authorized representative will re-evaluate the State regulatory authority's response including any additional information provided;

(*iii*) The State regulatory authority demonstrates that it lacks jurisdiction over the possible violation under the State regulatory program;

(*iv*) The State regulatory authority demonstrates that it is precluded from taking action on the possible violation because an administrative review body or court of competent jurisdiction has issued an order concluding that the possible violation does not exist or that the temporary relief standards of the State regulatory program counterparts to section 525(c) or 526(c) of the Act have been satisfied; or

(*v*) Regarding abandoned sites, as defined in 30 CFR 840.11(g), the State regulatory authority is diligently pursuing or has exhausted all appropriate enforcement provisions of the State regulatory program.

* * * * *

(2) An authorized representative will have reason to believe that a violation, condition, or practice referred to in paragraph (b)(1)(i) of this section exists if the facts that a complainant alleges, or facts that are otherwise known to the authorized representative, constitute simple and effective documentation of the alleged violation, condition, or practice. In making this determination, the authorized representative will consider any information readily available to him or her, including any information a citizen complainant or the relevant State regulatory authority submits to the authorized representative.

* * * * *

■ 11. Revise § 842.12(a) to read as follows:

§ 842.12 Requests for Federal inspections.

(a) Any person may request a Federal inspection under § 842.11(b) by providing to an authorized representative a signed, written statement (or an oral report followed by a signed written statement) setting forth information that, along with any other readily available information, may give the authorized representative reason to believe that a violation, condition, or practice referred to in § 842.11(b)(1)(i) exists. The statement must also set forth the fact that the person has notified the State regulatory authority, if any, in writing, of the existence of the possible violation, condition, or practice, and the basis for the person's assertion that the State regulatory authority has not taken action with respect to the possible violation. The statement must set forth a phone number, address, and, if available, an email address where the person can be contacted.

* * * * *

[FR Doc. 2020–10165 Filed 5–13–20; 8:45 am]

BILLING CODE 4310–05–P

POSTAL SERVICE

39 CFR Part 111

Extra Services Refund Time Limit

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: The Postal Service is proposing to amend *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM®) in subsection 604.9.2 to revise the time limit for extra service refunds.

DATES: Submit comments on or before June 15, 2020.

ADDRESSES: Mail or deliver written comments to the manager, Product Classification, U.S. Postal Service, 475 L'Enfant Plaza SW, Room 4446, Washington, DC 20260–5015. If sending comments by email, include the name and address of the commenter and send to *PCFederalRegister@usps.gov,* with a subject line of ''Extra Services Refund Time Limit''. Faxed comments are not accepted.

Confidentiality

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments that you consider to be confidential or inappropriate for public disclosure.

You may inspect and photocopy all written comments, by appointment only, at USPS® Headquarters Library, 475 L'Enfant Plaza SW, 11th Floor North, Washington, DC, 20260. These records are available for review on Monday through Friday, 9 a.m.–4 p.m., by calling (202) 268–2906.

FOR FURTHER INFORMATION CONTACT: Sheila Marano at (202) 268–4257, Adaisja Johnson at (202) 268–6724, or Garry Rodriguez at (202) 268–7281.

SUPPLEMENTARY INFORMATION:

Currently, DMM Exhibit 604.9.2.1, *Postage and Fees Refunds,* provides that a customer must apply for an extra service refund no sooner than 10 days, or no later than 60 days, from the date the service was purchased.

Certain extra services (*e.g.,* Certified Mail®) have workflow timelines that extend beyond the current 10-day limit to initially file for a refund. As a result, to meet the required workflow timelines for these extra services, and for consistency in application of the refund processes, the Postal Service is proposing to extend the current 10-day time limit to a 30-day time limit before a customer can file for a refund.

In addition, the Postal Service is proposing to add another category for refunds, ''All other classes of mail with an extra service'' for consistency. This proposed revision to the 30-day time limit will apply for refunds of both pieces of all other classes of mail with an extra service and for an extra service. This revision will not affect the ''Priority Mail Express® with an extra service'' refund category.

We believe this proposed revision will provide customers with a more efficient process and a more consistent customer experience.

Although exempt from the notice and comment requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites public comments on the following proposed revisions to *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. *See* 39 CFR 111.1.

We will publish an appropriate amendment to 39 CFR part 111 to reflect these changes.

Accordingly, 39 CFR part 111 is proposed to be amended as follows:

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

PART 111—[AMENDED]

■ 1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301–307; 18 U.S.C. 1692–1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3622, 3626, 3632, 3633, and 5001.

■ 2. Revise the *Mailing Standards of the United States Postal Service,* Domestic Mail Manual (DMM) as follows:

Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM)

* * * * *

600 Basic Standards for All Mailing Services

* * * * *

604 Postage Payment Methods and Refunds

* * * * *

9.0 Exchanges and Refunds

* * * * *

9.2 Postage and Fee Refunds

* * * * *

9.2.1 General Standards

* * * * *

Exhibit 9.2.1 Postage and Fees Refunds

Customers must apply for a refund within the time limits in the chart below.

Mail type or service	When to apply (from mailing date)	
	No sooner than	No later than
* * *	* *	* *
[Revise the text of the ''Extra Services'' line item to read as follows:]		
All other classes of mail with an Extra Service or Extra Services (9.2.4h).	30 days	60 days.

* * * * *

9.2.4 Postage and Fee Refunds Not Available

Refunds are not made for the following:

* * * * *

[Revise the text of item h to read as follows:]

h. Except for extra service fees paid with Priority Mail Express under 9.2.1, fees paid for extra services, as allowed under 9.2.3, when refund request is made by the mailer less than 30 days, or more than 60 days, from the date the service was purchased, unless otherwise authorized by the manager, Revenue and Field Accounting (see 608.8.0 for address).

* * * * *

Ruth B. Stevenson,

Attorney, Federal Compliance.

[FR Doc. 2020–09843 Filed 5–13–20; 8:45 am]

BILLING CODE 7710–12–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2019–0195; FRL–10008–41–Region 4]

Air Plan Approval; GA; Revision to I/M Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a State Implementation Plan (SIP) revision submitted by the State of Georgia through a letter dated March 15, 2019, through the Georgia Department of Natural Resources (GA DNR), Environmental Protection Division (GA EPD). The proposed changes are to remove obsolete references, clarify the State's inspection and maintenance (I/M) requirements, and update terminology, including to reflect advances in technology. EPA has evaluated the SIP revision and has preliminarily determined the changes will not impact emissions under the Georgia I/M program. EPA is proposing to conclude that approval of the SIP revision will not interfere with attainment or maintenance of any national ambient air quality standard (NAAQS) or with any other applicable requirement of the Clean Air Act (CAA or Act). Therefore, EPA is proposing to determine that Georgia's March 15, 2019, SIP revision is consistent with the applicable provisions of the CAA.

DATES: Written comments must be received on or before June 15, 2020.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2019–0195 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* 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. 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 *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Kelly Sheckler, Air Regulatory Management Section, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303–8960. The telephone number is (404) 562–9222. Ms. Sheckler can also be reached via electronic mail at *sheckler.kelly@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. What is the background of Georgia's SIP-approved I/M program?

The CAA requires certain areas that are designated as moderate, serious, severe, or extreme ozone nonattainment areas to establish a motor vehicle I/M program to ensure regular monitoring of gasoline fueled motor vehicle emissions by requiring that vehicles undergo periodic emissions testing. *See* CAA sections 182(b)(4), (c)(3). This emissions testing ensures that vehicles are well maintained and operating as designed, and do not exceed established vehicle pollutant limits. A basic I/M program is required for certain moderate areas and an enhanced I/M program is required for certain serious, severe, or extreme ozone nonattainment areas.

In 1991, EPA classified a 13-county area in and around the Atlanta, Georgia, metropolitan area as a serious ozone nonattainment area for the 1990 1-hour ozone NAAQS, triggering the requirement for the State to establish an enhanced I/M program for this area.[1] In 1996, Georgia submitted its enhanced I/M program to EPA for incorporation into the SIP. EPA granted interim approval of the State's program. *See* 62 FR 42916 (August 11, 1997). Full approval was subsequently granted. *See* 65 FR 4133 (January 26, 2000). Since that time, EPA has approved several SIP revisions regarding the State's I/M program.

In 1997, EPA established an 8-hour ozone NAAQS and subsequently designated areas. On April 30, 2004 (69 FR 23858), EPA designated a 20-county area, in and around metropolitan Atlanta, as a marginal ozone nonattainment area for the 1997 8-hour ozone NAAQS.[2] EPA reclassified these counties as a moderate ozone nonattainment area on March 6, 2008 (73 FR 12013), because the area failed to attain the 1997 8-hour ozone NAAQS by the required attainment date of June 15, 2007. Subsequently, the area attained the 1997 8-hour ozone standard, and on December 2, 2013 (78 FR 72040), EPA redesignated the counties to attainment for the 1997 8-hour ozone NAAQS.

On March 12, 2008, EPA revised the 8-hour ozone NAAQS. *See* 73 FR 16436 (March 27, 2008). EPA designated a 15-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 2008 8-hour ozone NAAQS on April 30, 2012 (effective July 20, 2012).[3] *See* 77 FR 30088 (May 21, 2012). EPA reclassified these counties as a moderate ozone nonattainment area on April 11, 2016, because the area failed to attain the 2008 8-hour ozone NAAQS by the required attainment date of July 20, 2015. *See* 81 FR 26697 (May 4, 2016). Subsequently, the area attained the 2008 8-hour ozone standard and EPA redesignated the counties to attainment for the 2008 8-hour ozone NAAQS. *See* 40 CFR 25523 (June 2, 2017).

On October 1, 2015, EPA again revised the 8-hour ozone NAAQS to 0.070 parts per million (ppm). *See* 80 FR 16436 (October 26, 2015). EPA designated a 7-county area in and around metropolitan Atlanta as a marginal ozone nonattainment area for the 2015 8-hour ozone NAAQS on April 30, 2018 (effective August 3, 2018).[4] The attainment date is August 3, 2021.

II. What is being proposed?

EPA is proposing to approve changes to the Georgia SIP that were provided to EPA under a cover letter dated March 15, 2019.[5] Specifically, GA EPD provided three different changes to Georgia's Rule 391–3–20—*Enhanced Inspection and Maintenance* (''Georgia I/M Regulation''), which were adopted by the GA DNR Board of Directors and became state-effective on November 22, 2016, March 28, 2018, and February 17,

[1] On November 6, 1991, EPA designated and classified the following counties in and around the Atlanta, Georgia, metropolitan area as a serious ozone nonattainment area for the 1-hour ozone NAAQS: Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Paulding, and Rockdale. *See* 56 FR 56694.

[2] The nonattainment area for the 1997 8-hour ozone standard consisted of the following counties: Barrow, Bartow, Carroll, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Hall, Henry, Newton, Paulding, Rockdale, Spalding, and Walton.

[3] The nonattainment area for the 2008 8-hour ozone standard consisted of the following counties: Bartow, Cherokee, Clayton, Cobb, Coweta, DeKalb, Douglas, Fayette, Forsyth, Fulton, Gwinnett, Henry, Newton, Paulding, and Rockdale.

[4] The nonattainment area for the 2015 8-hour ozone standard consisted of the following counties: Bartow, Clayton, Cobb, DeKalb, Fulton, Gwinnett, and Henry.

[5] EPA officially received Georgia's I/M SIP revision request on March 21, 2019.

2019.[6] With respect to 391–3–20–.06, GA EPD provided additional changes that the GA DNR Board adopted on January 31, 2014 and became state-effective on June 19, 2014.

The proposed changes are to update the SIP to remove obsolete references, clarify the State's I/M requirements, and update terminology, including to reflect advances in technology. These proposed changes include adding, removing, and revising definitions applicable to the Georgia I/M Regulation. EPA is proposing to determine that the changes will not impact emissions. Additional detail on the changes and EPA's analysis is contained in Section III.

III. State's Submittal and EPA's Analysis

Georgia's March 15, 2019, SIP revision seeks to modify the following sections of the Georgia's SIP-approved I/M Regulation: Rule 391–3–20–.01, ''Definitions;'' Rule 391–3–20–.03, ''Covered Vehicles: Exemptions;'' Rule 391–3–20–.04, ''Emission Inspection Procedures;'' Rule 391–3–20–.05, ''Emission Standards;'' Rule 391–3–20–.06, ''Testing of Exhaust Emissions by Remote Sensing Technology or Other Means;'' Rule 391–3–20–.07, ''Inspection Equipment System Specification;'' Rule 391–3–20–.09, ''Inspection Station Requirements;'' Rule 391–3–20–.10, ''Certificates of Authorization;'' Rule 391–3–20–.11, ''Inspector Qualifications and Certification;'' Rule 391–3–20–.13, ''Certificate of Emission Inspection;'' Rule 391–3–20–.15, ''Repairs and Retests;'' Rule 391–3–20–.17, ''Waivers;'' and Rule 391–3–20–.18, ''Sale of Vehicles.'' EPA's analysis of these changes is provided in sections III.A through III.N.

A. Rule 391–3–20–.01, ''Definitions''

Georgia's March 15, 2019, SIP revision includes the following: (1) Changes to the definitions of Acceleration Simulation Mode 2525/5015 exhaust emission test, Calibration, DLC, E-Certs, Georgia Analyzer System, Grandfathered Vehicle, Light Duty Vehicle, Management Contractor, Station Owner, and 2-speed idle (TSI) test; (2) additions of definitions for Certificate of Authorization, Certificate of Emissions Inspection, Emissions Inspector Certification Training Program Manual, Georgia Analyzer System Hardware and Software Specifications, Georgia's Clean Air Force, Inspection Term, Responsible Motor Vehicle, Revolutions per Minute, and State-Certified Emissions Inspection Station; and (3) removal of the terms I/M Inspection Procedures Manual, I/M Test Manual, and State Inspection Program. EPA has evaluated the changes to the definitions and has made the preliminary determination that the changes are to clarify the requirements, to delete obsolete references, and to add definitions. EPA's analysis of each of these changes is provided in further detail in the following discussion.

1. Revised Definitions

The following provides details and EPA's analysis of definition rule provisions related to the Georgia I/M program that were revised by Georgia, and for which the State has requested that EPA incorporate into the Georgia SIP.

a. Acceleration Simulation Mode 2525/5015 Exhaust Emission Test

The term ''Acceleration Simulation Mode 2525/5015 exhaust emission test'' is revised to remove references to a chassis dynamometer and the I/M Inspection Procedures Manual, which are obsolete.[7] The rule now provides specific language on testing requirements by identifying the manner in which 2525 and 5015 tests are to be run (25 percent engine load at 25 miles per hour and 50 percent engine load at 15 miles per hour, respectively). EPA has made the preliminary determination that these changes are SIP strengthening because the edits provide additional clarity within the SIP and will not impact emissions. Therefore, EPA is proposing to approve this change.

b. Calibration

The term of ''Calibration'' contains a minor revision to more clearly explain the test values of the GAS emissions bench. EPA has made the preliminary determination that this change will not impact emissions. Therefore, EPA is proposing to approve this change.

c. DLC

The term ''DLC'' adds the word ''diagnostic'' to the definition to include both data and the diagnostics. This addition is consistent with the outputs the tests provides. EPA has made the preliminary determination that this minor change will not impact emissions. Therefore, EPA is proposing to approve this change.

d. E-Certs

The term ''E-Certs'' adds the word blank to electronic certification of emission inspection, to avoid confusion that they are not prepopulated, and adds wording that these forms must be purchased by the official emission inspection station preforming the test. EPA has made the preliminary determination that this minor change will not impact emissions. Therefore, EPA is proposing to approve this change.

e. Georgia Analyzer System

The definition of ''Georgia Analyzer System'' clarifies that this test system must be approved by GA EPD. EPA has made the preliminary determination that this minor change will not impact emissions. Therefore, EPA is proposing to approve this change.

f. Grandfathered Vehicle

The term ''Grandfathered Vehicle'' adds language to clarify that vehicles manufactured outside of the United States are subject to the Georgia Motor Vehicle Emission Inspection and Maintenance Act. EPA has made the preliminary determination that this minor change will not impact emissions. Therefore, EPA is proposing to approve this change.

g. Light Duty Vehicle

The term light duty vehicle is revised to specify that such vehicles have a gross vehicle weight rating (''GVWR'') 8,500 pounds or less. This change is intended to avoid confusion as to which vehicles are considered light duty and revises the term to match the federal vehicle classification and 40 CFR 51.356. EPA has made the preliminary determination that this change is consistent with EPA's inspection and maintenance regulations at 40 CFR 51 subpart S and will not impact emissions. Therefore, EPA is proposing to approve this change.

h. Management Contractor

The term ''Management Contractor'' is revised to remove the word ''certain'' before the other functions that the management contractor performs for the state I/M program. EPA has made the preliminary determination that this minor change will not impact emissions. Therefore, EPA is proposing to approve this change.

i. Station Owner

The term ''Station Owner'' is revised to specify that the entity is the owner or

[6] Changes adopted by the GA DNR Board on October 26, 2016, became state-effective on November 22, 2016; adopted on February 28, 2018, became state-effective on March 28, 2018; and adopted on January 16, 2019, became state-effective on February 17, 2019.

[7] *See* sections III.A.2.c. and 3.a. of this document for further information about the I/M Inspection Procedures Manual and the Emissions Inspector Certification Training Program Manual, respectively.

has control of the daily operation of an inspection station and is not the person preforming the actual emissions test. EPA notes that the person certified to perform emissions is defined as ''Inspector.'' EPA has made the preliminary determination that this change will not impact emissions. Therefore, EPA is proposing to approve this change.

j. 2-Speed Idle (TSI) Test

The term ''2-speed idle (TSI)'' test is revised to remove a reference to the I/M Inspection Procedures Manual and instead provide specific language on the testing requirement by describing that the TSI test is run at idle at revolutions per minute (RPM) speed and higher RPM speed as determined by the GAS Specs. EPA has made the preliminary determination that this change is SIP strengthening because the edits provide additional clarity within the SIP and will not impact emissions. EPA has made the preliminary determination that this change will not impact emissions. Therefore, EPA is proposing to approve this change.

2. Added Definitions

The following provides details and EPA's analysis of definition rule provisions related to the Georgia I/M program that were added by Georgia, and for which the State has requested that EPA incorporate into the Georgia SIP.

a. Certificate of Authorization

The term ''Certificate of Authorization'' is defined as a certificate issued to each station designated as an official emissions station. EPA has made the preliminary determination that this change is SIP strengthening by identifying the different types of I/M-related certificates issued by GA EPD and will not impact emissions. Therefore, EPA is proposing to approve this change.

b. Certificate of Emissions Inspection

The term ''Certificate of Emissions Inspection'' is defined as a certificate issued to stations that have been inspected and approved by GA EPD. EPA has made the preliminary determination that this change is SIP strengthening by identifying the different types of I/M-related certificates issued by GA EPD and will not impact emissions. Therefore, EPA is proposing to approve this change.

c. Emissions Inspector Certification Training Program Manual

The definition of ''Emissions Inspector Certification Training Program Manual'' is added to provide that the manual is supplied to inspectors during the initial certification and replaces the I/M Inspection Procedures Manual. It also adds informational language that the manual is available on-line on the Georgia Clean Air Force (GCAF) website. EPA has made the preliminary determination that these changes will not negatively impact implementation of the I/M program and will not impact emissions. Therefore, EPA is proposing to approve this change.

d. Georgia Analyzer System Hardware and Software Specifications

The changes include the addition of the term ''Georgia Analyzer System Hardware and Software Specifications'' (''GAS Specs''), which provides the specifications for the hardware and software requirements of the Georgia Analyzer System (''GAS''). EPA has made the preliminary determination that this change is SIP strengthening by providing clarification as to the exact hardware and software requirements for the GAS Specs system used and will not impact emissions. Therefore, EPA is proposing to approve this change.

e. Georgia's Clean Air Force

The term ''Georgia's Clean Air Force'' is added, defined as the partnership between GA EPD and the Management Contractor to implement Georgia's I/M Program. This term is used throughout the program and is added to provide clarity as to who this group is and its relationship to GA EPD and the state I/M program. EPA has made the preliminary determination that this change is consistent with 40 CFR part 51 Subpart S and will not impact emissions. Therefore, EPA is proposing to approve this change.

f. Inspection Term

The term ''Inspection Term'' is added. This term is defined as the time period a certificate of emission inspection is considered valid. EPA notes that time period of the inspection term is provided in 391–3–20–.12. EPA has made the preliminary determination that this change provides additional clarity and will not impact emissions. Therefore, EPA is proposing to approve this change.

g. Responsible Motor Vehicle

The definition of ''Responsible Motor Vehicle'' is added to provide clarity as to which vehicles are subject to the requirements of the I/M program, specifically those defined as light duty vehicles or light duty trucks. The EPA has made the preliminary determination that the definition is consistent with 40 CFR part 51 subpart S (*see, e.g.* 40 CFR 51.351), and the change will not impact emissions. Therefore, EPA is proposing to approve this change.

h. Revolutions per Minute

The term ''Revolutions per Minute'' is added to explain that RPM means the number of times the crankshaft of an engine makes a complete 360 degree turn in one minute. EPA has made the preliminary determination the definition is consistent with the federal testing requirement,[8] and the change will not impact emissions. Therefore, EPA is proposing to approve this change.

i. State-Certified Emissions Inspection Station

The term ''State Certified Emissions Inspection Station'' is defined as a facility that has met all the qualifications of the Georgia Air Quality Control Act (''GAQCA'') and the Georgia I/M Regulation and is certified by the GA EPD Director. EPA has made the preliminary determination that this change is SIP strengthening by providing additional clarity within the SIP, will not impact implementation of the SIP and will not impact emissions. Therefore, EPA is proposing to approve this change.

3. Removed Definitions

The following provides details and EPA's analysis of definition rule provisions related to the Georgia I/M program that the State has requested EPA remove from the Georgia SIP.

a. I/M Inspection Procedures Manual

Georgia requests removal of the term ''I/M Inspection Procedures Manual'' from the SIP. This term is no longer used in the Georgia I/M Regulation, as reliance in the program on hard copy manuals has been replaced with the GAS system. In addition, this manual has been replaced with the Emissions Inspector Certification Training Program Manual, which is supplied to emissions inspectors upon their initial certification. EPA has made the preliminary determination that this change will not impact emissions. Therefore, EPA is proposing to approve this change.

b. I/M Test Manual

Georgia requests removal of the term ''I/M Test Manual'' from the SIP. This term is no longer used in the Georgia I/M Regulation, as reliance in the program on hard copy manuals has been

[8] *See* IM240 & Evap Technical Guidance, April 2000, available at *https://nepis.epa.gov/Exe/ZyPdf.cgi?Dockey=P1008F0I.pdf.*

replaced with the GAS system. EPA has made the preliminary determination that this change will not impact emissions. Therefore, EPA is proposing to approve this change.

c. State Inspection Program

Georgia requests removal of the term ''State Inspection Program'' from the SIP. This term is no longer used in the Georgia I/M Regulation as 391–3–20 now references the program as the ''Georgia I/M Program.'' EPA has made the preliminary determination that this change will not affect implementation of the SIP and will not impact emissions. Therefore, EPA is proposing to approve this change.

B. Rule 391–3–20–.03, ''Covered Vehicles: Exemptions''

Rule 391–3–20–.03, ''Covered Vehicles: Exemptions,'' is being amended for clarity and consistency with terminology, such as replacing ''covered vehicle'' with ''responsible motor vehicle'' to differentiate between the term defined in 391–3–20–.01 and the applicability of ''Covered Vehicles'' as defined in 391–3–20–.03. Further, changes to 391–3–20–.03 clarify that 391–3–20 applies to all vehicles required to be registered rather than just vehicles that are registered or are pending registration.

EPA has reviewed the changes and preliminarily determined that these changes do not impact emissions and are consistent with 40 CFR 51 subpart S. These changes are SIP strengthening by providing additional clarity to the SIP. Accordingly, EPA is proposing to approve the changes to Rule 391–3–20–.03 into Georgia's SIP.

C. Rule 391–3–20–.04, ''Emission Inspection Procedures''

Rule 391–3–20–.04, ''Emission Inspection Procedures,'' is being amended to insert the word ''initial'' into the requirement for annual inspections to differentiate with re-inspections in the same year, to require inspectors to perform reinspection of the portions of a previously-failed inspection, and to revise terminology for consistency within Georgia's regulations. In addition, the changes allow inspectors to use any published traction control chart available, rather than a specific EPD approved traction control chart. EPA has reviewed these changes and preliminarily determined that they do not impact emissions and are consistent with 40 CFR part 51 subpart S. Accordingly, EPA is proposing to approve the changes to Rule 391–3–20–.04 into Georgia's SIP.

D. Rule 391–3–20–.05, ''Emission Standards''

Rule 391–3–20–.05, ''Emission Standards'' is amended to delete an outdated reference to the emission inspector training program as well as updating references from the test manual name to the GAS. Rule 391–3–20–.05 adds clarifying language to reflect that the vehicle manufacturer programs the malfunction illumination light. EPA has made the preliminary determination that these changes provide additional clarity within the SIP, and will not impact emissions. Accordingly, EPA is proposing to approve the changes to Rule 391–3–20–.05 into Georgia's SIP.

E. Rule 391–3–20–.06, ''Testing of Exhaust Emissions by Remote Sensing Technology or Other Means''

Rule 391–3–20–.06, ''Testing of Exhaust Emissions by Remote Sensing Technology or Other Means,'' is being amended to require on-road testing of the lesser of 0.5 percent of the vehicle population or 20,000 vehicles, and also to provide flexibility to the State as to the type of on-road testing that can be conducted.[9] In addition, the changes replace a testing scheme for cars that are identified as high emitting vehicles by on-road testing with the testing procedures in 391–3–20–.04 and .05. Last, edits to 391–3–20–.06 remove a provision specifying that vehicle owners would be in violation of section 391–3–20 under certain circumstances.

EPA has reviewed the changes and preliminarily determined that these changes will not impact emissions and are consistent with 40 CFR part 51 subpart S. With respect to the additional flexibility as to the type of on-road testing, the State will be obligated to conduct on-road testing on the lesser of 0.5 percent of the vehicle population or 20,000 vehicles, and identify high emitting vehicles, consistent with 40 CFR part 51 subpart S. Since high emitting vehicles must present their vehicles for emissions inspection, and—if the high emitting vehicle fails the emission inspection under 391–3–20–.04 and 391–3–20–.05—must pass a reinspection under 391–3–20–.15, EPA does not anticipate emissions increases associated with this change. With respect to the removal of the provision regarding violations, EPA does not anticipate emissions increases associated with the removal of this requirement because the regulations will continue to require a vehicle owner present the vehicle for inspection within 30 days of notification. Further, without a passing emission certificate the vehicle cannot be registered, and without registration, the vehicle cannot legally operate on highways. Accordingly, EPA is proposing to approve the revisions to Rule 391–3–20–.06 into Georgia's SIP.

F. Rule 391–3–20–.07, ''Inspection Equipment System Specification''

Rule 391–3–20–.07, ''Inspection Equipment System Specification,'' is being amended to add language requiring station owners to acquire a specific manufacturer's published Fuel Cap Testing Application Chart, and to clarify that inspection stations must have an appropriate GAS for their class of station. In addition, the changes to 391–3–20–.07 include language to specify that the inspection stations must have systems that have been approved by the GA EPD.

EPA has reviewed the changes and preliminarily determined that these changes will not impact emissions and are consistent with 40 CFR part 51 subpart S. These changes are SIP strengthening by updating the SIP to reflect more recent technology and providing additional clarity to the SIP. Accordingly, EPA is proposing to approve the revisions to Rule 391–3–20–.07 into Georgia's SIP.

G. Rule 391–3–20–.09, ''Inspection Station Requirements''

Rule 391–3–20–.09, ''Inspection Station Requirements,'' is amended to remove language at 391–3–20–.09(c)(4), specifying that the Director can suspend or revoke a station's Certificate of Authorization if it fails to comply with the requirements of the mobile GAS. Additional changes identify the materials that must be provided by a public inspection station by adding language to specify that the relevant poster is the one provided at the time of station certification, and that a Q&A brochure must be provided. Changes to the requirements for station owners include edits to require a specific Emissions Repair Form (replacing the term ''repair information form''), broaden the type of traction control charts each station must maintain, provide a web address for the location of the OBD DLC Location Chart, and require station owners to maintain

[9] See 1/16/2014 changes at A–5 (''[R]evised Paragraph (1) . . . provides the Division flexibility in implementing a remote sensing or alternative program as needed to meet federal requirements''), and 1/2/2019 changes at D–3 (''Paragraph (1) is being revised to include ''on-road testing measures'' as a type of exhaust testing and to describe remote sensing or other means of established testing. Paragraph (1) is also being revised to specify that the federal requirement for on-road testing and high emitter testing is 'at least 0.5% of the vehicle population or 20,000 vehicles, whichever is less.' '').

Version 1.4 of the Emissions Inspector Certification Training Program Manual. Requirements for fleet inspection stations are revised to remove language requiring certain fleet inspection technicians to be certified in the area of advanced automotive engine diagnostic and repair. In addition, 391–3–20–.09 is amended to clarify that the sign posted at inspection stations reflects a state certified station, to clarify that the Repair Watch Public Report is issued quarterly, and to require station owners to provide an email address with their contact information. Finally, changes to paragraphs (i)(3) and (5) revise the requirements for the required type of internet connection.

EPA has reviewed the changes and has made the preliminary determination that these changes do not impact emissions and are consistent with 40 CFR part 51 subpart S. With respect to the removal of language at 391–3–1–.09(c)(4), the general provisions regarding Certificates of Authorization at 391–3–20–.10 provide that the GA EPD Director can suspend or revoke a station's Certificate of Authorization. With respect to the changes related to internet requirements and the removal of the requirement for certain fleet inspection technicians to be certified in the area of advanced automotive engine diagnostic and repair, the changes reflect current technology as the diagnostic tools now perform the required analysis, and EPA is proposing to make the determination that the changes will not impact implementation of the SIP and will not impact emissions. The remainder of the changes, including those regarding materials and internet requirements, are minor changes that will not impact the implementation of the I/M testing to be performed and thus will not impact emissions. Accordingly, EPA is proposing to approve the change to Rule 391–3–20–.09 into Georgia's SIP.

H. Rule 391–3–20–.10, ''Certificates of Authorization''

Rule 391–3–20–.10, ''Certificates of Authorization,'' is being amended to use the acronym for Georgia Analyzer System and deleting spelling out the words. EPA has reviewed the changes and has made the preliminary determination that these minor changes do not impact emissions and are consistent with the I/M program requirements. Accordingly, EPA is proposing to approve the change to Rule 391–3–20–.10 into Georgia's SIP.

I. Rule 391–3–20–.11, ''Inspector Qualifications and Certification''

Rule 391–3–20–.11, ''Inspector Qualifications and Certification,'' is amended to clarify that an inspector's certificate is valid for two years from the date of issuance; to state that an inspector's certificate application is due 30 days before the expiration of an existing application; and to add language that a certificate will be renewed on timely receipt of an application, if there is no cause to deny a certificate; and clarify that it is the inspector that must pass the written test. In addition, 391–3–20–.11 is revised to require emissions inspectors to pass a practical (rather than hands-on) test, and to have knowledge about conducting all parts of the inspection (replacing the words ''can perform'').

EPA has reviewed the changes and has made the preliminary determination that these minor changes do not impact implementation of the SIP, do not impact emissions, and are consistent with 40 CFR part 51 subpart S. Accordingly, EPA is proposing to approve the revisions to Rule 391–3–20–.11 into Georgia's SIP.

J. Rule 391–3–20–.13, ''Certificate of Emission Inspection''

Rule 391–3–20–.13, ''Certificate of Emission Inspection,'' is amended replace terms with standard terminology (for example ''Emissions Repair Form'' replaces ''repair information form''), to provide the website address to obtain an Emissions Repair Form, and to clarify that the Repair Watch Public Report is issued quarterly. EPA has reviewed these minor changes and preliminarily finds that the changes are SIP strengthening by providing additional clarity to the SIP. Accordingly, EPA is proposing to approve the revisions to Rule 391–3–20–.13 into Georgia's SIP.

K. Rule 391–3–20–.15, ''Repairs and Retests''

Rule 391–3–20–.15, ''Repairs and Retests,'' is being amended by replacing the term ''repair information form'' with standard terminology of ''Emissions Repair Form.'' EPA has reviewed this change and is preliminarily determining that it is a minor change that is SIP strengthening by providing additional clarity to the SIP. Accordingly, EPA is proposing to approve this change to Rule 391–3–20–.15 into the Georgia SIP.

L. Rule 391–3–20–.17, ''Waivers''

Rule 391–3–20–.17, ''Waivers,'' is revised to specify the dollar amount of expenditures that must be made annually in order to qualify for a waiver from the I/M program requirements, and language is added to provide a web-address where the waiver amount will be posted. In addition, language is added to require the issuer of a waiver to visually inspect to confirm that repairs have been made.

EPA has reviewed these minor changes and preliminarily finds that the changes are SIP strengthening by providing additional clarity to the SIP, are consistent with 40 CFR part 51 subpart S, and will not impact emissions. Accordingly, EPA is proposing to approve the changes to Rule 391–3–20–.17 into Georgia's SIP.

M. Rule 391–3–20–.18, ''Sale of Vehicles''

Rule 391–3–20–.18, ''Sale of Vehicles,'' is being amended to add that no person shall sell a vehicle without a valid passing certificate of emissions inspection if the vehicle will be registered in a covered county. In addition, language imposing criminal and civil penalties is removed.

EPA has reviewed these administrative changes and determined that do not impact emissions and are consistent with the 40 CFR part 51 subpart S. While the language imposing criminal and civil penalties is removed, a valid passing certificate of emissions inspections must be provided in order to register a vehicle for highway use. Since without an emission certificate the vehicle cannot be registered, and without registration, the vehicle cannot legally operate on highways, EPA does not anticipate emissions increases associated with the removal of the specific penalties previously listed in 391–3–20–.18.[10] Accordingly, EPA is proposing to approve this change to Rule 391–3–20–.18 into the Georgia SIP.

N. Other Minor Changes

In addition, Georgia's March 15, 2019, SIP revision contains several minor changes to Georgia's I/M Regulation 391–3–20. For example, rule 391–3–20–.01 contains changes to numbering to reflect the addition and deletion of several definitions, as described more fully above; rule 391–3–20–.03, ''Covered Vehicles: Exemptions,'' contains changes for grammatical purposes and to correct capitalization; and rules 391–3–20–.01, 391–3–20–.09 and 391–3–20–.11 contain changes that replace the term ''State Inspection'' with ''I/M'' program. Also, changes are made to replace terms with acronyms. For

[10] Although not relied on for approval, EPA also notes that the operation on highways without a certification of registration is subject to Georgia Code Title 40 Motor Vehicle and Traffic Subsection 40–6–15, which imposes civil and criminal penalties.

example, multiple rules include adding the acronym ''GAS'' or replacing ''Georgia Analyzer System'' with the acronym ''GAS;'' and 391–3–20–.13 substitutes the acronym ''EPA'' for ''U.S. Environmental Protection Agency.'' Further, the March 15, 2019, SIP revision contains a number of changes to reflect changing technology, such as removing references to hard copy manuals, since the material is now found within the GAS program. EPA is making the preliminary determination that these minor changes will not affect implementation of the SIP and thus will not impact emissions. Therefore, EPA is proposing to approve these changes into the SIP.

IV. Incorporation by Reference

In this rule, EPA is proposing to include in a final GA EPD rule regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Georgia Rules 391–3–20–.04, 391–3–20–.05, 391–3–20–.07, 391–3–20–.08, 391–3–20–.10, 391–3–20–.13, 391–3–20–.15, 391–3–20–.18, and 391–3–20–.20, state effective on March 28, 2018, and Georgia Rules 391–3–20–.01, 391–3–20–.03, 391–3–20–.06, 391–3–20–.09, 391–3–20–.11, and 391–3–20–.17, state effective on February 17, 2019, within Chapter 391–3–20, titled ''Enhanced inspection and Maintenance'' to remove obsolete references, clarify the State's I/M requirements, and update terminology, including to reflect advances in technology. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Proposed Action

For the reasons explained above, EPA is proposing to approve Georgia's March 15, 2019, SIP revision. Specifically, EPA is proposing to approve the changes to Georgia's I/M Regulation 391–3–20 because they are consistent with the CAA and 40 CFR part 51 subpart S.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submittal that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, if they meet the criteria of the CAA. Accordingly, this proposed action merely proposes to approve state law as meeting Federal requirements and does not propose to impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Is not an Executive Order 13771 (82 FR 9339, February 2, 2017) regulatory action because SIP approvals are exempted under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, October 7, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000) nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Mary Walker,

Regional Administrator, Region 4.

[FR Doc. 2020–09242 Filed 5–13–20; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 200506–0128]

RIN 0648–BJ55

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery of the South Atlantic Region; Regulatory Amendment 33

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to implement management measures described in Regulatory Amendment 33 to the Fishery Management Plan (FMP) for the Snapper-Grouper Fishery of the South Atlantic Region (Snapper-Grouper FMP), as prepared and submitted by the South Atlantic Fishery Management Council (Council). If implemented, this proposed rule would remove the requirement that if the South Atlantic red snapper season (commercial or recreational) is projected to be 3 days or less, the respective season would not open for that fishing year. The purpose of this proposed rule is to improve access to South Atlantic red snapper, particularly for the recreational sector.

DATES: Written comments on the proposed rule must be received by June 15, 2020.

ADDRESSES: You may submit comments on the proposed rule, identified by ''NOAA–NMFS–2020–0017,'' by either of the following methods:

- *Electronic submission:* Submit all electronic comments via the Federal e-Rulemaking Portal. Go to *http://www.regulations.gov/docket?D=NOAA-NMFS-2020-0017, click the* ''*Comment*

Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Frank Helies, NMFS Southeast Regional Office, 263 13th Avenue South, St. Petersburg, FL 33701.

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 required fields if you wish to remain anonymous).

Electronic copies of Regulatory Amendment 33 to the Snapper Grouper FMP (Regulatory Amendment 33) may be obtained from *www.regulations.gov* or the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/regulatory-amendment-33-red-snapper-fishing-seasons.* Regulatory Amendment 33 includes an environmental assessment, regulatory impact review, and Regulatory Flexibility Analysis (RFA).

FOR FURTHER INFORMATION CONTACT: Frank Helies, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *frank.helies@noaa.gov.*

SUPPLEMENTARY INFORMATION: NMFS and the Council manage the snapper-grouper fishery under the Snapper-Grouper FMP, which includes red snapper. The Snapper-Grouper FMP was prepared by the Council and is implemented by NMFS through regulations at 50 CFR part 622 under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*).

Background

The harvest of red snapper from South Atlantic Federal waters was prohibited in 2010 through Amendment 17A to the Snapper Grouper FMP when the stock was determined to be overfished and undergoing overfishing (75 FR 76874; December 9, 2010). In 2013, the Council developed a process for allowing limited harvest of red snapper through Amendment 28 to the Snapper-Grouper FMP (78 FR 44461; July 24, 2013). In 2018, the Council revised the commercial and recreational annual catch limits (ACLs) through Amendment 43 to the Snapper-Grouper FMP (83 FR 35428; July 26, 2018).

The commercial ACL is 124,815 lb (56,615 kg) round weight, and the commercial season begins on the second Monday in July each year. The commercial ACL is monitored during the season and the sector is closed when the ACL is reached or projected to be reached. The commercial fishing season was open for 60 days in 2017, 116 days in 2018, and 54 days in 2019.

The recreational ACL is 29,656 fish and the season begins on the second Friday in July, and the recreational season consists of weekends only (Friday, Saturday, and Sunday). The length of the recreational red snapper season is projected based on catch rate estimates from previous years, and the length of the projected fishing season is announced each year in the **Federal Register** before the start of the season.

For South Atlantic red snapper, NMFS annually projects the number of days that it would take for the commercial and recreational sectors to reach their respective ACL. If NMFS projects the South Atlantic red snapper season (commercial or recreational) to be 3 days or less, the respective season would not open for that fishing year. Under both current and proposed regulations, the red snapper commercial and recreational seasons are projected and managed independently of each other; that is, harvest for one sector can occur without the other. NMFS notes that to date, there has not been a fishing year where one sector was allowed harvest of red snapper and the other was not. NMFS initially implemented the 3-day minimum season length provision in 2013 because the Council determined in Amendment 28 to the Snapper-Grouper FMP that a season of less than 4 days would not provide sufficient fishing opportunity to the public (78 FR 44461, July 24, 2013).

Recreational fishermen have expressed concern to the Council and NMFS that as the South Atlantic red snapper population recovers and catch rates improve, access to the red snapper resource could decline due to shortened fishing seasons. Specifically, as the red snapper population rebuilds, more fish are available for harvest and the South Atlantic red snapper recreational fishing season has generally experienced increased effort over the last 3 years, particularly off the east coast of Florida. Since the recreational red snapper ACL has remained the same over recent years, fishing seasons in future years could get shorter despite the population rebuilding because the ACL would be met in less time due to the increased effort and increased availability of fish. The length of the red snapper recreational season has declined from 10 days in 2017, to 6 days in 2018, and to 5 days in 2019 as a result of the recreational ACL being projected to be reached sooner in each year. To better ensure recreational access to red snapper regardless of season length projections, the Council is proposing in Regulatory Amendment 33 to remove the 3-day minimum season length requirement. In addition, because the commercial season for red snapper has remained open for several months each year in recent years when harvest of red snapper was allowed, NMFS expects that the commercial season duration will not be impacted by this action.

Management Measures Contained in This Proposed Rule

This proposed rule would remove the requirement that if a red snapper season (commercial or recreational) is projected by NMFS to be 3 days or less, the respective fishing season will not open for that fishing year. If this provision is removed, red snapper harvest could be open for either commercial or recreational harvest for less than 4 days. Therefore, for the recreational sector specifically, this measure could allow for a fishing season to occur that otherwise would not be allowed under the existing regulations. NMFS expects this measure to increase the flexibility for recreational sector access to red snapper and enhance recreational fishing opportunities. NMFS notes that if this measure is implemented, the recreational ACL and accountability measures are not changing in this rule, and thus the measure is not expected to negatively impact the stock.

NMFS is analyzing the data and information on which the 2020 season length is based, and expects to announce information about the 2020 recreational and commercial fishing seasons soon.

Management Measure in Regulatory Amendment 33 Not in This Proposed Rule

Regulatory Amendment 33 also contains an action to consider changing the start date of the commercial season. Currently, unless otherwise specified, the commercial season is expected to open on the second Monday of July. The Council considered different commercial season start dates of May 1 and the second Monday of June in Regulatory Amendment 33. However, after receiving public input the Council decided not to modify the start date for the commercial red snapper season. The Council determined that a commercial season start date change may not benefit

the majority of stakeholders or provide overall biological benefits to the red snapper stock. The Council also determined that the change would likely create conflict between the commercial and recreational sectors as the red snapper season for the commercial sector would begin over a month before the recreational sector. Therefore, the current commercial season start date of the second Monday in July will remain in place.

Classification

Pursuant to section 304(b)(1)(A) of the Magnuson-Stevens Act, the Assistant Administrator has determined that this proposed rule is consistent with Regulatory Amendment 33, the Snapper-Grouper FMP, the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

This proposed rule has been determined to be not significant for purposes of Executive Order 12866. This rule is expected to be an Executive Order 13771 deregulatory action.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration (SBA) that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities. The factual basis for this determination is as follows:

A description of the proposed rule and its purpose are contained at the beginning of the **SUPPLEMENTARY INFORMATION** section and in the **SUMMARY** section of the preamble. The Magnuson-Stevens Act provides the statutory basis for this rule. No duplicative, overlapping, or conflicting Federal rules have been identified. In addition, no new reporting, record keeping, or other compliance requirements are introduced by this proposed rule. Accordingly, this proposed rule does not implicate the Paperwork Reduction Act.

This proposed rule would remove the requirement that if the South Atlantic red snapper season (commercial or recreational) is projected to be 3 days or less, the respective season would not open for that fishing year. Because the RFA does not apply to recreational anglers, only the effects on commercial vessels were analyzed. Any impact to the profitability or competitiveness of charter vessel and headboat (for-hire) fishing businesses would be the result of changes in for-hire angler demand and would, therefore, be indirect in nature; the RFA does not consider indirect impacts.

The proposed action would directly affect federally permitted commercial fishermen fishing for South Atlantic red snapper. For RFA purposes only, NMFS has established a small business size standard for businesses, including their affiliates, whose primary industry is commercial fishing (see 50 CFR 200.2). A business primarily engaged in commercial fishing (NAICS code 11411) is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including affiliates), and has combined annual receipts not in excess of $11 million for all its affiliated operations worldwide.

Any fishing vessel that harvests and sells any of the snapper-grouper species from the South Atlantic exclusive economic zone must have a valid South Atlantic commercial snapper-grouper permit, which is a limited access permit. As of January 23, 2020, there were 523 valid or renewable South Atlantic snapper-grouper unlimited permits and 104 valid or renewable 225-lb (102 kg) trip-limited permits. After a permit expires, it can be renewed or transferred up to 1 year after the date of expiration. In any given year, however, not all federally permitted commercial vessels harvest red snapper in the South Atlantic. From 2014 through 2018, an average of 113 federally permitted commercial vessel took 749 trips and landed approximately 49,000 lb (22,226 kg), gutted weight, of red snapper and 306,000 lb (138,799 kg), gutted weight, of other species co-harvested with red snapper. These vessels also took an average of 3,128 trips that landed approximately 1.94 million lb (879,968 kg), gutted weight, of various species but without red snapper. These vessels generated a total of approximately $8.40 million (2018 dollars) of revenues from all species, of which approximately $1.03 million (2018 dollars) were from red snapper. The 2014–2018 average revenue per vessel was approximately $84,000 (2018 dollars). The average annual price per lb, gutted weight, of red snapper was $5.49 (2018 dollars) and ranged from $4.28 in 2015 to $5.57 in 2018.

Based on the revenue information, all commercial vessels directly affected by the proposed action may be considered small entities. Because all directly affected entities are small entities, the issue of disproportional effects on small versus large entities does not arise.

The commercial harvest of red snapper is limited by the commercial ACL. If the projected red snapper season is determined to be more than 3 days, the economic effects of the proposed action would be the same as those of the *status quo.* If the projected red snapper fishing season is 3 days or less, the proposed action would allow the commercial sector to generate some revenues where otherwise the season may be forgone based on a projected shortened season. In either scenario, the proposed action is expected to not reduce the revenues and profits of directly affected small entities.

The information provided above supports a determination that this proposed rule would not have a significant economic impact on a substantial number of small entities. Because this proposed rule, if implemented, is not expected to have a significant economic impact on any small entities, an initial regulatory flexibility analysis is not required and none has been prepared.

List of Subjects in 50 CFR Part 622

Fisheries, Fishing, Red snapper, Seasons, South Atlantic.

Dated: May 7, 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 622 is proposed to be amended as follows:

PART 622—FISHERIES OF THE CARIBBEAN, GULF OF MEXICO, AND SOUTH ATLANTIC

■ 1. The authority citation for part 622 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

§ 622.183 [Amended]

■ 2. In § 622.183, remove paragraph (b)(5)(iii).

[FR Doc. 2020–10107 Filed 5–13–20; 8:45 am]

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Notices

Federal Register

Vol. 85, No. 94

Thursday, May 14, 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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Meeting

Pursuant to the Federal Advisory Committee Act, notice is hereby given of a public meeting of the Board for International Food and Agricultural Development (BIFAD), *Food Security and Nutrition in the Context of COVID–19: Impacts and Interventions.* The meeting will be held on June 4, 2020 from 1:30 to 3:30 p.m. EDT at *http://www.aplu.org/projects-and-initiatives/international-programs/bifad/bifad-meetings.html.* A public comment period is scheduled from 3:10 to 3:30 p.m., EDT.

The Coronavirus Disease–19 (COVID–19) pandemic will have secondary impacts on all intermediate results of the U.S. Government Global Food Security Strategy, including agricultural productivity, livelihoods, markets, trade and policy actions, food consumption and nutrition, hygiene, and resilience. The Board for International Food and Agricultural Development (BIFAD), an advisory committee to the U.S. Agency for International Development (USAID), will convene a virtual public meeting to share the thinking of leading experts in food security and nutrition that relates to COVID–19 impacts. This will include consideration of the most promising short-, medium-, and long-term responses across several key areas: Farm-level productivity, markets and trade, access to finance, nutrition, safe and hygienic food systems, gender, and national and local policy. The meeting will include presentations of credible modeling data about the scale and breadth of anticipated food security impacts in the developing world and a summary spanning near to longer-term interventions and guidance that may help to mitigate COVID–19 impacts. The meeting will also provide leading sources of curated information (*e.g.,* landing pages for information related to the crisis and response). The meeting is intended to help to support decision making by USAID and its partners and stakeholders working to advance food security, nutrition, and resilience at global, regional and national levels.

On the basis of testimony, including public comments, shared at the meeting, BIFAD will provide formal findings, conclusions, and recommendations to the Agency on best-bet operational and programmatic investments.

BIFAD is a seven-member, presidentially appointed advisory board to USAID established in 1975 under Title XII of the Foreign Assistance Act, as amended. The provisions of Title XII concern bringing the assets of U.S. universities to bear on development challenges in agriculture and food security, and the BIFAD's role is to help carry out this function.

Participants may register at *http://www.aplu.org/projects-and-initiatives/international-programs/bifad/bifad-meetings.html.* For questions about registration, please contact Susan Johnson at (202) 478–6023 or *sjohnson@aplu.org.* For questions about BIFAD, please contact Clara Cohen, Designated Federal Officer for BIFAD in the Bureau for Resilience and Food Security, USAID at *ccohen@usaid.gov* or (202) 712–0119.

Clara Cohen,

Designated Federal Officer, BIFAD.

[FR Doc. 2020–10297 Filed 5–13–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–LRSS–20–0032]

Notice of Request for an Extension of a Currently Approved Information Collection: Qualitative Feedback on Agency Service Delivery

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Agricultural Marketing Service's (AMS) intention to request approval from the Office of Management and Budget (OMB), for an extension of a currently approved information collection associated with qualitative customer and stakeholder feedback on service delivery by the AMS.

DATES: Comments on this notice must be received by July 13, 2020.

ADDRESSES: Comments are welcome and should referenced OMB No. 0581–0269 and AMS' Qualitative Feedback on Agency Service Delivery, and the date and page number of this issue of the **Federal Register**. Comments may be submitted by mail to the Docket Clerk, Legislative & Regulatory Review Staff, AMS, USDA, 1400 Independence Avenue SW, Stop 0202, Room 3943–S, Washington, DC 20250; Fax: (202) 690–3767; or submitted online at *www.regulations.gov.* All comments received will be available for public inspection in the Office of the Docket Clerk during regular USDA business hours or they can be viewed at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Joell Gilham, Legislative & Regulatory Review Staff, AMS, USDA, 1400 Independence Avenue SW, Stop 0202, Room 3943–S, Washington, DC 20250; Telephone: (202) 720–2986; Fax: (202) 690–3767.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery-AMS.

OMB Number: 0581–0269.

Expiration Date of Approval: August 31, 2020.

Type of Request: Extension of a Currently Approved Information Collection.

Abstract: The proposed information collection activity provides a means for AMS to garner qualitative customer and stakeholder feedback in an efficient and timely manner, in accordance with the Agency's commitment to improving service delivery.

By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations; provide an early warning of issues with service; or focus attention on areas where communication, training, or changes in operations might improve delivery of

products or services. This collection will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback will target areas such as: Timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public. If this information is not collected, vital feedback from customers and stakeholders on the Agency's services will be unavailable.

AMS will only submit a collection for approval under this generic clearance if it meets the following conditions:

- The collection is voluntary;
- The collection is low-burden for respondents (based on considerations of total burden hours, total number of respondents, or burden-hours per respondent) and is low-cost for both the respondents and the Federal Government;
- The collection is non-controversial and does not raise issues of concern to other Federal agencies;
- The collection is targeted to the solicitation of opinions from respondents who have experience with the program or may have experience with the program in the near future;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Information gathered is intended to be used only internally for general service improvement and program management purposes and is not intended for release outside of AMS (if released, AMS must indicate the qualitative nature of the information);
- Information gathered will not be used for the purpose of substantially informing influential policy decisions; and
- Information gathered will yield qualitative information; the collection will not be designed or expected to yield statistically reliable results or used as though the results are generalizable to the population of study.

Feedback collected under this generic clearance provides useful information, but it does not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential nonresponse bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior to fielding this study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

As a general matter, this information collection will not result in any new system of records containing privacy information and will not ask questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

AMS currently has approval from the Office of Management and Budget (OMB) for this information collection. This approval is for 60,000 burden hours, based on our initial request to OMB in April 2011. We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average .50 hours per response.

Respondents: Individuals and households; businesses and organizations; State, local, or Tribal government.

Estimated Annual Number of Respondents: 110,000.

Estimated Number of Responses: 110,000.

Estimated Annual Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 60,000/(Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

Comments: Comments are invited on: (1) Whether the proposed collection of the 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, including the validity of the methodology and assumptions used; (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, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–10313 Filed 5–13–20; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Docket number AMS–FTPP–20–0023]

Proposed Posting, and Posting of Stockyards

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: The Agricultural Marketing Service (AMS), USDA, is taking action to post stockyards under the Packers and Stockyards Act (P&S Act). Specifically, we are proposing that 10 stockyards now operating subject to the P&S Act be posted. We are also posting 10 stockyards that were identified previously as operating subject to the P&S Act.

DATES: For the proposed posting of stockyards, we will consider comments that we receive on or before May 29, 2020.

ADDRESSES: We invite you to submit comments on this notice. You may submit comments by any of the following methods:

- *Internet:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Fax:* (202) 690–3207.
- *Mail, hand delivery, or courier:* Stuart Frank, USDA, AMS, 1400 Independence Avenue SW, Room 2507–S, Washington, DC 20250–3601.

Instructions: All comments should refer to the date and page number of this issue of the **Federal Register**. The comments and other documents relating to this action will be available for public inspection during regular business hours.

FOR FURTHER INFORMATION CONTACT: Contact Donna A. Ash, Program

Analyst, AMS, Packers and Stockyards Division at (202) 720–0222 or *Donna.a.ash@usda.gov.*

SUPPLEMENTARY INFORMATION: AMS administers and enforces the P&S Act of 1921, (7 U.S.C. 181 *et seq.*). The P&S Act prohibits unfair, deceptive, and fraudulent practices by livestock market agencies, dealers, stockyard owners, meat packers, swine contractors, and live poultry dealers in the livestock, poultry, and meatpacking industries.

Section 302 of the P&S Act (7 U.S.C. 202) defines the term ''stockyard'' as, ''. . . any place, establishment, or facility commonly known as stockyards, conducted, operated, or managed for profit or nonprofit as a public market for livestock producers, feeders, market agencies, and buyers, consisting of pens, or other enclosures, and their appurtenances, in which live cattle, sheep, swine, horses, mules, or goats are received, held, or kept for sale or shipment in commerce.''

Section 302 (b) of the P&S Act requires the Secretary of Agriculture to determine which stockyards meet this definition, and to notify the owner of the stockyard and the public of that determination by posting a notice in each designated stockyard. Once the Secretary provides notice to the stockyard owner and the public, the stockyard is subject to the provisions of Title III of the P&S Act (7 U.S.C. 201–203 and 205–217a) until the Secretary de-posts the stockyard by public notice. To post a stockyard, we assign the stockyard a facility number, notify the stockyard owner, and send an official posting notice to the stockyard owner to display in a public area of the stockyard. This process is referred to as ''posting.'' The date of posting is the date that the posting notices are physically displayed at the stockyard. A facility that does not meet the definition of a stockyard is not subject to the P&S Act and therefore cannot be posted. A posted stockyard can be ''de-posted,'' which occurs when the facility is no longer used as a stockyard.

We are hereby notifying stockyard owners and the public that the following 10 stockyards meet the definition of a stockyard and that we propose to designate these stockyards as posted stockyards.

Proposed facility No.	Stockyard name and location
NY–178	Davis Livestock Sales, Inc., Gouverneur, New York
NY–179	Argyle Livestock Station, LLC, Argyle, New York
OK–266	Geary Livestock Market, LLC, Geary, Oklahoma
OK–227	McDaniel Livestock Exchange LLC, Valliant, Oklahoma
TX–358	Mort Livestock Exchange, Canton, Texas
TX–359	Amarillo West Stockyards LLC, Wildorado, Texas
PA–164	Double E. Auction Service LLC, Quarryville, Pennsylvania
KY–190	Triple C. Auctions Ewing, Kentucky
FL–141	Cattleman's Market of Okeechobee LLC, Okeechobee, Florida
ND–134	Bismarck Livestock Auction, LLC, Bismarck, North Dakota

We are also notifying the public that the stockyards listed in the following table meet the P&S Act's definition of a stockyard, and therefore, we have posted these stockyards. On June 7, 2019, we published a notice in the **Federal Register** (Vol. 84. No. 110) proposing to post these 10 stockyards. Since we received no comments to our proposal, we assigned the stockyards a facility number and notified the owners of the stockyard facilities. Posting notices were sent to each stockyard owner to display in public areas of their stockyard. The table below reflects the date of posting for these stockyards.

Facility No.	Stockyard name and location	Date of posting
KS–210	Hill City Commission, LLC, Hill City, Kansas	07/15/2019
KY–189	Blue Grass Stockyards, LLC Lexington, Kentucky	07/15/2019
KY–190	Franklin Livestock Market Inc., Franklin, Kentucky	07/15/2019
MN–194	Heidelberger Farm Equipment, LLC, Pine City, Minnesota	07/15/2019
NE–189	Chappell Livestock LLC, Chappell, Nebraska	07/16/2019
NM–125	Santa Teresa Livestock Auction LLC, Santa Teresa, New Mexico	12/07/2019
OK–222	Heart & Soul Horse Co., Sallisaw Oklahoma	07/16/2019
OK–223	Hinz Auction Land and Cattle, LLC, Clinton, Oklahoma	07/17/2019
OK–225	C.M.S. Livestock Auction, LLC, Wanette, Oklahoma	12/03/2019
VA–163	Alex Eugene Dill Hollering Hill Auction LLC, Nathalie, Virginia	07/15/2019

Authority: 7 U.S.C. 202.

Bruce Summers,

Administrator, Agricultural Marketing Service.

[FR Doc. 2020–10340 Filed 5–13–20; 8:45 am]

BILLING CODE 3410–02–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Missouri Advisory Committee To Discuss Voting as a Topic of Study in the State

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act that the Missouri Advisory Committee (Committee) will hold a meeting on Thursday, May 28, 2020 at 13:00 p.m. (Central) for the purpose of discussing the proposal for the study on Covid-19 and voting preparations.

DATES: The meeting will be held on Thursday, May 28, 2020 at 13:00 p.m. (Central).

Public Call Information: Dial: 888–394–8218, Conference ID: 9627638.

FOR FURTHER INFORMATION CONTACT: David Barreras, DFO, at *dbarreras@usccr.gov* or 312–353–8311.

SUPPLEMENTARY INFORMATION: Members of the public can listen to the discussion. This meeting is available to the public through the following call-in number: 888–394–8218, conference ID: 9627638. Any interested member of the public may call this number and listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. The conference call operator will ask callers to identify themselves, the organization they are affiliated with (if any), and an email address prior to placing callers into the conference room. Callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–977–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are also entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be mailed to the Midwestern Regional Office, U.S. Commission on Civil Rights, 230 S Dearborn Street, Suite 2120, Chicago, IL 60604. They may also be faxed to the Commission at (312) 353–8324 or emailed to David Barreras at *dbarreras@usccr.gov.* Persons who desire additional information may contact the Midwestern Regional Office at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Midwestern Regional Office, as they become available, both before and after the meeting. Records of the meeting will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Missouri Advisory Committee link (*https://facadatabase.gov/committee/committee.aspx?cid=258&aid=17*). Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Midwestern Regional Office at the above email or street address.

Agenda

Welcome and Roll Call
Discussion of Proposal for Voting Report
Next Steps
Public Comment
Adjournment

Dated: May 8, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–10309 Filed 5–13–20; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the California Advisory Committee

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement of meeting.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the California Advisory Committee (Committee) to the Commission will be held at 2:00 p.m. (Pacific Time) Wednesday, May 20, 2020. The purpose of the meeting is for the Committee to review the first draft of their report on immigration enforcement.

DATES: The meeting will be held on Wednesday, May 20, 2020, at 2:00 p.m. PT.

PUBLIC CALL INFORMATION: *Dial:* 800–263–0877, *Conference ID:* 1557037.

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer (DFO) at *afortes@usccr.gov* or (202) 681–0857.

SUPPLEMENTARY INFORMATION: This meeting is available to the public through the following toll-free call-in number: 800–263–0877, conference ID number: 1557037. Any interested member of the public may call this number and listen to the meeting. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Persons with hearing impairments may also follow the proceedings by first calling the Federal Relay Service at 1–800–877–8339 and providing the Service with the conference call number and conference ID number.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be mailed to the Western Regional Office, U.S. Commission on Civil Rights, 300 North Los Angeles Street, Suite 2010, Los Angeles, CA 90012 or email Ana Victoria Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Unit at (202) 681–0857.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkUAAQ.*

Please click on ''Committee Meetings'' tab. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

AGENDA

I. Welcome
II. Review Report Findings and Recommendations
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: May 11, 2020.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2020–10357 Filed 5–13–20; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–28–2020]

Foreign-Trade Zone 116—Port Arthur, Texas; Application for Subzone, Golden Pass LNG Terminal LLC, Port Arthur, Texas

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Foreign-Trade Zone of Southeast Texas, Inc., grantee of FTZ 116, requesting subzone status for the facility of Golden Pass LNG Terminal LLC located in Port Arthur, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on May 11, 2020.

The proposed subzone (1,186.4 acres) is located at 3752 South Gulfway Drive in Port Arthur, Texas. A notification of proposed production activity has been submitted and is being processed under 15 CFR 400.37 (Doc. B–26–2020).

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary and sent to: *ftz@trade.gov.* The closing period for their receipt is June 23, 2020. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to July 8, 2020.

A copy of the application will be available for public inspection in the ''Reading Room'' section of the FTZ Board's website, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: May 11, 2020.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2020–10348 Filed 5–13–20; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–805]

Certain Circular Welded Non-Alloy Steel Pipe From Mexico: Rescission of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is rescinding its administrative review of the antidumping duty order on certain circular welded non-alloy steel pipe from Mexico for the period of review (POR) November 1, 2018, through October 31, 2019.

DATES: Applicable May 14, 2020.

FOR FURTHER INFORMATION CONTACT: Mark Flessner, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6312.

SUPPLEMENTARY INFORMATION:

Background

On November 1, 2019, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the antidumping duty order [1] on certain circular welded non-alloy steel pipe from Mexico for the POR.[2] On November 26, 2019, Commerce received a timely request from domestic interested parties Independence Tube Corporation, and Southland Tube, Incorporated (collectively, Nucor Tubular [3]), in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.213(b), to conduct an administrative review of the *Order* for 36 companies.[4] On November 27, 2019, Commerce received a timely request from petitioner Wheatland Tube (Wheatland), in accordance with section 751(a) of the Act and 19 CFR 351.213(b), to conduct an administrative review of the *Order* for 24 companies.[5] No other party requested an administrative review.

On January 17, 2020, Commerce published in the **Federal Register** a notice of initiation with respect to 36 companies.[6] On March 5, 2020, Wheatland timely withdrew its request for an administrative review for all 24 companies it had requested.[7] On March 10, 2020, Nucor Tubulars timely withdrew its request for an administrative review for all 36 companies it had requested.[8] These withdrawals covered all 36 companies listed in the *Initiation Notice.*[9]

On April 24, 2020, Commerce tolled all deadlines in administrative reviews by 50 days, thereby extending the deadline for these results until September 21, 2020.[10]

Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation of the requested review. All parties which requested an administrative review withdrew their requests for review for all companies by the 90-day deadline, and no other party requested an administrative review of this order. Therefore, we are rescinding the administrative review of the antidumping duty order on certain circular welded non-alloy steel pipe from Mexico covering the period November 1, 2018, through October 31, 2019, in its entirety.

Assessment

Commerce will instruct U.S. Customs and Border Protection (CBP) to assess antidumping duties on all appropriate entries. Antidumping duties shall be assessed at rates equal to the cash deposit of estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP 41 days after publication of this notice in the **Federal Register**.

Notification to Importers

This notice serves as the only reminder to importers of their responsibility, under 19 CFR 351.402(f)(2), to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement may result in the presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

[1] *See Notice of Antidumping Duty Orders: Certain Circular Welded Non-Alloy Steel Pipe from Brazil, the Republic of Korea (Korea), Mexico, and Venezuela and Amendment to Final Determination of Sales at Less Than Fair Value: Certain Welded Non-Alloy Steel Pipe from Korea,* 57 FR 49453 (November 2, 1992) (the *Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review,* 84 FR 58690 (November 1, 2019).

[3] Subsequent to their joint filing of this request for review, these companies merged and are now known as Nucor Tubular Products Inc.

[4] *See* Nucor Tubular's Letter, ''Certain Circular Welded Non-Alloy Steel Pipe from Mexico: Request for Administrative Review,'' dated November 26, 2019.

[5] *See* Wheatland's Letter, ''Certain Circular Welded Non-Alloy Steel Pipes and Tubes from Mexico: Request for Administrative Review,'' dated November 27, 2019. Each of these 24 companies had already been requested by Nucor Tubular.

[6] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 3014 (January 17, 2020) (*Initiation Notice*) for a list of the 36 companies.

[7] *See* Wheatland's Letter, ''Certain Circular Welded Non-Alloy Steel Pipes and Tubes from Mexico: Withdrawal of Request for Administrative Review,'' dated March 5, 2020.

[8] *See* Nucor Tubular's Letter, ''Certain Circular Welded Non-Alloy Steel Pipes and Tubes from Mexico: Withdrawal of Request for Administrative Review,'' dated March 10, 2020.

[9] *See Initiation Notice,* 85 FR 3015–3016.

[10] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Administrative Reviews in Response to Operational Adjustments Due to COVID–19,'' dated April 24, 2020.

Notification Regarding Administrative Protective Orders

This notice serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until May 19, 2020, unless extended.[11]

This notice is published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(d)(4).

Dated: May 8, 2020.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2020–10350 Filed 5–13–20; 8:45 am]

BILLING CODE 3510–DS–P

[11] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006 (March 26, 2020).

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Open Meeting of the Information Security and Privacy Advisory Board

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The Information Security and Privacy Advisory Board (ISPAB) will meet Wednesday, June 24, 2020 from 9:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, June 25, 2020 from 9:00 a.m. until 4:30 p.m., Eastern Time. All sessions will be open to the public.

DATES: The meeting will be held on Wednesday, June 24, 2020, from 9:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, June 25, 2020, from 9:00 a.m. until 4:30 p.m., Eastern Time.

ADDRESSES: The meeting will be a virtual meeting via webinar. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Jeff Brewer, Information Technology Laboratory, National Institute of Standards and Technology, Telephone: (301) 975–2489, Email address: *jeffrey.brewer@nist.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. App., notice is hereby given that the ISPAB will hold an open meeting Wednesday, June 24, 2020 from 9:00 a.m. until 5:00 p.m., Eastern Time, and Thursday, June 25, 2020 from 9:00 a.m. until 4:30 p.m. Eastern Time. All sessions will be open to the public. The ISPAB is authorized by 15 U.S.C. 278g–4, as amended, and advises the National Institute of Standards and Technology (NIST), the Secretary of Homeland Security, and the Director of the Office of Management and Budget (OMB) on information security and privacy issues pertaining to Federal government information systems, including through review of proposed standards and guidelines developed by NIST. Details regarding the ISPAB's activities are available at *https://csrc.nist.gov/projects/ispab.*

The agenda is expected to include the following items:

—Discussion of the United States Methods of Product Testing and Standards Conformance,
—Presentation from the United States Government Testing Programs,
—Discussion of International Testing requirements and conformance regimes,
—Discussion of Executive Order 13905—Strengthening National Resilience Through Use of Positioning, Navigation, and Timing (PNT) Services,
—Discussion on telework cybersecurity and privacy, and potential lessons learned

Note that agenda items may change without notice. The final agenda will be posted on the ISPAB event page at: *https://cms.csrc.nist.gov/Events/2020/ispab-june-meeting.*

Public Participation: Written questions or comments from the public are invited and may be submitted electronically by email to Jeff Brewer at the contact information indicated in the **FOR FURTHER INFORMATION CONTACT** section of this notice by 5 p.m. June 22, 2020.

The ISPAB agenda will include a period, not to exceed thirty minutes, for submitted questions or comments from the public (Wednesday, June 24, 2020, between 4:30 p.m. and 5:00 p.m.). Submitted questions or comments from the public will be selected on a first-come, first-served basis and limited to five minutes per person.

Members of the public who wish to expand upon their submitted statements, those who had wished to submit a question or comment but could not be accommodated on the agenda, and those who were unable to attend the meeting via webinar are invited to submit written statements. In addition, written statements are invited and may be submitted to the ISPAB at any time. All written statements should be directed to the ISPAB Secretariat, Information Technology Laboratory by email to: *jeffrey.brewer@nist.gov.*

Admittance Instructions: All participants will be attending via webinar and must register on ISPAB's event page at: *https://cms.csrc.nist.gov/Events/2020/ispab-june-meeting* by 5 p.m. Eastern Time, June 22, 2020.

Kevin A. Kimball,

Chief of Staff.

[FR Doc. 2020–10375 Filed 5–13–20; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No.: PTO–P–2020–0026]

COVID–19 Prioritized Examination Pilot Program

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

ACTION: Notice.

SUMMARY: The United States Patent and Trademark Office (USPTO or Office) is implementing a pilot program to provide prioritized examination of certain patent applications. To qualify, the claim(s) of an application must cover a product or process related to COVID–19, and such product or process must be subject to an applicable FDA approval for COVID–19 use.

Under this pilot program, the USPTO will grant qualified requests for prioritized examination without payment of certain fees associated with prioritized examination for applicants that qualify for small or micro entity status. The goal of prioritized examination is to provide a final disposition within 12 months, on average, from the date the prioritized status has been granted. Furthermore, the USPTO believes it can achieve final disposition in six months if applicants provide more timely responses to notices and actions from the USPTO, as compared to those required by prioritized examination. This notice outlines the conditions, eligibility requirements, and guidelines of the pilot program.

DATES: Comments must be received by July 13, 2020 to ensure consideration.

Pilot Duration: The COVID–19 Prioritized Examination Pilot Program will accept requests for prioritized examination beginning July 13, 2020 until such time as the USPTO has accepted a total of 500 requests. The USPTO may extend the pilot program (with or without modifications) or terminate it depending on the workload and resources needed to administer the program, feedback from the public, and the effectiveness of the program. If the pilot program is extended or terminated, the USPTO will notify the public.

ADDRESSES: Comments should be sent by email addressed to *Covid19PrioritizedExamPilot@uspto.gov.* If submission of comments by email is not feasible due to, *e.g.,* a lack of access to a computer and/or the internet, please contact the USPTO for special instructions using the contact information provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Comments will be available for viewing via the USPTO's website (*https://www.uspto.gov*). Because the comments will be made available for public viewing, information the submitter does not desire to make public, such as an address or phone number, should not be included in the comments.

FOR FURTHER INFORMATION CONTACT: Robert A. Clarke, Editor of the Manual of Patent Examining Procedure (MPEP) (telephone at 571–272–7735; email at *robert.clarke@uspto.gov*).

SUPPLEMENTARY INFORMATION: New patent applications are normally taken up for examination in the order of their U.S. filing dates. See section 708 of the MPEP (9th ed., Rev. 08.2017, 2018). The USPTO has procedures under which an application will be advanced out of turn (accorded special status) for examination if the applicant files a petition to make special under 37 CFR 1.102(c) and (d) with the appropriate showing. See 37 CFR 1.102(c) and (d) and MPEP 708.02 and 708.02(a).

In addition, an application can be advanced out of turn (accorded special status) for examination if the applicant files a grantable request for prioritized examination under 37 CFR 1.102(e). Section 11(h) of the Leahy-Smith America Invents Act, Public Law 112–29, 125 Stat. 284 (2011), effective September 26, 2011, provides for prioritized examination whereby an applicant may request prioritized examination upon payment of appropriate fees and compliance with certain requirements. See MPEP 708.02(b). 35 U.S.C. 2(b)(2)(G) authorizes the USPTO to provide for prioritization of examination of applications for products, processes, or technologies that are important to the national economy or national competitiveness without requiring the prioritized examination fee.

In an extraordinary situation, 37 CFR 1.183 permits the USPTO to suspend or waive *sua sponte* any requirement of its regulations that is not a requirement of the patent statutes. The USPTO considers the effects of the COVID–19 outbreak that began in approximately January 2020 to be an ''extraordinary situation'' within the meaning of 37 CFR 1.183 for affected patent applicants and innovators. Consistent with this determination and the provisions of 35 U.S.C. 2(b)(2)(G), the USPTO has decided to implement a pilot program to provide prioritized examination without payment of the additional fees for prioritized examination for certain applications that claim products or processes that are subject to an applicable FDA approval for COVID–19 use. Such approvals may include, but are not limited to, an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an Emergency Use Authorization (EUA). Information on INDs, IDEs, NDAs, BLAs, PMAs, and EUAs may be obtained at *www.fda.gov.* To focus the USPTO's resources on those applicants that may be more resource constrained, the pilot is limited to applicants that qualify for either small or micro entity status. The USPTO will periodically evaluate the pilot program to determine whether and to what extent its coverage should be expanded or limited.

The USPTO currently provides for prioritized examination of utility and plant original applications if certain requirements are met. See 37 CFR 1.102(e) and MPEP 708.02(b). Upon filing a request for prioritized examination, an applicant must pay certain fees, including a prioritized examination fee set forth in 37 CFR 1.17(c) and a processing fee set forth in 37 CFR 1.17(i)(1). The requirement to pay these two fees will be waived under this pilot program if the requirements are met. The remaining fees listed in 37 CFR 1.102(e) and MPEP 708.02(b), subsection I. A. 2., that are not currently set to $0 must be paid by all applicants, and the requirement to pay those fees by the time the request for prioritized examination is made is not waived under this pilot program.

Part I. Requirements To Participate

(1) The request for prioritized examination under the pilot program must be made:

(a) With the filing of a non-continuing original utility or plant nonprovisional application;

(b) with the filing of an original utility or plant nonprovisional application claiming the benefit of an earlier filing date under 35 U.S.C. 120, 121, or 365(c) of one prior nonprovisional application or one prior international application designating the United States; or

(c) with or after the filing of a request for continued examination (RCE) of such plant or utility application or of a national stage of an international application. Consistent with 37 CFR 1.102(e)(2), only a single request for prioritized examination filed with or after filing an RCE may be granted in an application.

The pilot program is reserved for the above nonprovisional applications. Any application that claims the benefit of the filing date of two or more prior filed nonprovisional U.S. applications or international applications designating the United States under 35 U.S.C. 120, 121, or 365(c) is not eligible for participation under the pilot program, but the applicant may request prioritized examination under 37 CFR 1.102(e). Claiming the benefit under 35 U.S.C. 119(e) of one or more prior provisional applications or claiming a right of foreign priority under 35 U.S.C. 119(a)–(d) or (f) to one or more foreign applications will not cause a nonprovisional application to be ineligible for the pilot program.

The USPTO encourages the use of form PTO/SB/450, titled ''Certification and Request for COVID–19 Prioritized Examination Pilot Program under 37 CFR 1.102(e),'' to make the request for prioritized examination under the pilot. Form PTO/SB/450 is available at *https://www.uspto.gov/patent/forms/forms-patent-applications-filed-or-after-september-16-2012.* Form PTO/SB/450 contains the necessary certifications for qualification to participate in the pilot. Use of form PTO/SB/450 will also enable the USPTO to quickly identify and timely process the request.

(2) The applicant must certify that at least one of the pending claims covers a product or process related to COVID–19 and that such product or process is subject to an applicable FDA approval for COVID–19 use. Form PTO/SB/450 contains this certification.

(3) The request must include a certification that the applicant qualifies for either small entity (37 CFR 1.27) or micro entity (37 CFR 1.29) status when

the request is made. Form PTO/SB/450 contains this certification.

(4) The request must include an executed application data sheet meeting the conditions specified in 37 CFR 1.53(f)(3)(i).

Part II. Internal Processing of the Request Under the Pilot Program

Requests complying with the four requirements above will be further reviewed to determine if the other requirements for prioritized examination are met, *e.g.,* the requirements of 37 CFR 1.102(e) other than payment of the fees set forth in 37 CFR 1.17(c) and 1.17(i)(1). These requirements include: Filing the application and request for prioritized examination under the pilot program via the USPTO's patent electronic filing systems (EFS-Web or Patent Center) if the application is a utility application; presenting no more than four independent claims and 30 total claims, and no multiple dependent claims; and paying the other required fees (*e.g.,* the basic filing fee, search fee, and examination fee). In addition, obtaining an extension of time to a notice before the request has been acted upon will result in the request being denied. See MPEP 708.02(b), subsection I, for a discussion of the requirements.

Part III. Office Actions and Replies Under the Pilot Program

The time periods set for reply in Office actions for applications undergoing prioritized examination under the pilot program will be the same as those for other applications undergoing prioritized examination and are set forth in MPEP 710.02(b). If an applicant files a petition for an extension of time to file a reply or a request for suspension of action, the petition or request will be acted upon, but the prioritized examination of the application under the pilot program will be terminated, as is the case with other applications undergoing prioritized examination. In addition, in order to maintain special status, filing an amendment to the application that results in more than four independent claims, more than 30 total claims, or a multiple dependent claim will terminate the prioritized examination, as is the case with other applications undergoing prioritized examination. Upon termination of prioritized examination, the application will be removed from the examiner's special docket and placed on the examiner's regular docket in accordance with its stage of prosecution, as is the case with other applications undergoing prioritized examination.

A reply to an Office action must be fully responsive to the rejections, objections, and requirements made by the examiner. Any amendment filed in reply to a non-final Office action will be treated as not fully responsive if it attempts to: (1) Add claims that would result in more than four independent claims or more than 30 total claims pending in the application; or (2) add any multiple dependent claim. If a reply to a non-final Office action is not fully responsive because it does not comply with the pilot program requirements but is a *bona fide* attempt to advance the application to final action, the examiner may, at his or her discretion, provide one month or 30 days, whichever is longer, for the applicant to supply a fully responsive reply, in which case prioritized examination would not be terminated. Submission of a petition for extension of time under 37 CFR 1.136(a) to the notice of nonresponsive amendment will result in termination of special status. Any further nonresponsive amendment will not be treated as *bona fide,* and the time period set in the prior notice will continue to run.

Part IV. After-Final and Appeal Procedures

The mailing of a final Office action or the filing of a Notice of Appeal, whichever is earlier, is a final disposition for purposes of the 12-month goal for the pilot program. During the appeal process, the application will be treated in accordance with the normal appeal procedure (see MPEP chapter 1200). Any amendment, affidavit, or other evidence submitted after a final Office action and prior to appeal must comply with 37 CFR 1.116. The filing of an RCE for an application in the pilot program is a final disposition for purposes of the 12-month goal for the program. The application will not retain its special status after the filing of a proper RCE.

Part V. Proceedings Outside the Normal Examination Process

If an application becomes involved in proceedings outside the normal examination process (*e.g.,* a secrecy order or petitions under 37 CFR 1.181–1.183), the USPTO will place the application in special status under the pilot program before and after such proceedings. During those proceedings, however, the application will not be under special status. For example, while under a secrecy order, the application will be treated in accordance with the normal secrecy order procedures and will not be in special status under the pilot program. Once the proceeding outside the normal examination process is completed, the application will continue in special status until it reaches a final disposition, which may occur later than 12 months from the grant of special status under the pilot program.

Part VI. First Action Interview (FAI) Pilot Program Is Not Available

Applications accepted into the FAI Pilot Program are not eligible for this pilot program. In addition, applications accepted into this pilot program will not be eligible to participate in the FAI Pilot Program. However, standard interview practices and procedures applicable to regular *ex parte* prosecution will still be available. See MPEP 713.02. For more information about the FAI Pilot Program, please visit *https://www.uspto.gov/patent/initiatives/first-action-interview/full-first-action-interview-pilot-program.*

Part VII. Actions Resulting in Termination From the Pilot Program

There is no provision for withdrawal from special status under the pilot program. However, the filing of a petition for any extension of time under 37 CFR 1.136(a) will result in the termination of special status under the pilot program. Presenting more than one benefit claim to previously filed nonprovisional U.S. applications or international applications designating the United States under 35 U.S.C. 120, 121, or 365(c) will also result in the termination of special status under the pilot program.

An applicant may abandon the application that has been granted special status under the pilot program in favor of a continuing application. However, a continuing application will not automatically be given prioritized examination status based on the request filed in the parent application. Each application (including each continuing application) must, on its own, meet all requirements for prioritized examination under the pilot program.

Part VIII. Twelve-Month Goal

The objective of the pilot program is to complete, on average, the examination of an application within 12 months of special status being granted (*i.e.,* within 12 months from the mailing date of the decision granting the petition to make special). The 12-month goal is successfully achieved when one of the following final dispositions occurs within 12 months from the grant of special status under the pilot program: (1) The mailing of a notice of allowance; (2) the mailing of a final Office action; (3) the filing of an RCE; (4) the

abandonment of the application; or (5) the filing of a Notice of Appeal. The final disposition of an application, however, may occur later than the 12-month time frame in certain situations (*e.g.,* when the applicant filed a petition under 37 CFR 1.181). In any event, however, the 12-month time frame is a goal. Any failure to meet the 12-month goal, or other issues related to this goal that arise, are neither petitionable nor appealable matters.

Applicants may shorten the overall pendency of an application in the pilot program by replying to Office actions and notices earlier than required by the USPTO. For example, the USPTO will endeavor to reduce pendency, from approval of the request for prioritized examination to final disposition, to six months if all replies occur within 30 days of a notice by the USPTO. This goal depends on additional factors, including the demands placed on specific examiners by multiple co-pending applications under the pilot program. Current statistics for prioritized examination are available at *https://www.uspto.gov/corda/dashboards/patents/main.dashxml?CTNAVID=1007.*

Andrei Iancu,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2020–10372 Filed 5–13–20; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2020–HQ–0006]

Proposed Collection; Comment Request

AGENCY: Department of the Air Force, DoD.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Air Force announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 13, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to CMOS, 200 East Moore Dr., Maxwell AFB Gunter Annex, AL 36114–3004, ATTN: Daniel J. Mangum, (334) 416–4679.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Cargo Movement Operations System (CMOS); OMB Control Number 0701–CMOS.

Needs and Uses: CMOS is used by the DoD to plan, manage, and execute the movement of cargo and personnel. In addition to the deployment of active military personnel, the passenger manifest capability supports military retirees and military family members traveling on a ''Space A CAT VI'' basis. Those passengers are considered to be ''general public.'' The data required for a passenger manifest includes PII, such as a Passport Number, and is deemed to be a ''Collection.'' This ''general public'' data is collected when passengers are at the Air Terminal; no solicitation is involved.

Affected Public: Individuals and Household.

Annual Burden Hours: 18.

Number of Respondents: 180.

Responses per Respondent: 1.

Annual Responses: 180.

Average Burden per Response: 0.1 hour.

Frequency: Approximately 180 times per year.

This passenger data is collected only on an as-needed basis when the passengers request the Space A travel, and is collected only at the Air Terminal. CMOS does not seek out these respondents and does not in any way solicit their participation. There are no paper forms for information requests sent to the travelers for them to return.

The sole purpose of this data is to provide a complete manifest of the passengers onboard the military flight. It is not used for any other reporting or statistical purposes.

Dated: May 11, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–10342 Filed 5–13–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2020–HQ–0005]

Proposed Collection, Comment Request

AGENCY: Headquarters Air Force Personnel Center/Airman and Family Sustainment Branch, Department of Defense.

ACTION: Information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Airman and Family Sustainment Branch, Headquarters Air Force Personnel Center, announces the proposed reinstatement of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 13, 2020.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: DoD cannot receive written comments at this time due to the

COVID–19 pandemic. Comments should be sent electronically to the docket listed above.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Airman and Family Sustainment Branch (DPFFF), Headquarters Air Force Personnel Center, 550 C Street West, Joint Base, San Antonio, TX, 78150–4713, ATTN: Mrs. Denise Blount or call 210–565–2158.

SUPPLEMENTARY INFORMATION:

Title, Associated Form, and OMB Number: Foreign Government Employment Application; OMB Number 0701–0134.

Needs and Uses: The information collection requirement is to obtain the information needed by the Secretary of the Air Force and Secretary of State on which to base a decision to approve/disapprove a request to work for a foreign government. This approval is specified by Title 37, United States Code, and Section 908. This statute delegates such approval (authority of Congress to the respective service secretaries and to the Secretary of State.

Affected Public: Individuals and households.

Annual Burden Hours: 20.

Number of Respondents: 20.

Responses per Respondent: 1.

Annual Responses: 20.

Average Burden per Response: 1 hour.

Frequency: On occasion.

The collection instrument includes a foreign government employment memorandum, employment questionnaire, and an SF 312, a nondisclosure agreement. The information received from these documents include a detailed description of duty, name of employer, Social Security Number, and statements specifying whether or not the employee will be compensated; declaring if employee. will be required or plans to obtain foreign citizenship; declaring that the member will not be required to execute an oath of allegiance to the foreign government; verifying that the member understands that retired pay equivalent to the amount received from the foreign government may be withheld if he or she accepts employment with a foreign government before receiving approval. Reserve members only must include a request to be reassigned to Inactive Status List Reserve Section (Reserve Section Code RB).

Dated: May 11, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–10337 Filed 5–13–20; 8:45 am]

BILLING CODE 5001–06–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 U.S. Air Force Scientific 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) of 1972 (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 Air Force, with independent advice and recommendations on matters relating to the Department of the Air Force's scientific, technical, manufacturing, acquisition, logistics, and business management functions, as well as other Department of the Air Force related matters as determined by the Secretary of the Air Force. The Board shall: (a) Conduct studies on topics deemed critical by the Secretary of the Air Force; (b) recommend applications of technology to improve U.S. Air Force capabilities; and (c) provide an independent review of the quality and relevance of the U.S. Air Force science and technology program. The Board shall be composed of no more than 20 members appointed in accordance with DoD policy and procedures, who are eminent authorities in one or more of the following disciplines: science, technology, manufacturing, acquisition, logistics, and business management functions, as well as other matters of special interest to the Department of the Air Force.

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: May 8, 2020.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2020–10312 Filed 5–13–20; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0067]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Submission of the Fulbright-Hays Group Projects Abroad Program Application (CFDA 84.021A)

AGENCY: Office of Postsecondary Education (OPE), 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 June 15, 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 Gary Thomas, 202–453–7199.

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: Submission of the Fulbright-Hays Group Projects Abroad Program Application (CFDA 84.021A).

OMB Control Number: 1840–0792.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 6,600.

Abstract: The Fulbright-Hays, Group Projects Abroad program is authorized by section 102(b)(6) of the Mutual Educational and Cultural Exchange Act of 1961 (Pub. L. 87–256), most commonly known as the Fulbright-Hays Act. The purpose of Section 102(b)(6) of the Mutual Educational and Cultural Exchange Act of 1961 (Fulbright-Hays Act) is to promote and develop modern foreign language training and area studies throughout the educational structure of the United States.

The Fulbright-Hays GPA program provides grants for overseas projects in training, research, and curriculum development in modern foreign languages and area studies for groups of teachers, students, and faculty.

Dated: May 11, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–10333 Filed 5–13–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2020–SCC–0066]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Submission of the Fulbright-Hays Doctoral Dissertation Research Abroad Program Application (CFDA 84.022A)

AGENCY: Office of Postsecondary Education (OPE), 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 June 15, 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 Pamela Maimer, 202–453–6891.

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: Submission of the Fulbright-Hays Doctoral Dissertation Research Abroad Program Application (CFDA 84.022A).

OMB Control Number: 1840–0005.

Type of Review: An extension of an existing information collection.

Respondents/Affected Public: Individuals or Households; Private Sector.

Total Estimated Number of Annual Responses: 360.

Total Estimated Number of Annual Burden Hours: 9,000.

Abstract: This application package is used by both institutions of higher education and individual applicants to apply for fellowships under the Fulbright-Hays Doctoral Dissertation Research Abroad (DDRA) program. Information submitted in this collection will be used during the peer review to evaluate and score the applications, and to make funding decisions. The Department requires this information collection in order to make discretionary grant awards under this program.

Dated: May 11, 2020.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2020–10332 Filed 5–13–20; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–417–000]

Transwestern Pipeline Company, LLC; Notice of Request Under Blanket Authorization

Take notice that on May 1, 2020, Transwestern Pipeline Company, LLC (Transwestern), 1300 Main Street, Houston TX 77002, filed in the above referenced docket a prior notice request pursuant to sections 157.205, 157.208, and 157.210 of the Commission's regulations under the Natural Gas Act and its blanket certificate issued in Docket No. CP82–534–000 for authorization to construct, own, operate, and maintain a new compressor unit. The Station 8 Project comprises a 5,000 HP site-rated motor, compressor, compressor building and other ancillary facilities at its Compressor Station 8 in Lincoln County, New Mexico. Transwestern estimates the cost of the project to be approximately $11.4 million, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Any questions regarding this application should be directed to Mr. Kelly Allen, Manager Regulatory Affairs Department for Transwestern Pipeline Company, LLC, 1300 Main Street, Houston, TX 77002, or call (713)–989–2606, or by email at *Kelly.Allen@energytransfer.com.*

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 FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the NGA.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list and will be notified of any meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* 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.

Dated: May 8, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–10326 Filed 5–13–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 178–045]

[Pacific Gas and Electric Company, Kern & Tule Hydro LLC; Notice of Application for Transfer of License and Amendment of License and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Type of Application:* Transfer of License and License Amendment.

b. *Project No.:* 178–045.

c. *Date Filed:* March 12, 2020.

d. *Applicants:* Pacific Gas and Electric Company (transferor), Kern & Tule Hydro LLC (transferee).

e. *Name of Project:* Kern Canyon Hydroelectric Project.

f. *Location:* The project is located on the Kern River, Kern County, California and occupies 11.26 acres of federal lands located within the Sequoia National Forest and administered by the U.S. Forest Service.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a–825r.

h. *Applicant Contacts: For Transferor:* Ms. Annette Faraglia, Chief Counsel, Hydro Generation, Pacific Gas and Electric Company, 77 Beale Street, B30A–3005, San Francisco, CA 94105, phone: (415)–973–7145, Email: *annette.faraglia@pge.com* and Ms. Stephanie Maggard, Director, Power Generation, Pacific Gas and Electric Company, 245 Market Street, N11E–1136, San Francisco, CA 94105, phone: (415) 973–2812, Email: *stephanie.maggard@pge.com.*

For Transferee: Ms. Ted S. Sorenson, P.E., Manager, Kern & Tule Hydro LLC, P.O. Box 1855, Idaho Falls, ID 83403, phone: (208) 589–6908, Email:

Ted@tsorenson.net and Mr. Miriah R. Elliott, Agent, Kern & Tule Hydro LLC, 498 West 140 South, Ivins, UT 84738, phone: (435) 429–1878, Email: *miriah@tsorenson.net.*

i. *FERC Contact:* Mrs. Anumzziatta Purchiaroni, (202) 502–6191 or *Anumzziatta.purchiaroni@ferc.gov* or Mark Ivy, (202) 502–6156 or *mark.ivy@ferc.gov.*

j. *Deadline for filing comments, motions to intervene, and protests:* Within 30 days from the issuance date of this notice.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. The first page of any filing should include docket number P–178–045. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, it must also serve a copy of the document on that resource agency.

k. *Description of Transfer and Amendment Request:* The applicants request that the Commission transfer the Kern Canyon Hydroelectric Project No. 178 from Pacific Gas and Electric Company (PG&E) to Kern & Tule Hydro LLC (KTH). The applicants also request that the Commission remove from the project an approximately 8.2-mile-long, 70 kilovolt (kV) transmission line that connects the project powerhouse with PG&E's integrated transmission system. The applicants state that the transmission line segment is not used solely to transmit power from the project to the interconnected grid and would remain part of the interconnected transmission system even if the project did not exist. Therefore, the transmission line segment does not qualify as a primary transmission line and does not need to be part of the licensed project. The switchyard adjacent to the powerhouse, as well as an approximately 300-foot-long segment of the 70–kV line running from the project powerhouse to pole 9/1 will remain in the license and will be transferred to KTH. Furthermore, the applicants request that the Commission revise the project boundary to remove 47.5 acres of land which is occupied by the transmission line corridor.

l. 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. Currently, 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 FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

m. The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* 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.

n. *Comments, Protests, or Motions to Intervene:* Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Documents:* Any filing must (1) bear in all capital letters the title COMMENTS, PROTEST, or MOTION TO INTERVENE as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: May 8, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–10324 Filed 5–13–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 539–015]

Lock 7 Hydro Partners, LLC; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 539–015.

c. *Date filed:* April 30, 2020.

d. *Applicant:* Lock 7 Hydro Partners, LLC.

e. *Name of Project:* Mother Ann Lee Hydroelectric Project.

f. *Location:* On the Kentucky River, in Mercer and Jessamine Counties, Kentucky. The project would be located at the Commonwealth of Kentucky's existing Lock and Dam No. 7. The project does not occupy any federal land.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791 (a)–825(r)

h. *Applicant Contact:* David Brown Kinloch, Lock 7 Hydro Partners, LLC, 414 S. Wenzel Street, Louisville, KY 40204; (502) 589–0975; email *kyhydropower@gmail.com.*

i. *FERC Contact:* Joshua Dub, (202) 502–8138 or *Joshua.Dub@ferc.gov.*

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. Deadline for filing additional study requests and requests for cooperating agency status: June 29, 2020.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the eFiling link at *http://www.ferc.gov.* 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. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY).

m. The application is not ready for environmental analysis at this time.

n. The Mother Ann Lee Hydroelectric Project is operated in a run-of-river mode and consists of the following existing facilities: (1) A reservoir with a normal pool elevation of 514.6 feet and an estimated surface area of about 830 acres; (2) a 230-foot-long concrete-capped, timber crib dam; (3) a 50-foot-wide, 300-foot-long stone lock chamber; (4) a 120-foot-long by 100-foot-wide forebay; (5) a 116-foot long concrete substructure containing trash racks, 6 intake gates, 3 turbines, and discharge facilities; (6) a 93-foot-long by 25-foot-wide superstructure/powerhouse located above the spillway containing three generating units with a total installed capacity of 2.209 megawatts; (7) a substation connected to the powerhouse by an 85-foot-long footbridge; (8) a 0.86-mile-long, 34.5-kilovolt transmission line; and (9) appurtenant facilities. The estimated average annual generation is 9,200 megawatt-hours.

o. 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.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. Procedural schedule and final amendments: The application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Issue Deficiency Letter (if necessary), July 2020.
Request Additional Information, July 2020.
Issue Notice of Acceptance, November 2020.
Issue Scoping Document 1 for comments, December 2020.
Comments on Scoping Document 1, January 2021.
Issue Notice of Ready for Environmental Analysis, February 2021.
Commission issues EA, September 2021.
Comments on draft EA, October 2021.

Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: May 8, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–10330 Filed 5–13–20; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC19–42–000]

Commission Information Collection Activities (FERC–521); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission, Department of Energy.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995 (PRA), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on FERC–521 (Payments for Benefits from Headwater Improvements) and will be submitting FERC–521 to the Office of Management and Budget (OMB) for review of the information collection requirements.

DATES: Comments on the collection of information are due July 13, 2020.

ADDRESSES: You may submit comments identified by Docket No. IC19–42–000 by either of the following methods:

- *eFiling at Commission's website: http://www.ferc.gov/docs-filing/efiling.asp.*
- *Mail/Express Services:* 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.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: *http://www.ferc.gov/help/submission-guide.asp.* For user assistance contact FERC Online Support by email at *ferconlinesupport@ferc.gov,* or by phone at: (866) 208–3676 (toll-free).

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at *http://www.ferc.gov/docs-filing/docs-filing.asp.*

FOR FURTHER INFORMATION CONTACT: Ellen Brown may be reached by email at *DataClearance@FERC.gov,* telephone at (202) 502–8663.

SUPPLEMENTARY INFORMATION:

Title: FERC–521, Payments for Benefits from Headwater Improvements.

OMB Control No.: 1902–0087.

Type of Request: Three-year extension of the FERC–521 information collection

requirements with no changes to the reporting requirements.

Abstract: The information collected under the requirements of FERC–521 is used by the Commission to implement the statutory provisions of Section 10(f) of the Federal Power Act (FPA).[1] The FPA authorizes the Commission to determine headwater benefits received by downstream hydropower project owners. Headwater benefits are the additional energy production possible at a downstream hydropower project resulting from the regulation of river flows by an upstream storage reservoir.

When the Commission completes a study of a river basin, it determines headwater benefits charges that will be apportioned among the various downstream beneficiaries. A headwater benefits charge and the cost incurred by the Commission to complete an evaluation are paid by downstream hydropower project owners. In essence, the owners of non-federal hydropower projects that directly benefit from a headwater improvement must pay an equitable portion of the annual charges for interest, maintenance, and depreciation of the headwater project to the U.S. Treasury. The regulations provide for apportionment of these costs between the headwater project and downstream projects based on downstream energy gains and propose equitable apportionment methodology that can be applied to all river basins in which headwater improvements are built. The Commission requires owners of non-federal hydropower projects to file data for determining annual charges as outlined in 18 Code of Federal Regulations (CFR) Part 11.

Type of Respondents: There are two types of entities that respond, Federal and Non-Federal hydropower project owners. The Federal entities that typically respond are the U.S. Army Corps of Engineers and the U.S. Department of Interior Bureau of Reclamation. The Non-Federal entities may consist of any Municipal or Non-Municipal hydropower project owner.

Estimate of Annual Burden [1] and cost [2] The Commission estimates the total Public Reporting Burden for this information collection as:

FERC–521: PAYMENTS FOR BENEFITS FROM HEADWATER IMPROVEMENTS

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden and cost per response (4)	Total annual burden hours and total annual cost (3) * (4) = (5)	Cost per respondent ($) (5) ÷ (1)
Federal and Non-Federal hydropower project owners.	3	1	3	40 hrs.; $3,200	120 hrs.; $9,600	$3,200
Total Cost					120 hrs.; $9,600	$3,200

The total estimated annual cost burden to each respondent is $3,200 [40 hours * $80.00/hour = $3,].

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: May 8, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–10328 Filed 5–13–20; 8:45 am]

BILLING CODE 6717–01–P

[1] 16 U.S.C. 803.

[1] Burden is defined as the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, refer to 5 Code of Federal Regulations 1320.3.

[2] The estimates for cost per response are derived using the 2019 FERC average salary plus benefits of $167,091/year (or $80.00/hour). Commission staff finds that the work done for this information collection is typically done by wage categories similar to those at FERC.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP20–21–000]

Port Arthur Pipeline, LLC; Notice of Availability of the Environmental Assessment for the Proposed Louisiana Connector Amendment Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) has prepared an environmental assessment (EA) for the Louisiana Connector Amendment Project (Project), proposed by Port Arthur Pipeline, LLC (PAPL) in the above-referenced docket. The Project is an amendment to the Louisiana Connector Project (Docket CP18–7–000), which was previously authorized by the Commission on April 18, 2019. In its amended Project, PAPL requests authorization to construct and operate natural gas transportation facilities (including compression) in Beauregard Parish, Louisiana. Specifically, the Project would relocate the previously certificated but as yet not constructed compressor station from its authorized site in Allen Parish, Louisiana to a site in Beauregard Parish. The Project would also consist of associated facilities within the new Beauregard Parish Compressor Station boundaries.

The EA assesses the potential environmental effects of construction and operation of the Project in accordance with the requirements of the National Environmental Policy Act. The FERC staff concludes that approval of the proposed Project, with appropriate mitigating measures, would not constitute a major federal action significantly affecting the quality of the human environment.

The proposed Project includes the following new facilities in Beauregard Parish:

- A 93,880-horsepower compressor station;
- four pipeline interconnections ranging from 30 inches to 42 inches in diameter;
- four meter stations;
- one mainline block valve; and

• one pig launcher/receiver facility.[1]

The Commission mailed a copy of the *Notice of Availability* to federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; potentially affected landowners and other interested parties; and local libraries and newspapers. The EA is only available in electronic format. It may be viewed and downloaded from FERC's website (*www.ferc.gov*), on the Environmental Documents page (*https://www.ferc.gov/industries/gas/enviro/eis.asp*). In addition, the EA may be accessed by using the eLibrary link on FERC's website. Click on the eLibrary link (*https://www.ferc.gov/docs-filing/elibrary.asp*), click on General Search, and enter the docket number in the Docket Number field, excluding the last three digits (*i.e.,* CP20–21). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Any person wishing to comment on the EA may do so. Your comments should focus on the EA's disclosure and discussion of potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. The more specific your comments, the more useful they will be. To ensure that the Commission has the opportunity to consider your comments prior to making its decision on this Project, it is important that we receive your comments in Washington, DC on or before 5:00 p.m. Eastern Time on June 8, 2020.

For your convenience, there are three methods you can use to file your comments to the Commission. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the eComment feature on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. This is an easy method for submitting brief, text-only comments on a project;

(2) You can also file your comments electronically using the eFiling feature on the Commission's website (*www.ferc.gov*) under the link to Documents and Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on eRegister. You must select the type of filing you are making. If you are filing a comment on a particular project, please select ''Comment on a Filing;'' or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP20–21–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426.

Any person seeking to become a party to the proceeding must file a motion to intervene pursuant to Rule 214 of the Commission's Rules of Practice and Procedures (18 CFR 385.214). Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.* Only intervenors have the right to seek rehearing or judicial review of the Commission's decision. The Commission may grant affected landowners and others with environmental concerns intervenor status upon showing good cause by stating that they have a clear and direct interest in this proceeding which no other party can adequately represent. *Simply filing environmental comments will not give you intervenor status, but you do not need intervenor status to have your comments considered.*

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website (*www.ferc.gov*) using the *eLibrary* link. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: May 8, 2020.

Kimberly D. Bose,

Secretary.

[FR Doc. 2020–10325 Filed 5–13–20; 8:45 am]

BILLING CODE 6717–01–P

[1] A pipeline pig is a device used to clean or inspect the pipeline. A pig launcher/receiver is an aboveground facility where pigs are inserted or retrieved from the pipeline.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC20–56–000.
Applicants: Imperial Valley Solar, LLC.
Description: Supplement to April 24, 2020 Application for Authorization Under Section 203 of the Federal Power Act, et al. of Imperial Valley Solar, LLC.
Filed Date: 5/7/20.
Accession Number: 20200507–5180.
Comments Due: 5 p.m. ET 5/18/20.

Docket Numbers: EC20–63–000.
Applicants: Crowned Ridge Wind, LLC, Crowned Ridge Wind II, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Crowned Ridge Wind, LLC, et al.
Filed Date: 5/6/20.
Accession Number: 20200506–5247.
Comments Due: 5 p.m. ET 5/27/20.

Docket Numbers: EC20–64–000.
Applicants: Catalyst Old River Hydroelectric Limited Partnership, Brookfield Power US Holding America Co.
Description: Joint Application for Authorization Under Section 203 of the Federal Power Act, et al. of Catalyst Old River Hydroelectric Limited Partnership, et al.
Filed Date: 5/7/20.
Accession Number: 20200507–5200.
Comments Due: 5 p.m. ET 5/28/20.

Docket Numbers: EC20–65–000.
Applicants: Jersey Central Power & Light Co., Yards Creek Energy, LLC.
Description: Application for Authorization Under Section 203 of the Federal Power Act, et al. of Jersey Central Power & Light Company, et al.
Filed Date: 5/6/20.
Accession Number: 20200506–5257.
Comments Due: 5 p.m. ET 5/27/20.

Take notice that the Commission received the following exempt wholesale generator filings:.

Docket Numbers: EG20–152–000.
Applicants: Day County Wind I, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Day County Wind I, LLC.
Filed Date: 5/7/20.
Accession Number: 20200507–5169.
Comments Due: 5 p.m. ET 5/28/20.

Docket Numbers: EG20–153–000.
Applicants: Baldwin Wind Energy, LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Baldwin Wind Energy, LLC.
Filed Date: 5/7/20.
Accession Number: 20200507–5171.
Comments Due: 5 p.m. ET 5/28/20.

Take notice that the Commission received the following electric rate filings:.

Docket Numbers: ER17–802–008.
Applicants: Exelon Generation Company, LLC.
Description: Report Filing: Refund Report – Informational Filing to be effective N/A.
Filed Date: 5/8/20.
Accession Number: 20200508–5113.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1248–001.
Applicants: GenOn Energy Management, LLC.
Description: Tariff Amendment: Amendment to Market-Based Rate Tariff Revision Filing to be effective 3/13/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5238.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1256–001.
Applicants: Shawville Power, LLC.
Description: Tariff Amendment: Amendment to Market-Based Rate Tariff Revision Filing to be effective 3/13/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5220.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1383–001.
Applicants: PECO Energy Company, PJM Interconnection, L.L.C.
Description: Tariff Amendment: PECO submits Amendment to OATT Att. H–7A re: Depreciation and Amortization Rates to be effective 5/29/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5237.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1783–000.
Applicants: PJM Interconnection, L.L.C., NextEra Energy Transmission MidAtlantic Indiana, Inc.
Description: § 205(d) Rate Filing: Revisions to Tariff for NextEra Energy Transmission MidAtlantic Indiana, Inc. to be effective 12/31/9998.
Filed Date: 5/7/20.
Accession Number: 20200507–5163.
Comments Due: 5 p.m. ET 5/28/20.

Docket Numbers: ER20–1784–000.
Applicants: PJM Interconnection, L.L.C., NextEra Energy Transmission MidAtlantic Indiana, Inc.
Description: § 205(d) Rate Filing: Revisions to CTOA for NextEra Energy Transmission MidAtlantic Indiana, Inc. to be effective 12/31/9998.
Filed Date: 5/7/20.
Accession Number: 20200507–5164.
Comments Due: 5 p.m. ET 5/28/20.

Docket Numbers: ER20–1786–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: § 205(d) Rate Filing: 2020–05–08_SA 3489 Duke-Speedway Solar GIA (J805) to be effective 4/24/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5092.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1787–000.
Applicants: Southern California Edison Company.
Description: Tariff Cancellation: Resubmit Notices of Cancellation Ralph Laks GIA and Service Agreement Solar 66 to be effective 5/11/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5174.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1788–000.
Applicants: Dominion Energy South Carolina, Inc.
Description: Initial rate filing: DESC—Georgia Power Affected System Agreement to be effective 7/8/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5183.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1789–000.
Applicants: Arizona Public Service Company.
Description: § 205(d) Rate Filing: Service Agreement No. 380—sPower E&P Agreement to be effective 5/1/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5208.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1790–000.
Applicants: Aurora Wind Project, LLC.
Description: Baseline eTariff Filing: Aurora Wind Project, LLC MBR eTariff Filing to be effective 7/8/2020.
Filed Date: 5/8/20.
Accession Number: 20200508–5216.
Comments Due: 5 p.m. ET 5/29/20.

Docket Numbers: ER20–1791–000.
Applicants: Jersey Central Power & Light Co.
Description: Notice of Cancellation of records applicable to Reactive Service charges, et al. of Jersey Central Power & Light Company.
Filed Date: 5/6/20.
Accession Number: 20200506–5263.
Comments Due: 5 p.m. ET 5/27/20

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: May 8, 2020.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2020–10334 Filed 5–13–20; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–10009–82–OA]

Request for Nominations of Experts To Augment the EPA's Science Advisory Board Radiation Advisory Committee for the Review of the EPA's Draft Multi-Agency Radiation Survey and Site Investigation Manual (MARSSIM) Revision 2

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) Staff Office invites public nominations of technical experts to augment the SAB's Radiation Advisory Committee (RAC) to conduct a review on Revision 2 to the Multi-Agency Radiation Survey and Site Investigation Manual.

DATES: Nominations should be submitted in time to arrive no later than June 4, 2020.

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information regarding this Notice and Request for Nominations may contact Dr. Diana Wong, Designated Federal Officer (DFO), by telephone at (202) 564–2049 or at *wong.diana-m@epa.gov.* General information concerning the EPA SAB can be found at the EPA SAB website at *http://www.epa.gov/sab.*

SUPPLEMENTARY INFORMATION:

Background

The SAB (42 U.S.C. 4365) is a chartered Federal Advisory Committee that provides independent scientific and technical peer review, advice and

recommendations to the EPA Administrator on the technical basis for EPA actions. As a Federal Advisory Committee, the SAB conducts business in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and related regulations. The SAB Radiation Advisory Committee (RAC) is a subcommittee of the SAB that provides strategic advice through the chartered SAB on radiation protection, radiation science, and radiation science applications. The SAB and the RAC, augmented with additional experts, will comply with the provisions of FACA and all appropriate SAB Staff Office procedural policies.

MARSSIM provides information on planning, conducting, evaluating, and documenting environmental radiological surveys of surface soil and building surfaces for demonstrating compliance with regulations. MARSSIM, when finalized as Revision 2, will update this multi-agency consensus document.

MARSSIM was originally developed by the technical staffs of the four Federal agencies having authority for control of radioactive materials: DoD, DOE, EPA, and NRC (60 FR 12555; March 7, 1995). The four agencies issued Revision 1 to MARSSIM in August 2000, and additional edits to Revision 1 in June 2001. MARSSIM has not been updated since 2001; updates prior to 2001 primarily consisted of minor non-technical edits. Revision 2 updates the science, clarifies methods, and implements lessons learned from over 20 years of the document's use in industry.

Request for Nominations

The SAB Staff Office is seeking nominations of nationally and internationally recognized scientists and engineers with demonstrated expertise and experience to augment the RAC for the peer review of MARSSIM, Revision 2. The SAB Staff Office is looking for experts in one or more of the following disciplinary areas: Environmental monitoring and sampling, geology, hydrogeology, measurement protocols and statistics. Expertise should include a focus on radionuclides.

Additional Information

For questions concerning ''MARSSIM, Rev. 2 (2020) please contact Kathryn Snead of the U.S. EPA, Office of Radiation and Indoor Air, by telephone at (202) 343–9228, or email at *snead.kathryn@epa.gov.*

Process and Deadline for Submitting Nominations

Any interested person or organization may nominate qualified individuals with relevant experience for possible service on the SAB MARSSIM Review Panel identified in this notice. Nominations should be submitted in electronic format (preferred) following the instructions for ''Nominating Experts to Advisory Panels and Ad hoc Committees Being Formed,'' provided on the SAB website (see the ''Nomination of Experts'' link under ''Current Activities'') at *http://www.epa.gov.sab.*

To receive full consideration, EPA's SAB Staff Office requests contact information about the person making the nomination; contact information about the nominee; the disciplinary and specific areas of expertise of the nominee; the nominee's resume or curriculum vitae; sources of recent grant and/or contract support; and a biographical sketch of the nominee indicating current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations.

Persons having questions about the nomination procedures, or who are unable to submit nominations through the SAB website, should contact Dr. Diana Wong as indicated above in this notice. Nominations should be submitted in time to arrive no later than June 4, 2020. EPA values and welcomes diversity. All qualified candidates are encouraged to apply regardless of sex, race, disability, or ethnicity.

The EPA SAB Staff Office will acknowledge receipt of nominations. The names and biosketches of qualified nominees identified by respondents to this **Federal Register** notice, and additional experts identified by the SAB Staff, will be posted in a List of Candidates on the SAB website at *http://www.epa.gov/sab.* Public comments on the List of Candidates will be accepted for 21 days. The public will be requested to provide relevant information or other documentation on nominees that the SAB Staff Office should consider in evaluating candidates.

For the EPA SAB Staff Office, a balanced review panel includes candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience. The SAB Staff Office will consider public comments on the List of Candidates, information provided by the candidates themselves, and background information independently gathered by the SAB Staff Office. Selection criteria to be used for panel membership include: (a) Scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a loss of impartiality; and (e) skills working in panels and advisory committees; and, (f) for the panel as a whole, diversity of expertise and scientific points of view.

Candidates invited to serve will be asked to submit the ''Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency'' (EPA Form 3110–48). This confidential form allows EPA to determine whether there is a statutory conflict between that person's public responsibilities as a Special Government Employee and private interests and activities, or the appearance of a loss of impartiality, as defined by Federal regulation.. The form may be viewed and downloaded from the following URL address *http://yosemite.epa.gov/sab/sabproduct.nsf/Web/ethics?OpenDocument.*

Dated: May 11, 2020.

V. Khanna Johnston,

Deputy Director, EPA Science Advisory Board Staff Office.

[FR Doc. 2020–10414 Filed 5–13–20; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0720; FRL–10008–07]

Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Several Pesticides for Several Isothiazolinones; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration review of Methylisothiazolinone/Chloromethylisothiazolinone (MIT/CMIT), Octhilinone (OIT), Benzisothiazolin-3-one, 3(2H)-Isothiazolone (BIT), 1,2-Benzisothiazol-3(2H)-one,2-butyl (BBIT), and 3(2H)-isothiazolone, 4,5-dichloro-2-octyl-(DCOIT).

DATES: Comments must be received on or before July 13, 2020.

ADDRESSES: Submit your comments, to the docket identification (ID) number for the specific pesticide of interest provided in the Table in Unit IV, 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 *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, are available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact:* The Chemical Review Manager for the pesticide of interest identified in the Table in Unit IV.

For general questions on the registration review program, contact: Richard Fehir, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; telephone number: (703) 347–8101; email address: f*ehir.richard@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the Chemical Review Manager identified in the Table in Unit IV.

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 *http://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Background

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed comprehensive draft human health and/or ecological risk assessments for all pesticides listed in the Table in Unit IV. After reviewing comments received during the public comment period, EPA may issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments and may request public input on risk mitigation before completing a proposed registration review decision for the pesticides listed in the Table in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

III. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

IV. What action is the Agency taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's human health and ecological risk assessments for the pesticides shown in the following table and opens a 60-day public comment period on the risk assessments.

TABLE—DRAFT RISK ASSESSMENTS BEING MADE AVAILABLE FOR PUBLIC COMMENT

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
MIT/CMIT Case 3092	EPA–HQ–OPP–2013–0605	Stephen Savage, *savage.stephen@epa.gov,* (703) 347–0345.
OIT Case 2475	EPA–HQ–OPP–2014–0160	Stephen Savage, *savage.stephen@epa.gov,* (703) 347–0345.
BIT Case 3026	EPA–HQ–OPP–2014–0159	Stephen Savage, *savage.stephen@epa.gov,* (703) 347–0345.
BBIT Case 5017	EPA–HQ–OPP–2015–0736	Stephen Savage, *savage.stephen@epa.gov,* (703) 347–0345.

TABLE—DRAFT RISK ASSESSMENTS BEING MADE AVAILABLE FOR PUBLIC COMMENT—Continued

Registration review case name and No.	Docket ID No.	Chemical review manager and contact information
DCOIT Case 5023	EPA–HQ–OPP–2014–0403	Stephen Savage, *savage.stephen@epa.gov,* (703) 347–0345.

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft human health and/or ecological risk assessments for the pesticides listed in the Table in Unit IV. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to a draft human health and/or ecological risk assessment. For specific comments the Agency is soliciting, see Unit V of this notice. EPA may then issue a revised risk assessment as part of the proposed interim decision (PID), explain any changes to the draft risk assessment, and respond to comments.

Information submission requirements. Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

V. Request for Comment

The EPA specifically requests comment concerning the draft risk assessments in the following areas:

- The use of *in vitro* and the artificial neural network-based defined approach (DA) to determine points of departure used in the isothiazolinone draft risk assessments instead of using laboratory animal data to evaluate risks for dermal sensitization.
- The use of a 100-fold uncertainty factor (UF) for the *in vitro* points of departure and use of a 10-fold UF for the human study point of departure selected for the human health dermal assessment.

Additionally, EPA requests information that may help the Agency refine the draft risk assessments. For the human health risk assessment, EPA welcomes the following information:

- For the assessment of inhalation risk, the inhalation toxicity study for DCOIT has been bridged to assess hazard of both BIT and BBIT, which do not have inhalation toxicity data. While the no observed adverse effect level (NOAEC) value from the DCOIT study is conservative, refinement of the NOAEC through benchmark dosing is not possible. Due to the 32-fold difference between the NOAEC and lowest observed adverse effect level (LOAEC) values in the DCOIT study, the inhalation risks may be overestimated using the conservative, unrefined endpoint from DCOIT. Additional chemical-specific inhalation toxicity data using proper dose spacing to conduct benchmark dose analysis would help to refine the inhalation risk assessments for the isothiazolinones.
- Residue transfer data are not available at this time for textiles/clothing, plastics, and carpets and 100% of the application rate was assumed to transfer to children. Data currently being collected by the Antimicrobial Exposure Assessment Task Force (AEATF II) will potentially help to refine the human incidental oral and dermal exposures.

For the environmental risk assessments, EPA requests the following information:

- Degradation studies to show potential degradation in wastewater treatment facilities.
- More robust usage data on paper production, including information on how the compounds are used in paper production.

Authority: 7 U.S.C. 136 *et seq.*

Dated: April 9, 2020.

Anita Pease,

Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 2020–10376 Filed 5–13–20; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0912; FRS 16752]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; 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; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control

number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before July 13, 2020. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: As part of its continuing effort to reduce paperwork burdens, and as required by the PRA of 1995 (44 U.S.C. 3501–3520), the FCC invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; 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; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees.

OMB Control Number: 3060–XXXX.

Title: 3.7 GHz Band Relocation Coordinator and Relocation Payment Clearinghouse Real-Time Disclosure of Communications Required by Sections 27.1413(c)(6) and 27.1414(b)(4)(i).

Form Number: N/A.

Type of Review: New information collection.

Respondents: Business or other for profit entities.

Number of Respondents: 2 respondents; 12 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to Obtain or retain benefits. Statutory authority for this information collection is contained in sections 1, 2, 4(i), 4(j), 5(c), 201, 302, 303, 304, 307(e), and 309 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 155(c), 201, 302, 303, 304, 307(e), 309.

Total Annual Burden: 12 hours.

Total Annual Costs: No cost.

Nature and Extent of Confidentiality: The information collected under this collection will be made publicly available.

Privacy Act Impact Assessment: No impact(s).

Needs and Uses: On February 28, 2020, in furtherance of the goal of releasing more mid-band spectrum into the market to support and enable next-generation wireless networks, the Commission adopted a Report and Order, FCC 20–22, (*3.7 GHz Report and Order*) in which it reformed the use of the 3.7–4.2 GHz band, also known as the C-Band. The 3.7–4.2 GHz band currently is allocated in the United States exclusively for non-Federal use on a primary basis for Fixed Satellite Service (FSS) and Fixed Service. Domestically, space station operators use the 3.7–4.2 GHz band to provide downlink signals of various bandwidths to licensed transmit-receive, registered receive-only, and unregistered receive-only earth stations throughout the United States. The *3.7 GHz Report and Order* calls for the relocation of existing FSS operations in the band into the upper 200 megahertz of the band (4.0–4.2 GHz) and making the lower 280 megahertz (3.7–3.98 GHz) available for flexible-use throughout the contiguous United States through a Commission-administered public auction of overlay licenses in the 3.7 GHz Service that is scheduled to occur later this year, with the 20 megahertz from 3.98–4.0 GHz reserved as a guard band. The Commission adopted a robust transition schedule to achieve an expeditious relocation of FSS operations and ensure that a significant amount of spectrum is made available quickly for next-generation wireless deployments, while also ensuring effective accommodation of relocated incumbent users. The *3.7 GHz Report and Order* establishes a deadline of December 5, 2025, for full relocation to ensure that all FSS operations are cleared in a timely manner, but provides an opportunity for accelerated clearing of the band by allowing incumbent space station operators, as defined in the *3.7 GHz Report and Order,* to commit to voluntarily relocate on a two-phased accelerated schedule (with additional obligations and incentives for such operators), with a Phase I deadline of December 5, 2021, and a Phase II deadline of December 5, 2023.

The Commission concluded in the *3.7 GHz Report and Order* that a neutral, independent third-party Relocation Payment Clearinghouse (RPC) should be established to administer the cost-related aspects of the transition in a fair, transparent manner, mitigate financial disputes among stakeholders, and collect and distribute payments in a timely manner to transition incumbent space station operators out of the 3.7–3.98 GHz band. The Commission also concluded that a Relocation Coordinator (RC) should be appointed to ensure that all incumbent space station operators are relocating in a timely manner, and to be responsible for receiving notice from earth station operators or other satellite customers of any disputes related to comparability of facilities, workmanship, or preservation of service during the transition and notify the Commission of disputes and recommendations for resolution.

To protect the fair and level playing field for applicants to participate in the Commission's auction for overlay licenses in the 3.7 GHz Service, the RPC and the RC are each required to make real-time, public disclosures of the content and timing of and the parties to communications, if any, from or to such applicants, as applicants are defined by the Commission's rule prohibiting certain auction-related communications, 47 CFR 1.2105(c)(5)(i), whenever the prohibition in 47 CFR 1.2105(c) applies to competitive bidding for licenses in the 3.7 GHz Service. *See* 47 CFR 27.1413(c)(6), 27.1414(b)(4)(i) (as adopted in the *3.7 GHz Report and Order*). The Commission is seeking approval for a new information collection to permit the RPC and the RC to make the required real-time, public disclosure of any such communications, as necessary.

Federal Communications Commission.

Marlene Dortch,

Secretary.

[FR Doc. 2020–10343 Filed 5–13–20; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities: Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Federal Trade Commission.

ACTION: 30-day notice of submission of information collection approval from the Office of Management and Budget (''OMB'') and request for comments.

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the

public on service delivery, the Federal Trade Commission (''FTC'' or ''Commission'') is submitting a Generic Information Collection Request (Generic ICR): ''Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery'' to OMB for approval under the Paperwork Reduction Act.

DATES: Comments must be submitted by June 15, 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: Bridget Small, Federal Trade Commission, 600 Pennsylvania Avenue NW, CC–10402, Washington, DC 20580, (202) 326–3266.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions, but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of Activities: 35.

Estimated Number of Annual Respondents: 5,764.[1]

Frequency of Response: Once per request.

Annual Responses: 5,764.

Average Minutes Per Response: 18 (rounded to nearest whole minute).

Estimated Total Annual Burden Hours: 1,759.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The control number for the existing clearance (expiring May 31, 2020) is 3084–0159. The FTC seeks renewed three-year clearance under this control number for the prospective collection of information and the associated burden estimates.

Request for Comment:

On December 26, 2019, the Commission sought comment on the renewal of this generic clearance. 84 FR 70972. One relevant comment was received from an interested person. The commenter stated that he believed the collection and analysis of these qualitative statistics will be useful in improving the delivery of the many services of the FTC.

[1] Projected activities: (1) Eleven customer satisfaction surveys per year of 500 respondents each (surveys to get feedback about major campaigns, publications, websites, branding and other consumer and business education products to test their appeal and effectiveness), 0.25 hours (*i.e.* 15 minutes) per response; (2) Twelve focus groups per year, 10 respondents each (to test education products and websites), 2 hours per response; and (3) Twelve usability sessions per year, 12 respondents per website (to test the usability of FTC websites by inviting people to complete common tasks on those sites), 1 hour per response.

Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing this second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for those information collection requirements. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a valid OMB control number.

Your comment—including your name and your state—will be placed on the public record of this proceeding. Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any ''[t]rade secret or any commercial or financial information which is . . . privileged or confidential'' as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

Josephine Liu,

Assistant General Counsel for Legal Counsel.

[FR Doc. 2020–10307 Filed 5–13–20; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers CMS–10275, CMS–R–64, and CMS–10710]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect

information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *June 15, 2020.*

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.*

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

2. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* CAHPS Home Health Care Survey; *Use:* The national implementation of the Home Health Care CAHPS Survey is designed to collect ongoing data from samples of home health care patients who receive skilled services from Medicare-certified home health agencies.

The survey is necessary because it fulfills the goal of transparency with the public about home health patient experiences. The survey is used by Medicare-certified home health agencies to improve their internal quality assurance in the care that they provide in home health. The HHCAHPS survey is also used in a Medicare payment program. Medicare-certified home health agencies (HHAs) must contract with CMS-approved survey vendors that conduct the HHCAHPS on behalf of the HHAs to meet their requirements in the Home Health Quality Reporting Program. *Form Number:* CMS–10257 (OMB control number: 0938–1066); *Frequency:* Yearly; *Affected Public:* Individuals and Households; *Number of Respondents:* 1,195,930; *Total Annual Responses:* 1,294,820; *Total Annual Hours:* 453,239. (For policy questions regarding this collection contact Lori Teichman at 410–786–6684.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Indirect Medical Education and Direct Graduate Medical Education; *Use:* Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, Title 42, Part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment for the costs of direct graduate medical educational activities. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2018, the estimated Medicare program payments for indirect medical education (IME) costs was $6.4 billion. Medicare program payment for direct graduate medical education (GME) is also based upon the number of FTE–IRs that work at a hospital. In FY 2018, the estimated Medicare program payments for GME costs was $3.1 billion.

Since it is important to accurately count the number of IRs FTEs working at each hospital, original approval was obtained from the Office of Management and Budget (OMB) in 1985 to collect the IR information required in 42 CFR 412.105(f) and timeframes for filing. All Medicare health plans are required to use these standardized notices. *Form Number:* CMS–R–64 (OMB control number: 0938–0456); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 1,245; *Total Annual Responses:* 1,245; *Total Annual Hours:* 2,490. (For policy questions regarding this collection contact Owen Osaghae at 410–786–7550.)

3. *Type of Information Collection Request:* New collection (Request for a new OMB control number) collection; *Title of Information Collection:* Generic Clearance for Improving Customer Experience (OMB Circular A–11, Section 280 Implementation); *Use:* Whether seeking a loan, Social Security benefits, veterans benefits, or other services provided by the Federal Government, individuals and businesses expect Government customer services to be efficient and intuitive, just like services from leading private-sector organizations. Yet the 2016 American Consumer Satisfaction Index and the 2017 Forrester Federal Customer Experience Index show that, on average, Government services lag nine percentage points behind the private sector.

A modern, streamlined and responsive customer experience means: Raising government-wide customer experience to the average of the private sector service industry; developing indicators for high-impact Federal programs to monitor progress towards excellent customer experience and mature digital services; and providing

the structure (including increasing transparency) and resources to ensure customer experience is a focal point for agency leadership. To support this, OMB Circular A–11 Section 280 established government-wide standards for mature customer experience organizations in government and measurement. To enable Federal programs to deliver the experience taxpayers deserve, they must undertake three general categories of activities: Conduct ongoing customer research, gather and share customer feedback, and test services and digital products.

These data collection efforts may be either qualitative or quantitative in nature or may consist of mixed methods. Additionally, data may be collected via a variety of means, including but not limited to electronic or social media, direct or indirect observation (*i.e.,* in person, video and audio collections), interviews, questionnaires, surveys, and focus groups. The Centers for Medicare and Medicaid Services (CMS) will limit its inquiries to data collections that solicit strictly voluntary opinions or responses. Steps will be taken to ensure anonymity of respondents in each activity covered by this request.

The results of the data collected will be used to improve the delivery of Federal services and programs. It will include the creation of personas, customer journey maps, and reports and summaries of customer feedback data and user insights. It will also provide government-wide data on customer experience that can be displayed on *performance.gov* to help build transparency and accountability of Federal programs to the customers they serve.

CMS will collect this information by electronic means when possible, as well as by mail, fax, telephone, technical discussions, and in-person interviews. CMS may also utilize observational techniques to collect this information.

Form Number: CMS–10710 (OMB control number: 0938-New); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; Private Sector (business or other for-profits, not-for-profit institutions), State, Local or Tribal governments; Federal government; and Universities; *Number of Respondents:* 1,001,750; *Number of Responses:* Varied, dependent upon the data collection method used. The possible response time to complete a questionnaire or survey may be 3 minutes or up to 2 hours to participate in an interview.; *Total Annual Hours:* 51,175. (For questions regarding this collection contact Aaron Lartey at 410–786–7866).

Dated: May 8, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–10282 Filed 5–13–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1117]

Janssen Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 16 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 16 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of June 15, 2020.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 011529	Parafon Forte DSC (chlorzoxazone), Caplets, 500 milligrams (mg).	Janssen Pharmaceuticals, Inc., 1000 Route 202 South, P.O. Box 300, Raritan, NJ 08869.
NDA 018029	Ritalin-SR (methylphenidate hydrochloride (HCl)) Extended-Release Tablets, 20 mg.	Novartis Pharmaceuticals Corp., 1 Health Plaza, East Hanover, NJ 07936.
NDA 018082	Depakene (valproic acid) Oral Solution, 250 mg/5 milliliter (mL).	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 019579	Terazol 7 (terconazole) Vaginal Cream, 0.4%	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 020119	Vumon (teniposide) Injection, 10 mg/mL	HQ Specialty Pharma, 120 Route 17 North, Paramus, NJ 07652.
NDA 020388	Navelbine (vinorelbine tartrate) Injection, Equivalent to (EQ) 10 mg/mL base.	Pierre Fabre Medicament c/o Pierre Fabre Pharmaceuticals, Inc., 8 Campus Dr., Suite 202, Parsippany, NJ 07054.
NDA 020741	Prandin (repaglinide) Tablets, 0.5 mg, 1.0 mg, and 2.0 mg	Gemini Laboratories, LLC, 400 Crossing Blvd., 5th Floor, Bridgewater, NJ 08807.
NDA 020920	Natrecor (nesiritide) Injection, 1.5 mg/vial	Scios, LLC, 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 021001	Axert (almotriptan malate) Tablets, EQ 6.25 mg base and EQ 12.5 mg base.	Janssen Pharmaceuticals, Inc.
NDA 021203	Tricor (fenofibrate) Tablets, 54 mg and 160 mg	AbbVie Inc.
NDA 021543	Striant (testosterone buccal system) Extended-Release Tablets, 30 mg.	Auxilium Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355.
NDA 021604	Children's ElixSure IB (ibuprofen) Oral Suspension, 100mg/5 mL.	Moberg Pharma North America LLC, 7 East Frederick Place, Suite 100, Cedar Knolls, NJ 07927.

Application No.	Drug	Applicant
NDA 021611	Opana (oxymorphone HCl) Tablets, 5mg and 10mg	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355.
NDA 022321	Embeda (morphine sulfate and naltrexone HCl) Extended-Release Capsules, 20 mg/0.8 mg, 30 mg/1.2 mg, 50 mg/2 mg, 60 mg/2.4 mg, 80 mg/3.2 mg, and 100 mg/4 mg.	Alpharma Pharmaceuticals, LLC, 235 East 42nd St., New York, NY 10017.
NDA 022510	Abstral (fentanyl) Sublingual Tablets,100 micrograms (mcg), 200 mcg, 300 mcg, 400 mcg, 600 mcg, and 800 mcg.	Sentynl Therapeutics, Inc., 420 Stevens Ave., Suite 200, Solana Beach, CA 92075.
NDA 050641	Monodox (doxycycline monohydrate) Capsules, EQ 50mg base, EQ 75mg base, and EQ 100mg base.	Aqua Pharmaceuticals, LLC, 707 Eagleview Blvd., Suite 200, Exton, PA 19341.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of June 15, 2020. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on June 15, 2020 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: May 11, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10367 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0501]

Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's third-party disclosure and recordkeeping requirements for reportable food.

DATES: Submit either electronic or written comments on the collection of information by July 13, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 13, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 13, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2009–N–0501 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Disclosure and Recordkeeping Requirements for Reportable Food.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you

must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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, when appropriate, and other forms of information technology.

Third Party Disclosure and Recordkeeping Requirements for Reportable Food—21 U.S.C. 350f

OMB Control Number 0910–0643—Extension

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85), requires the establishment of a Reportable Food Registry (the Registry) by which instances of reportable food must be submitted to FDA by responsible parties and may be submitted by public health officials. Section 417 of the FD&C Act (21 U.S.C. 350f) defines ''reportable food'' as an article of food (other than infant formula) for which there is a reasonable probability that the use of, or exposure to, such article of food will cause serious adverse health consequences or death to humans or animals. (See section 417(a)(2) of the FD&C Act.) We believe that the most efficient and cost-effective means to implement the Registry is by utilizing our electronic Safety Reporting Portal. The information collection provisions associated with the submission of reportable food reports has been approved under OMB control number 0910–0643.

In conjunction with the reportable foods requirements, section 417 of the FD&C Act also establishes third-party disclosure and recordkeeping burdens. Specifically, we may require the responsible party to notify the immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(6)(B)(i) to (ii) of the FD&C Act). Similarly, we may also require the responsible party that is notified (*i.e.,* the immediate previous source and/or immediate subsequent recipient) to notify their own immediate previous source(s) and/or immediate subsequent recipient(s) of a reportable food (sections 417(d)(7)(C)(i) to (ii) of the FD&C Act).

Notification to the immediate previous source(s) and immediate subsequent recipient(s) of the article of food may be accomplished by electronic communication methods such as email, fax, or text messaging or by telegrams, mailgrams, or first-class letters. Notification may also be accomplished by telephone call or other personal contacts, but we recommend that such notifications also be confirmed by one of the previous methods and/or documented in an appropriate manner. We may require that the notification include any or all of the following data elements: (1) The date on which the article of food was determined to be a reportable food; (2) a description of the article of food including the quantity or amount; (3) the extent and nature of the adulteration; (4) the results of any investigation of the cause of the adulteration if it may have originated with the responsible party, if known; (5) the disposition of the article of food, when known; (6) product information typically found on packaging including product codes, use-by dates, and the names of manufacturers, packers, or distributors sufficient to identify the article of food; (7) contact information for the responsible party; (8) contact information for parties directly linked in the supply chain and notified under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act, as applicable; (9) the information required by FDA to be included in the notification provided by the responsible party involved under section 417(d)(6)(B) or 417(d)(7)(C) of the FD&C Act or required to report under section 417(d)(7)(A) of the FD&C Act; and (10) the unique number described in section 417(d)(4) of the FD&C Act (section 417(d)(6)(B)(iii)(I), (d)(7)(C)(iii)(I), and (e) of the FD&C Act). We may also require that the notification provides information about the actions that the recipient of the notification will perform and/or any other information we may require (section 417(d)(6)(B)(iii)(II) and (III) and (d)(7)(C)(iii)(II) and (III) of the FD&C Act).

Section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods for a period of 2 years.

The congressionally-identified purpose of the Registry is to provide a reliable mechanism to track patterns of adulteration in food which would support efforts by FDA to target limited inspection resources to protect the public health (see FDAAA, section 1005(a)(4)). The reporting and recordkeeping requirements described previously are designed to enable FDA to quickly identify and track an article of food (other than infant formula) for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals. We use the information collected under these regulations to help ensure that such products are quickly and efficiently removed from the market.

As required under section 1005(f) of FDAAA and to assist industry, we have issued the guidance entitled, ''Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007,'' which is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-reportable-food-registry-established-food-and-drug.* The guidance contains questions and answers relating to the requirements under section 417 of the FD&C Act, including: (1) how, when and where to submit reports to FDA; (2) who is required to submit reports to FDA; (3) what is required to be submitted to FDA; and (4) what may be required when providing notifications to other persons in the supply chain of an article of food. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in questions 20 and 21 of the guidance have been approved under OMB control number 0910–0249.

Description of Respondents: Mandatory respondents to this collection of information are the owners, operators, or agents in charge of a domestic or foreign facility engaged in manufacturing, processing, packing, or holding food for consumption in the United States (''responsible parties'') who have information on a reportable food. Voluntary respondents to this collection of information are Federal, State, and local public health officials who have information on a reportable food.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Notifying immediate previous source of the article of food under section 417(d)(6)(B)(i) of the FD&C Act (mandatory reporters only)..	1,200	1	1,200	0.6 (36 minutes) ..	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(6)(B)(ii) of the FD&C Act (mandatory reporters only)..	1,200	1	1,200	0.6 (36 minutes) ..	720
Notifying immediate previous source of the article of food under section 417(d)(7)(C)(i) of the FD&C Act (mandatory reporters only)..	1,200	1	1,200	0.6 (36 minutes) ..	720
Notifying immediate subsequent recipient of the article of food under section 417(d)(7)(C)(ii) of the FD&C Act (mandatory reporters only)..	1,200	1	1,200	0.6 (36 minutes) ..	720
Total					2,880

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Third Party Disclosure: We estimate that approximately 1,200 reportable food events with mandatory reporters occur annually. Based on past FDA experiences, we estimate that we could receive 200 to 1,200 ''reportable'' food reports annually from 200 to 1,200 mandatory and voluntary users of the electronic reporting system. We utilized the upper-bound estimate of 1,200 for these calculations.

We estimate that notifying the immediate previous source(s) takes 0.6 hours per reportable food and notifying the immediate subsequent recipient(s) takes 0.6 hours per reportable food. We also estimate that it takes 0.6 hours for the immediate previous source and/or the immediate subsequent recipient to also notify their immediate previous source(s) and/or immediate subsequent recipient(s). The Agency bases its estimate on its experience with mandatory and voluntary reports submitted to FDA.

Although it is not mandatory under section 1005 of FDAAA that responsible persons notify the sources and recipients of instances of reportable food, for purposes of the burden estimate we are assuming FDA would exercise its authority and require such notifications in all such instances for mandatory reporters. This notification burden does not affect voluntary reporters of reportable food events. Therefore, we estimate that the total burden of notifying the immediate previous source(s) and immediate subsequent recipient(s) under section 417(d)(6)(B)(i) and (ii), (d)(7)(C)(i) and (ii) of the FD&C Act for 1,200 reportable foods is 2,880 hours annually (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours) + (1,200 × 0.6 hours). This annual burden is shown in table 1.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Maintenance of reportable food records under section 417(g) of the FD&C Act—mandatory reports..	1,200	1	1,200	0.25 (15 minutes)	300
Maintenance of reportable food records under section 417(g) of the FD&C Act—voluntary reports..	4	1	4	0.25 (15 minutes)	1
Total					301

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping: As noted previously, section 417(g) of the FD&C Act requires that responsible persons maintain records related to reportable foods reports and notifications for a period of 2 years. Based on past FDA experiences, we estimate that each mandatory report and its associated notifications requires 30 minutes of recordkeeping for the 2-year period, or 15 minutes per record per year. The annual recordkeeping burden for mandatory reportable food reports and their associated notifications is thus estimated to be 300 hours (1,200 × 0.25 hours).

We do not expect that records will always be kept in relation to voluntary reportable food reports. Therefore, we estimate that records will be kept for 4 voluntary reports we expect to receive annually. The recordkeeping burden associated with voluntary reports is thus estimated to be 1 hour annually (4 × 0.25 hours). The estimated total annual recordkeeping burden is 301 hours annually (1,200 × 0.25 hours) + (4 × 0.25 hours). This annual burden is shown in table 2.

Dated: April 28, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10351 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0084]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Program for Medical Devices (Medical Product Safety Network)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted 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. The OMB control number for this information collection is 0910–0471. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Adverse Event Program for Medical Devices (Medical Product Safety Network (MedSun))—OMB Control Number 0910–0471—Extension

Section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) authorizes FDA to require (1) manufacturers to report medical device-related deaths, serious injuries, and malfunctions; and (2) user facilities to report device-related deaths directly to manufacturers and FDA and serious injuries to the manufacturer. Section 213 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 519(b) of the FD&C Act relating to mandatory reporting by user facilities of deaths, serious injuries, and serious illnesses associated with the use of medical devices. This amendment legislated the replacement of universal user facility reporting by a system that is limited to a ''. . .subset of user facilities that constitutes a representative profile of user reports'' for device-related deaths and serious injuries. This amendment is reflected in section 519(b)(5)(A) of the FD&C Act. This legislation provides FDA with the opportunity to design and implement a national surveillance network, composed of well-trained clinical facilities, to provide high-quality data on medical devices in clinical use. This system is called the Medical Product Safety Network (MedSun).

FDA is seeking OMB clearance to continue to use electronic data collection to obtain the information on Form FDA 3500A (approved under OMB control number 0910–0291) related to medical devices and tissue products from the user facilities participating in MedSun, to obtain a demographic profile of the facilities, and for additional questions, which will permit FDA to better understand the cause of reported adverse events. Participation in the program is voluntary and includes approximately 300 facilities.

In addition to collecting data on the electronic adverse event report form, MedSun collects additional information from participating sites about reported problems emerging from the MedSun hospitals. This data collection is also voluntary and is collected on the same website as the report information.

The burden estimate is based on the number of facilities participating in MedSun (300). FDA estimates an average of 18 reports per site annually. This estimate is based on MedSun working to promote reporting in general from the sites, as well as promoting reporting from specific parts of the hospitals, such as the pediatric intensive care units, the electrophysiology laboratories, and the hospital laboratories.

In the **Federal Register** of September 20, 2019 (84 FR 49526), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received offering general support for the collection but offered no suggested changes to the burden estimate.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Adverse event reporting	300	18	5,400	0.50 (30 minutes)	2,700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information

Our estimated burden for the information collection reflects an overall decrease of 113 hours despite a corresponding increase of 1,650 responses. We attribute this adjustment to an increase in the number of submissions we received over the last few years but a decrease in the amount of time spent entering data due to IT efficiencies that have been built into the MedSun reporting system to reduce data entry by user facilities.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10353 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0275]

Agency Information Collection Activities; Proposed Collection; Comment Request; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirements for certain FDA applications or submissions to be accompanied by a certification, Form FDA 3674, to ensure all applicable statutory requirements have been met.

DATES: Submit either electronic or written comments on the collection of information by July 13, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before July 13, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 13, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2011–N–0275 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Certification to Accompany Drug, Biological Product, and Device Applications or Submissions.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (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, when appropriate, and other forms of information technology.

Certification To Accompany Drug, Biological Product, and Device Applications or Submissions (Form FDA 3674)

OMB Control Number 0910–0616—Extension

The information required under section 402(j)(5)(B) of the Public Health Service Act (PHS Act) (42 U.S.C. 282(j)(5)(B)) is submitted in the form of a certification, Form FDA 3674, which accompanies applications and submissions currently submitted to FDA and already approved by OMB. The OMB control numbers and expiration dates for those applications and submissions are: 21 CFR parts 312 and 314 (human drugs), OMB control number 0910–0014, expiring March 31, 2022, and OMB control number 0910–0001, expiring March 31, 2021; 21 CFR parts 312 and 601 (biological products), OMB control number 0910–0014, expiring March 31, 2022, and OMB control number 0910–0338, expiring February 28, 2023; 21 CFR parts 807 and 814 (devices), OMB control number 0910–0120, expiring June 30, 2020, and OMB control number 0910–0231, expiring March 31, 2023.

Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) amended the PHS Act by adding section 402(j). The provisions broadened the scope of clinical trials subject to submitting information and required additional information to be submitted to the clinical trials databank (*https://clinicaltrials.gov/*) (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website after this document publishes in the **Federal Register**) previously established by the National Institutes of Health (NIH)/National Library of Medicine. This includes expanded information on applicable clinical trials and summary information on the results of certain clinical trials. The provisions include responsibilities for FDA as well as several amendments to the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

One provision, section 402(j)(5)(B) of the PHS Act, requires that a certification accompany human drug, biological, and device product submissions made to FDA. Specifically, at the time of submission of an application under sections 505, 515, or 520(m) of the FD&C Act (21 U.S.C. 355, 360e, or 360j(m)), or under section 351 of the PHS Act (42 U.S.C. 262), or submission of a report under section 510(k) of the FD&C Act (21 U.S.C. 360(k)), such application or submission must be accompanied by a certification, Form FDA 3674, that all applicable requirements of section 402(j) of the PHS Act have been met. Where available, such certification must include the appropriate National Clinical Trial (NCT) numbers that are assigned upon submission of required information to the NIH databank at *https://clinicaltrials.gov/*.

The proposed extension of the collection of information is necessary to satisfy the previously mentioned statutory requirement. The importance of obtaining these data relates to adherence to the legal requirements for submissions to the clinical trials registry and results data bank and ensuring that individuals and organizations submitting applications or reports to FDA under the listed provisions of the FD&C Act or the PHS Act adhere to the appropriate legal and regulatory requirements for certifying to having complied with those requirements. The failure to submit the certification required by section 402(j)(5)(B) of the PHS Act, and the knowing submission of a false certification, are both prohibited acts under section 301 of the FD&C Act (21 U.S.C. 331). Violations are subject to civil money penalties. Form FDA 3674 provides a convenient mechanism for sponsors/applicants/submitters to satisfy the certification requirements of the statutory provision.

To assist sponsors/applicants/submitters in understanding the statutory requirements associated with Form FDA 3674, we have provided a guidance available at: *https://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm.* This guidance recommends the applications and submissions FDA considers should be accompanied by the certification form, Form FDA 3674. The applications and submissions identified in the guidance are reflected in the burden analysis. FDA last updated this guidance in 2017.

Investigational New Drug Applications. FDA's Center for Drug Evaluation and Research (CDER) received 1,661 investigational new drug applications (INDs) and 11,328 clinical protocol IND amendments in calendar year (CY) 2019. CDER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future.

FDA's Center for Biologics Evaluation and Research (CBER) received 639 new INDs and 581 clinical protocol IND amendments in CY 2019. CBER anticipates that IND and clinical protocol amendment submission rates will remain at or near this level in the near future. The estimated total number of submissions (new INDs and new protocol submissions) subject to mandatory certification requirements under section 402(j)(5)(B) of the PHS Act, is 12,989 for CDER plus 1,220 for CBER, or 14,209 submissions per year. The minutes per response is the estimated number of minutes that a respondent would spend preparing the information to be submitted to FDA under section 402(j)(5)(B) of the PHS Act, including the time it takes to enter the necessary information on the form.

Based on its experience with current submissions, FDA estimates that approximately 15 minutes on average would be needed per response for certifications that accompany IND applications and clinical protocol amendment submissions. It is assumed that most submissions to investigational applications will reference only a few protocols for which the sponsor/applicant/submitter has obtained a NCT number from *https://clinicaltrials.gov/* prior to making the submission to FDA. It is also assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

Marketing Applications/Submissions. In CY 2019, CDER and CBER received 252 new drug applications (NDA)/biologics license applications (BLA)/premarket approvals (PMA)/

resubmissions and 701 NDA/BLA amendments for which certifications are needed. CDER and CBER received 295 efficacy supplements/resubmissions to previously approved NDAs/BLAs in CY 2019. CDER and CBER received 893 abbreviated new drug applications (ANDAs) in CY 2019. CDER received 765 bioequivalence amendments/supplements in CY 2019. CDER and CBER anticipate that new drug/biologic applications/resubmissions and efficacy supplement submission rates will remain at or near this level in the near future.

FDA's Center for Devices and Radiological Health (CDRH) received a total of 324 new applications for PMA, 510(k) submissions containing clinical information, PMA supplements, applications for humanitarian device exemptions (HDE) and amendments in CY 2019. CDRH anticipates that application, amendment, supplement, and annual report submission rates will remain at or near this level in the near future.

Based on its experience reviewing NDAs, BLAs, PMAs, HDEs, 510(k)s, and ANDAs and experience with current submissions of Form FDA 3674, FDA estimates that approximately 45 minutes on average would be needed per response for certifications which accompany NDA, BLA, PMA, HDE, 510(k), and ANDA marketing applications and submissions. It is assumed that the sponsor/applicant/submitter has electronic capabilities allowing them to retrieve the information necessary to complete the form in an efficient manner.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA; center activity	Number of respondents (investigational applications)	Number of respondents (marketing applications)	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER						
New Applications (IND)	1,661		1	1,661	0.25 (15 minutes)	415
Clinical Protocol Amendments (IND).	11,328		1	11,328	0.25 (15 minutes)	2,832
New Marketing Applications/Resubmissions (NDA/BLA).		220	1	220	0.75 (45 minutes)	165
Clinical Amendments to Marketing Applications.		701	1	701	0.75 (45 minutes)	526
Efficacy Supplements/Resubmissions.		257	1	257	0.75 (45 minutes)	193
Abbreviated New Drug Applications (ANDA)—Original Applications.		892	1	892	0.75 (45 minutes)	669
ANDA Bioequivalence Supplements/Amendments.		765	1	765	0.75 (45 minutes)	573
CBER						
New Applications (IND)	639		1	639	0.25 (15 minutes)	160
Clinical Protocol Amendments (IND).	581		1	581	0.25 (15 minutes)	145
New Marketing Applications/Resubmissions (NDA/BLA/PMA).		32	1	32	0.75 (45 minutes)	24
Clinical Amendments to Marketing Applications.		0	1	0	0.75 (45 minutes)	0
Efficacy Supplements/Resubmissions (BLA only).		38	1	38	0.75 (45 minutes)	28
Abbreviated New Drug Applications (ANDA)—Original Applications.		1	1	1	0.75 (45 minutes)	1
ANDA Bioequivalence Supplements/Amendments.		0	1	0	0.75 (45 minutes)	0
CDRH						
New Marketing Applications (includes PMAs, HDEs, Supplements and 510(k)s expected to contain clinical data).		324	1	324	0.75 (45 minutes)	243
Total						5,974

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10359 Filed 5–13–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted 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. The OMB control number for this information collection is 0910–0025. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Products

OMB Control Number 0910–0025—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in Title 21 of the Code of Federal Regulations, chapter I, subchapter J, parts 1000 through 1050 (21 CFR parts 1000 through 1050).

Section 532 of the FD&C Act directs the Secretary of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the FD&C Act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) of the FD&C Act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the FD&C Act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliance with performance standards. Section 537(b) of the FD&C Act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

The regulations under parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall. FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050.

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the FD&C Act or were developed to aid the Agency in performing its obligations under the FD&C Act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

- Form FDA 2579 ''Report of Assembly of a Diagnostic X-Ray System''
- Form FDA 2767 ''Notice of Availability of Sample Electronic Product''
- Form FDA 2877 ''Declaration for Imported Electronic Products Subject to Radiation Control Standards''
- Form FDA 3649 ''Accidental Radiation Occurrence (ARO)''
- Form FDA 3626 ''A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components''
- Form FDA 3627 ''Diagnostic X-Ray CT [Computed Tomography] Products Radiation Safety Report''
- Form FDA 3628 ''General Annual Report (Includes Medical, Analytical, and Industrial X-Ray Products Annual Report)''
- Form FDA 3629 ''Abbreviated Report''
- Form FDA 3630 ''Guide for Preparing Product Reports on Sunlamps and Sunlamp Products''
- Form FDA 3631 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamp Products''
- Form FDA 3632 ''Guide for Preparing Product Reports on Lasers and Products Containing Lasers''
- Form FDA 3633 ''General Variance Request''
- Form FDA 3634 ''Television Products Annual Report''
- Form FDA 3635 ''Laser Light Show Notification''
- Form FDA 3636 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products''
- Form FDA 3637 ''Laser Original Equipment Manufacturer (OEM) Report''
- Form FDA 3638 ''Guide for Filing Annual Reports for X-Ray Components and Systems''
- Form FDA 3639 ''Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40''
- Form FDA 3640 ''Reporting Guide for Laser Light Shows and Displays''
- Form FDA 3147 ''Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device''
- Form FDA 3641 ''Cabinet X-Ray Annual Report''

- Form FDA 3642 ''General Correspondence''
- Form FDA 3643 ''Microwave Oven Products Annual Report''
- Form FDA 3644 ''Guide for Preparing Product Reports for Ultrasonic Therapy Products''
- Form FDA 3645 ''Guide for Preparing Annual Reports for Ultrasonic Therapy Products''
- Form FDA 3646 ''Mercury Vapor Lamp Products Radiation Safety Report''
- Form FDA 3647 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps''
- Form FDA 3659 ''Reporting and Compliance Guide for Television Products''
- Form FDA 3660 ''Guidance for Preparing Reports on Radiation Safety of Microwave Ovens''
- Form FDA 3661 ''A Guide for the Submission of an Abbreviated Report on X-Ray Tables, Cradles, Film Changers, or Cassette Holders Intended for Diagnostic Use''
- Form FDA 3662 ''A Guide for the Submission of an Abbreviated Radiation Safety Report on Cephalometric Devices Intended for Diagnostic Use''
- Form FDA 3663 ''Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)''
- Form FDA 3801 ''Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps''

The respondents to this information collection are electronic product and x-ray manufacturers, importers, and assemblers. The burden estimates were derived by consultation with FDA and industry personnel, and are based on data collected from industry, including product report submissions. An evaluation of the type and scope of information requested was also used to derive some time estimates.

In the **Federal Register** of January 23, 2020 (85 FR 3925), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Product reports—1002.10(a) through (k).	3626—Diagnostic x-ray .. 3627—CT x-ray. 3639—Cabinet x-ray. 3632—Laser. 3640—Laser light show. 3630—Sunlamp. 3646—Mercury vapor lamp. 3644—Ultrasonic therapy. 3659—TV. 3660—Microwave oven. 3801—UV lamps.	1,400	2.2	3,080	24	73,920
Product safety or testing changes—1002.11(a) and (b).		480	2.5	1,200	0.5 (30 minutes)	600
Abbreviated reports—1002.12.	3629—General abbreviated report. 3661—X-ray tables, etc.. 3662—Cephalometric device. 3663—Microwave products (non-oven).	60	1.8	108	5	540
Annual reports—1002.13(a) and (b).	3628—General 3634—TV. 3638—Diagnostic x-ray. 3641—Cabinet x-ray. 3643—Microwave oven. 3636—Laser. 3631—Sunlamp. 3647—Mercury vapor lamp. 3645—Ultrasonic therapy.	1,660	1.3	2,158	18	38,844
Quarterly updates for new models—1002.13(c).		120	1.4	168	0.5 (30 minutes)	84
Accidental radiation occurrence reports—1002.20.	3649—ARO	30	6.7	201	2	402
Exemption requests—1002.50(a) and 1002.51.	3642—General correspondence.	4	1.3	5	1	5
Product and sample information—1005.10.	2767—Sample product ..	5	1	5	0.1 (6 minutes)	1

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity; 21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Identification information and compliance status—1005.25.	2877—Imports declaration.	12,620	2.5	31,550	0.2 (12 minutes)	6,310
Alternate means of certification—1010.2(d).		1	2	2	5	10
Variance—1010.4(b)	3633—General variance request. 3147—Laser show variance request. 3635—Laser show notification.	350	1.1	385	1.2	462
Exemption from performance standards—1010.5(c) and (d).		1	1	1	22	22
Alternate test procedures—1010.13.		1	1	1	10	10
Report of assembly of diagnostic x-ray components—1020.30(d), and (d)(1) and (2).	2579—Assembler report	1,230	34	41,820	0.3 (18 minutes)	12,546
Microwave oven exemption from warning labels—1030.10(c)(6)(iv).		1	1	1	1	1
Laser products registration—1040.10(a)(3)(i).	3637—OEM report	70	2.9	203	3	609
Total						134,366

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity; 21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [2]
Manufacturers records—1002.30 and 1002.31(a)	1,650	1,650	2,722,500	0.12 (7 minutes)	326,700
Dealer/distributor records—1002.40 and 1002.41	3,110	50	155,500	0.05 (3 minutes)	7,775
Information on diagnostic x-ray systems—1020.30(g)	50	1	50	0.5 (30 minutes)	25
Laser products distribution ;records—1040.10(a)(3)(ii)	70	1	70	1	70
Total					334,570

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Technical and safety information for users—1002.3	1	1	1	12	12
Dealer/distributor records—1002.40 and 1002.41	30	3	90	1	90
Television receiver critical component warning—1020.10(c)(4)	1	1	1	1	1
Cold cathode tubes—1020.20(c)(4)	1	1	1	1	1
Information on diagnostic x-ray systems—1020.30(g)	6	1	6	55	330
Statement of maximum line current of x-ray systems—1020.30(g)(2)	6	1	6	10	60
Diagnostic x-ray system safety and technical information—1020.30(h)(1) through (4)	6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5) and (6) and 1020.32(a)(1), (g), and (j)(4)	5	1	5	25	125
CT equipment—1020.33(c), (d), (g)(4), and (j)	5	1	5	150	750
Cabinet x-ray systems information—1020.40(c)(9)(i) and (ii)	6	1	6	40	240
Microwave oven radiation safety instructions—1030.10(c)(4)	1	1	1	20	20

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Microwave oven safety information and instructions—1030.10(c)(5)(i) through (iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i) through (vi)	3	1	3	20	60
Laser product service information—1040.10(h)(2)(i) and (ii)	3	1	3	20	60
Medical laser product instructions—1040.11(a)(2)	2	1	2	10	20
Sunlamp products instructions—1040.20	1	1	1	10	10
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	1	1	1	1	1
Mercury vapor lamp permanently affixed labels—1040.30(c)(2)	1	1	1	1	1
Ultrasonic therapy products—1050.10(d)(1) through (d), (f)(1), and (f)(2)(iii)	1	1	1	56	56
Total					3,058

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

Based on a review of the information collection, we have made no adjustments to our burden estimate.

Dated: May 6, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10373 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3065]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by June 15, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted 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. The OMB control number for this information collection is 0910–0800. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0800—Revision

This information collection supports Agency implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For efficiency of Agency operations, we are revising the information collection currently approved under OMB control number 0910–0800 pertaining to human drug compounding and section 503B of the FD&C Act (21 U.S.C. 355b) to include reference to Agency guidance regarding section 503A of the FD&C Act (21 U.S.C. 355a), and to also include information collection that we attribute to a final standard memorandum of understanding (MOU) provided for by section 503A (''final standard MOU''). Finally, we are revising the title of the information collection from ''Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act'' to ''Human Drug Compounding Under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act.'' As information collection activity is planned and undertaken by FDA, we find consolidating related collection elements better utilizes our resources.

Agency Guidance Regarding Section 503A

We are revising the information collection to include reference to the guidance entitled ''Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.'' The guidance is available from our website at: *https://www.fda.gov/media/94393/download.* The guidance was issued consistent with our Good Guidance Practice regulations (21 CFR 10.115), which provide for comment at any time. The guidance communicates FDA's intention with regard to enforcement of section 503A of the FD&C Act to regulate entities that compound drugs and notes that parts of section 503A require rulemaking and consultation with a Pharmacy Compounding Advisory Committee to implement and explains how the provisions will be applied pending those consultations and rulemaking. Although the guidance does not include recommended information collection, we are including the guidance as a supplemental reference for respondents.

The Final Standard MOU

We are also revising the information collection to include information collection associated with the standard MOU pursuant to the provisions of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) found in section 503A of the FD&C Act. Section 503A of the FD&C Act describes the conditions under which certain drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician are exempt from certain sections of the FD&C Act. One of the conditions to qualify for the exemptions listed in section 503A of the FD&C Act is that: (1) The drug product is compounded in a State that has entered into an MOU with FDA that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such a State or (2) if the drug product is compounded in a State that has not entered into such an MOU, the licensed pharmacist, licensed pharmacy, or licensed physician does not distribute, or cause to be distributed, compounded drug products out of the State in which they are compounded, in quantities that exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician (see section 503A(b)(3)(B) of the FD&C Act).

Section 503A(b)(3)(B) of the FD&C Act directs FDA, in consultation with the National Association of Boards of Pharmacy (NABP), to develop a standard MOU for use by States in complying with the provision that references an MOU that addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to drug products compounded in the State and distributed outside such State. Accordingly, we have developed the document entitled, ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [Insert State Board of Pharmacy or Other Appropriate State Agency] and the U.S. Food and Drug Administration,'' available in docket number FDA–2018–N–3065, which is available at: *https://www.regulations.gov/docket?D=FDA-2018-N-3065.*

For purposes of this analysis, FDA assumes that 45 States will sign the standard MOU with FDA.

Under section III.a of the final standard MOU, the State Board of Pharmacy (BOP) or other appropriate State agency will notify FDA by submission to an information sharing network or by sending an email to *StateMOU@fda.hhs.gov* as soon as possible, but no later than 5 business days, after receiving a complaint relating to a human drug product compounded at a pharmacy and distributed outside the State involving a serious adverse drug experience or serious product quality issue. The notification will include the following information: (1) The name and contact information of the complainant, if available; (2) the name and address of the pharmacy that is the subject of the complaint; and (3) a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint. After the State BOP or other appropriate State agency concludes its investigation of a complaint assessed to involve a serious adverse drug experience or serious product quality issue relating to a drug product compounded at a pharmacy and distributed outside the State, the State BOP or other appropriate State agency will share with FDA the results of the investigation as permitted by State law. The information will include: (1) The State BOP or other appropriate State agency's assessment of whether the complaint was substantiated, if available and (2) a description and date of any actions the State BOP or other appropriate State agency has taken to address the complaint. In addition, the State BOP or other appropriate State agency will maintain records of the complaints they receive, the investigation of each complaint, and any response to or action taken as a result of a complaint, beginning when the State BOP or other appropriate State agency receives notice of the complaint. The State BOP or other appropriate State agency will maintain these records for at least 3 years, beginning on the date of final action on a complaint or the date of a decision that the complaint requires no action.

The State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and will notify FDA by email at *StateMOU@fda.hhs.gov* or by submission to an information sharing network as soon as possible, but no later than 5 business days, after receiving any complaint relating to a drug product compounded by a physician and distributed outside the State involving an adverse drug experience or product quality issue. The information will include, if available: (1) The name and contact information of the complainant; (2) the name and address of the physician that is the subject of the complaint; and (3) a description of the complaint, including a description of any compounded human drug product that is the subject of the complaint.

In the **Federal Register** of September 10, 2018 (83 FR 45631), we published a 60-day notice requesting public comment on the proposed collection of information. We note that in the final MOU we changed the title from ''Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration'' to ''Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the [insert State Board of Pharmacy or other appropriate State Agency] and the U.S. Food and Drug Administration.'' A number of comments were received. Most comments focused on State resource issues including whether the extent, nature, and frequency of information collection and sharing was overly burdensome and whether or not the information collection imposed an unfunded mandate on State agencies. In consideration of the comments, FDA has made the following changes to the MOU:

- We have increased the time period, from 3 days to 5 business days, to communicate information about complaints that involve serious adverse drug experiences or serious product quality issues relating to a human drug product compounded at a pharmacy and complaints that involve adverse drug experiences or product quality issues relating to a human drug product compounded by a physician;
- we have increased the amount of time after the final standard MOU is available for signature from 180 days to 365 days before FDA intends to enforce the 5 percent limit in States that have not signed the final standard MOU; and
- we have coordinated with NABP to develop an information-sharing network to help reduce the information collection and sharing burden on the State BOPs or other appropriate State agencies.

We disagree that the information collections in the MOU create unfunded mandates. Entering into the MOU is voluntary. We believe the proposed collection of information satisfies the statutory objectives of providing FDA with the information it needs through the least burdensome means available. None of the comments received

provided alternative figures to the burden estimates proffered, and we therefore estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Compounding MOU between FDA and State BOPs or other appropriate State Agencies	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
State BOP or other appropriate State agency notifies FDA of compounding complaints	45	3	135	0.5 (30 minutes)	67.5
State BOP or other appropriate State agency identifies pharmacies that distribute inordinate amounts of compounded human drugs interstate using surveys or inspections or data submitted to an information sharing network.	45	145	6,525	1	6,525
State BOP or other appropriate State agency notifies FDA of the distribution of inordinate amounts of compounded human drug products.	45	44	1,980	0.5 (30 minutes)	990
State BOP or other appropriate State agency notifies FDA and appropriate State regulator of physicians about physicians who distribute compounded human drug products interstate.	45	5	225	0.5 (30 minutes)	112.5
State BOP or other appropriate State agency notifies FDA of a new liaison to the MOU.	13	1	13	0.2 (12 minutes)	2.6
State BOP or other appropriate State agency notifies FDA of its intent to terminate participation in the MOU.	1	1	1	0.2 (12 minutes)	0.2
Total					7,697.8

[1] There are no capital costs or operating and mainenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Compounding MOU between FDA and State BOPs or other appropriate State Agencies	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
State BOP or other appropriate State Agency Recordkeeping for 3 Years of Compounding Complaints about Drug Products Compounded at a Pharmacy	45	2	90	1	90

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Compounding MOU between FDA and State BOP or other appropriate State Agencies	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
State BOP or other appropriate State agency notifies pharmacies that compound human drugs, and the State authority that licenses or regulates physicians that its participation in the MOU has terminated	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on our knowledge of State regulation of compounding practices and related complaints, we estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 2) will notify FDA within 5 business days of receiving any complaint relating to a human drug product compounded by a pharmacy and distributed outside the State involving a serious adverse drug experience or serious product quality issue or any complaint relating to a drug product compounded by a physician and distributed outside the State involving any adverse drug experience or product quality issue. We estimate that each State BOP or other appropriate State agency will notify FDA annually of approximately 3 complaints it receives (''No. of Responses per Respondent'' in table 1, row 2), for a total of 135 notifications of complaints sent to FDA (''Total Annual Responses'' in table 1, row 2). We estimate that preparing and submitting this information to FDA as described in the MOU will take approximately 0.5 hours per response (''Average Burden per Response'' in table 1, row 1), for a total of 67.5 hours (''Total Hours'' in table 1, row 2).

We also estimate that a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Recordkeepers'' in table 2) will prepare and maintain records for 3 years of the complaints they receive, investigations of complaints, and any State action taken or response to complaints involving drug products compounded at a pharmacy and distributed outside the State. We estimate that each State BOP or other appropriate State agency will receive annually approximately 2 complaints about adverse drug experiences or product quality issues relating to human drug products compounded at a pharmacy and will prepare and maintain approximately 1 record per each complaint the State BOP or other appropriate State agency receives, for a total of 2 records per State BOP or other appropriate State agency (''No. of Records per Recordkeeper'' in table 2), and a total of 90 records annually across all States (''Total Annual Records'' in table 2). We further estimate that preparing and maintaining these records will take approximately 1 hour per record (''Average Burden per Recordkeeping (in hours)'' in table 2), for a total of 90 hours (''Total Hours'' in table 2).

Under section III.b of the final standard MOU, on an annual basis, the State BOP or other appropriate State agency will identify, using surveys, reviews of records during inspections, data submitted to an information sharing network, or other mechanisms available to the State BOP or other appropriate State agency, pharmacies that distribute inordinate amounts of compounded human drug products interstate by collecting information regarding the number of prescription

orders for compounded human drug products distributed interstate during any calendar year and the number of prescription orders for compounded human drug products that the pharmacy sent out of (or caused to be sent out of) the facility in which the drug products were compounded during that same calendar year and the number of prescription orders for compounded human drug products that were dispensed (*e.g.,* picked up by a patient) at the facility in which they are compounded during that same calendar year. If a pharmacy has been identified as distributing inordinate amounts of compounded human drug products interstate, the State BOP or other appropriate State agency will also collect information regarding: (1) The total number of prescription orders for sterile compounded human drug products distributed interstate; (2) the names of States in which the pharmacy is licensed; (3) the names of States into which the pharmacy distributed compounded human drug products; and (4) whether the State inspected for and found during its most recent inspection that the pharmacy distributed compounded human drug products without valid prescription orders for individually identified patients.

The State BOP or other appropriate State agency will notify FDA by submission to an information sharing network or by sending an email to *StateMOU@fda.hhs.gov* within 30 business days of identifying a pharmacy that has distributed inordinate amounts of compounded human drug products interstate, as described in the final standard MOU. The notification will include the name and address of the pharmacy and the information that the State BOP or other appropriate State agency collected, described in the previous paragraph.

The State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and FDA by submission to an information sharing network or by sending an email to *StateMOU@fda.hhs.gov* within 30 business days of identifying a physician that has distributed compounded human drug products interstate.

We estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 3) will identify pharmacies that distribute inordinate amounts of compounded human drug products interstate. We estimate that each State agency will perform surveys or inspections of 145 pharmacies or use the information sharing network to identify this information (''No. of Responses per Respondent'' in table 1, row 3). We estimate that this will take approximately 1 hour per response (''average burden per response'' in table 1, row 3), for a total of 6,525 hours (''Total Hours'' in table 1, row 3). We estimate that annually a total of 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 4) will find that a pharmacy has distributed inordinate amounts of compounded human drug products interstate and notify FDA of this finding. We estimate that each State BOP or other appropriate State agency will notify FDA annually of approximately 44 findings it makes (''No. of Responses per Respondent'' in table 1, row 4), for a total of 1,980 notifications (''Total Annual Responses'' in table 1, row 4). We estimate that preparing and submitting this information to FDA as described in the MOU will take approximately 0.5 hours per response (''Average Burden per Response'' in table 1, row 4), for a total of 990 hours (''Total Hours'' in table 1, row 4).

We estimate that annually a total of approximately 45 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 5) will become aware of physicians that distribute compounded human drug products interstate. We estimate that each State BOP or other appropriate State agency will notify the appropriate regulator of physicians within the State and FDA annually of approximately five physicians that distribute compounded human drug products interstate (''No. of Responses per Respondent'' in table 1, row 5), for a total of 225 notifications of physicians that distribute compounded human drug products interstate sent to FDA (''Total Annual Responses'' in table 1, row 5). We estimate that preparing and submitting this information to us as described in the MOU will take approximately 0.5 hours per response (''Average Burden per Response'' in table 1, row 1), for a total of 112.5 hours (''Total Hours'' in table 1, row 5).

Under section V of the final standard MOU, a State BOP or other appropriate State agency may designate a new liaison to the MOU by notifying FDA's liaison in writing. If a State BOP or other appropriate State agency's liaison becomes unavailable to fulfill its functions under the MOU, the State BOP or other appropriate State agency will name a new liaison within 2 weeks and notify FDA.

We estimate that annually a total of approximately 13 State BOPs or other appropriate State agencies (''No. of Respondents'' in table 1, row 5) will notify FDA of a new liaison to the MOU. We estimate that each State BOP or other appropriate State will submit to FDA annually approximately 1 notification of a new liaison (''No. of Responses per Respondent'' in table 1, row 6), for a total of 13 notifications of a new liaison (''Total Annual Responses'' in table 1, row 6). We estimate that preparing and submitting each notification as described in the MOU will take approximately 0.2 hours per response (''Average Burden per Response'' in table 1, row 6), for a total of 2.6 hours (''Total Hours'' in table 1, row 6).

Under section VI of the revised final standard MOU, a State BOP or other appropriate State agency may terminate its participation in the MOU by submitting to FDA a 60 calendar day notice of termination.

We estimate that annually a total of approximately one State BOP or other appropriate State agency (''No. of Respondents'' in table 1, row 7) will notify FDA that it intends to terminate its participation in the MOU. We estimate that this State BOP or other appropriate State agency will submit to FDA annually approximately one notification of termination (''No. of Responses per Respondent'' in table 1, row 7), for a total of one notification (''Total Annual Responses'' in table 1, row 7). We estimate that preparing and submitting the notification as described in the MOU will take approximately 0.2 hours per notification (''Average Burden per Response'' in table 1, row 7), for a total of 0.2 hours (''Total Hours'' in table 1, row 7).

We estimate that annually a total of approximately one State BOP or other appropriate State agency (''No. of Respondents'' in table 3, row 2) will notify pharmacists and the State authority that licenses or regulates physicians that its participation in the MOU has terminated. We estimate that this State BOP or other appropriate State agency will distribute approximately one notification of termination (''No. of Responses per Respondent'' in table 1, row 7), for a total of one notification (''Total Annual Responses'' in table 3, row 2).

We estimate that preparing and submitting the notification as described in the MOU will take approximately 1 hour per notification (''Average Burden per Response'' in table 3, row 2), for a total of 1 hour (''Total Hours'' in table 3, row 2).

Dated: May 8, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–10336 Filed 5–13–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Advisory Committee on Children and Disasters: Establishment

AGENCY: Office of the Assistant Secretary for Preparedness and Response (ASPR), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Office of the Assistant Secretary for Preparedness and Response (ASPR), in the Department of Health and Human Services (HHS) Office of the Secretary announces establishment of the National Advisory Committee on Children and Disasters (NACCD). The Advisory Committee will provide advice and consultation to the HHS Secretary on pediatric medical disaster planning, preparedness, response, and recovery with respect to the medical and public health needs of children in relation to disasters. The Office of the Assistant Secretary for Preparedness and Response (ASPR) shall provide management and administrative oversight to support the activities of the Advisory Committee. The Office of the Secretary is accepting application submissions from qualified individuals who wish to be considered for membership on the NACCD. Up to 13 new voting members with expertise in pediatric medical disaster planning, preparedness, response, or recovery will be selected for the Committee. Please visit the NACCD website at *www.phe.gov/naccd* for all application submission information and instructions. Application submissions will be accepted for 30 calendar days from the date this posting is published in the **Federal Register**.

Application Period: The application period is from midnight (Eastern Time) May 27th–June 27th.

FOR FURTHER INFORMATION CONTACT: Maxine Kellman, DVM, Ph.D., PMP, Alternate Designated Federal Official for National Advisory Committees, Washington, DC, Office (202) 260–0447 or email *maxine.kellman@hhs.gov.*

SUPPLEMENTARY INFORMATION: Pursuant to the Federal Advisory Committee Act (FACA) of 1972, the HHS Secretary, in consultation with the Secretary of the U.S. Department of Homeland Security, established the National Advisory Committee on Children and Disasters (NACCD). Section 2811A of the Public Health Service Act, as amended by Pandemic and All Hazard Preparedness and Advancing Innovation Act of 2019 (42 U.S.C. 300hh–10b) requires that the Secretary for Health and Human Services (HHS) establish the National Advisory Committee on Children and Disasters (NACCD) to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters. The purpose of the NACCD is to provide advice and consultation to the HHS Secretary with respect to the medical and public health needs of children in relation to disasters. The Office of the Assistant Secretary for Preparedness and Response provides management and administrative oversight to support the activities of the NACCD.

Description of Duties: The NACCD: (1) Provides advice and consultation with respect to the activities addressing at-risk individuals carried out as applicable and appropriate (2) evaluates and provides input with respect to the medical and public health needs of children as they relate to preparation for, response to, and recovery from all-hazards emergencies; (3) provides advice and consultation with respect to state emergency preparedness and response activities and children, including related drills and exercises pursuant to the preparedness goals under the National Health Security Strategy; and (4) provides advice and recommendations to the HHS Secretary with respect to children and the medical and public health grants and cooperative agreements implementing the Public Health Emergency Preparedness and Hospital Preparedness Programs and other activities, as applicable to preparedness and response activities.

Structure: The Advisory Committee consists of not more than 13 voting members, including the Chairperson. Members will be appointed by the HHS Secretary, in consultation with such other Secretaries as may be appropriate, from among the nation's preeminent scientific, public health, and medical experts in areas consistent with the purpose and functions of the NACCD. Section 2811A(d)(2) of the Public Health Services (PHS) Act States:

(2) REQUIRED NON–FEDERAL MEMBERS.—The Secretary, in consultation with such other heads of Federal agencies as may be appropriate, shall appoint to the Advisory Committee under paragraph (1) at least 13 individuals, including—

(A) at least 2 non-Federal professionals with expertise in pediatric medical disaster planning, preparedness, response, or recovery;

(B) at least 2 representatives from State, local, Tribal, or territorial agencies with expertise in pediatric disaster planning, preparedness, response, or recovery;

(C) at least 4 members representing health care professionals, which may include members with expertise in pediatric emergency medicine; pediatric trauma, critical care, or surgery; the treatment of pediatric patients affected by chemical, biological, radiological, or nuclear agents, including emerging infectious diseases; pediatric mental or behavioral health related to children affected by a public health emergency; or pediatric primary care; and

(D) other members as the Secretary determines appropriate, of whom—

(i) at least one such member shall represent a children's hospital;

(ii) at least one such member shall be an individual with expertise in schools or child care settings;

(iii) at least one such member shall be an individual with expertise in children and youth with special health care needs; and

(iv) at least one such member shall be an individual with expertise in the needs of parents or family caregivers, including the parents or caregivers of children with disabilities in the following categories: Non-federal health care professionals and representatives from state, local, territorial, or tribal agencies.

The NACCD shall also have up to 12 federal, non-voting members (*ex officio*), including the following officials or their designees:

A. The Assistant Secretary for Preparedness and Response;

B. The Director of the Biomedical Advanced Research and Development Authority;

C. The Director of the Centers for Disease Control and Prevention;

D. The Commissioner of Food and Drugs;

E. The Director of the National Institutes of Health;

F. The Assistant Secretary of the Administration for Children and Families;

G. The Administrator of the Health Resources and Services Administration;

H. The Administrator of the Federal Emergency Management Agency;

I. The Administrator of the Administration for Community Living;

J. The Secretary of Education;

K. The Assistant Secretary for Mental Health and Substance Use; and

L. The Administrator of the Environmental Protection Agency.

A voting member of the NACCD shall serve for a term of three years, except

that the Secretary may adjust the terms of appointees who are initially appointed after the date of enacted of the Pandemic and All-Hazards Preparedness and Advancing Innovation Act of 2019 (June 24, 2019) in order to provide for a staggered term of appointment for all members. A voting member may serve not more than three terms on the NACCD, and not more than two of such terms may be served consecutively. Voting members shall not be full-time or permanent part-time federal employees but shall be appointed by the Secretary as Special Government Employees (5 U.S.C. 3109). A member may serve after the expiration of his/her term until a successor has been appointed. Members whose term expires after this charter's renewal date will have a term length contingent upon renewal of the advisory committee. Vacancies will be filled as members rotate out or resign using the same procedures as the initial selection process.

Robert P. Kadlec,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2020–10323 Filed 5–13–20; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Mono-Specific Chimeric Antigen Receptor (CAR) Therapies for the Treatment of Cluster of Differentiation 33 (CD33) Expressing Malignancies

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Vor Biopharma Inc. (''Vor''), located in Cambridge, MA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before June 15, 2020 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Jim Knabb, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240)-276–7856; Facsimile: (240)-276–5504; Email: *jim.knabb@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–097–2018–0: Anti-CD33 Chimeric Antigen Receptors for Treatment of Human Acute Myeloid Leukemia

1. U.S. Provisional Patent Application 62/643,015, filed March 14, 2018 (E–097–2018–0–US–01);
2. International Patent Application PCT/US2019/022,309, filed March 14, 2019 (E–097–2018–0–PCT–02)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

An exclusive license to:

The development of a chimeric antigen receptor (CAR) therapy mono-specific for CD33 for the prophylaxis or treatment of CD33-expressing hematological malignancies wherein the CAR is comprised of the CD33-binding domain referenced as Hu195 or hP67.6, is delivered via lentiviral transduction, and the T cells are:

1. Derived autologously (meaning cells derived from one individual who is both the donor and the recipient) in the first-line or relapsed/refractory setting, or

2. derived allogeneically (meaning cells derived from a matched healthy donor), in the post-transplant setting.

This technology discloses a CAR therapy that targets CD33 by utilizing the anti-CD33 binder known as Hu195 or hP67.6 for the treatment of hematological malignancies. CD33 is a validated immunotherapeutic target that is expressed on the surface of the vast majority of acute myelogenous leukemia (AML) blasts and cells in chronic myeloid leukemia-blast crisis (CML–BC).

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within thirty (30) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 7, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020–10304 Filed 5–13–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: Development and Commercialization of Logic-Gated Chimeric Antigen Receptor (CAR) Therapies for the Treatment of Cluster of Differentiation 33 (CD33) Expressing Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this Notice to Senti Bio (''Senti''), located in South San Francisco, CA.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before June 15, 2020 will be considered.

ADDRESSES: Requests for copies of the patent applications, inquiries, and comments relating to the contemplated Exclusive Patent License should be directed to: Jim Knabb, Senior Technology Transfer Manager, NCI Technology Transfer Center, 9609

Medical Center Drive, RM 1E530, MSC 9702, Bethesda, MD 20892–9702 (for business mail), Rockville, MD 20850–9702; Telephone: (240)-276–7856; Facsimile: (240)-276–5504; Email: *jim.knabb@nih.gov.*

SUPPLEMENTARY INFORMATION:

Intellectual Property

E–097–2018–0: Anti-CD33 Chimeric Antigen Receptors for Treatment of Human Acute Myeloid Leukemia

1. U.S. Provisional Patent Application 62/643,015, filed March 14, 2018 (E–097–2018–0–US–01);
2. International Patent Application PCT/US2019/022,309, filed March 14, 2019 (E–097–2018–0–PCT–02)

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide, and the fields of use may be limited to the following:

An exclusive license to:

1. The development of a CD33-specific logic-gated CAR-based immunotherapy using autologous human T cells transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets CD33 (comprised of the CD33-binding domain referenced as Hu195 or hP67.6 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of CD33-expressing cancers. For clarity, ''CD33-specific logic-gated CAR-based immunotherapy'' means therapies where the CAR-expressing T cells recognize CD33 and are engineered to respond to one or more additional antigens (but not necessarily all of the signals).
2. The development of a CD33-specific logic-gated CAR-based immunotherapy using allogeneic human NK cells transduced with lentiviral vectors, wherein the viral transduction leads to the expression of a CAR that targets CD33 (comprised of the CD33-binding domain referenced as Hu195 or hP67.6 in the invention as well as an intracellular signaling domain), for the prophylaxis or treatment of CD33-expressing cancers. For clarity, ''CD33-specific logic-gated CAR-based immunotherapy'' means therapies where the CAR-expressing NK cells recognize CD33 and are engineered to respond to one or more additional antigens (but not necessarily all of the signals).

This technology discloses a CAR therapy that targets CD33 by utilizing the anti-CD33 binder known as Hu195 or hP67.6 for the treatment of hematological malignancies. CD33 is a validated immunotherapeutic target that is expressed on the surface of the vast majority of acute myelogenous leukemia (AML) blasts and cells in chronic myeloid leukemia-blast crisis (CML–BC).

This Notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within thirty (30) days from the date of this published Notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information from these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 7, 2020.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2020–10303 Filed 5–13–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act. To request a copy of these documents, call or email the SAMHSA Reports Clearance Officer on (240) 276–0361 or *carlos.graham@samhsa.hhs.gov.*

Project: Projects for Assistance in Transition from Homelessness (PATH) Program Annual Report (OMB No. 0930–0205)—Revision

The Center for Mental Health Services awards grants each fiscal year to each of the states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands from allotments authorized under the PATH program established by Public Law 101–645, 42 U.S.C. 290cc-21 *et seq.,* the Stewart B. McKinney Homeless Assistance Amendments Act of 1990 (section 521 *et seq.* of the Public Health Service (PHS) Act) and the 21st Century Cures Act (114–255 Pub. L). Section 522 of the PHS Act and the 21st Century Cures Act requires that the grantee states and territories must expend their payments under the Act solely for making grants to political subdivisions of the state, and to nonprofit private entities (including community-based veterans' organizations and other community organizations) for the purpose of providing services specified in the Act. Available funding is allotted in accordance with the formula provision of section 524 of the PHS Act.

This submission is for a revision of the current approval of the annual grantee reporting requirements. Section 528 of the PHS Act and the 21st Century Cures Act specify that not later than January 31 of each fiscal year, a funded entity will prepare and submit a report in such form and containing such information as is determined necessary for securing a record and description of the purposes for which amounts received under section 521 were expended during the preceding fiscal year and of the recipients of such amounts and determining whether such amounts were expended in accordance with statutory provisions.

The proposed changes to the PATH 2020 Annual Report are as follows:

1. HMIS Data Standards updates

When needed, field response options and questions have been updated to align with the most recent version of the HMIS Data Standards.

Effective October 1, 2019, the HMIS Data Standards have been further updated. The changes in the HMIS Data Standards are reflected in this version of the PATH Annual Report Manual, and include:

—Updates to response categories for Living Situation
—Addition of an ''Unable to Locate Client'' response option to PATH Status

—Addition of a demographic question on history with domestic violence

The estimated annual burden for these reporting requirements is summarized in the table below.

Respondents	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden
States	56	1	15	840
Local provider agencies	476	1	15	7,140
Total	532			7,980

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.

Carlos Graham,

Social Science Analyst.

[FR Doc. 2020–10308 Filed 5–13–20; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2020–0023; OMB No. 1660–0005]

Agency Information Collection Activities: Proposed Collection; Comment Request; FEMA Inspection and Claims Forms

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the collection of information related to the flood insurance claims process and the housing inspection damage assessment process.

DATES: Comments must be submitted on or before July 13, 2020.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2020–0023. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW, 8NE, Washington, DC 20472–3100.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy and Security Notice that is available via a link on the homepage of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For information related to Claims Forms, contact: Daniel Claire, Program Analyst, Federal Insurance & Mitigation Administration, 202–552–9891, *Daniel.Claire@fema.dhs.gov.* For information related to Housing Inspection Instruments, contact: Brian Thompson, Supervisory Program Specialist, FEMA Recovery Directorate, *Brian.Thompson6@fema.dhs.gov.* You may contact the Information Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Congress created the National Flood Insurance Program (NFIP) through enactment of the National Flood Insurance Act of 1968 (NFIA) (Title XIII of Pub. L. 90–448, 82 Stat. 476), codified at 42 U.S.C. 4001 *et seq.* The NFIP is a Federal program enabling property owners in participating communities to purchase insurance as a protection against flood losses in exchange for state and community floodplain management requirements that reduce the risk of future flood damages. Communities participate in the NFIP based on an agreement between the community and FEMA. If a community adopts and enforces a floodplain management ordinance to reduce future flood risk to new construction in floodplains, FEMA will make flood insurance available within the community as a financial protection against flood losses. Accordingly, the NFIP is comprised of three key activities: flood insurance, floodplain management and flood hazard mapping.

A prospective policyholder may purchase an NFIP flood insurance policy either: (1) Directly from the Federal Government through a direct servicing agent (referred to as ''NFIP Direct''), or (2) from a participating private insurance company through the Write Your Own (WYO) Program. The Standard Flood Insurance Policy (SFIP) sets out the terms and conditions of insurance. *See* 44 CFR part 61, Appendix A. FEMA establishes terms, rate structures, and premium costs of SFIPs. The terms, coverage limits, and flood insurance premiums are the same whether purchased from the NFIP Direct or the WYO Program. *See* 44 CFR 62.23(a).

All flood loss claims presented under the NFIP are paid directly with U.S. Treasury funds, regardless of whether the policy is issued by the government (FEMA) directly or by a WYO company. The information in this collection includes all the data necessary to adjudicate claims for damages and benefits resulting from flood losses.

In addition to the requirements of the NFIA, section 205 of the Bunning-Bereuter-Blumenauer Flood Insurance Reform Act of 2004 (42 U.S.C. 4011 note) required FEMA to establish a claims appeals process. FEMA implemented the claim appeal process at 44 CFR 62.20.

Pertaining to housing inspections, the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), Pub. L. 93–288, as amended, is the legal basis for FEMA to provide financial assistance and services to individuals applying for disaster assistance benefits in the event of a Federally-declared disaster. Regulations in 44 CFR 206.110—Federal Assistance

to Individuals and Households implement the policy and procedures set forth in section 408 of the Stafford Act, 42 U.S.C. 5174, as amended. This program provides financial assistance and, if necessary, direct assistance to eligible individuals and households who, as a direct result of a major disaster or emergency, have uninsured or under-insured, necessary expenses and serious needs, and are unable to meet such expenses or needs through other means. Individuals and households applying for assistance must provide information detailing their losses and needs through the disaster assistance registration process covered under collection 1660–0002, Disaster Assistance Registration. If FEMA determines the applicant had home or personal property damage, has no insurance, or that the applicant's insurance coverage may not meet their needs, an inspection is issued to verify disaster caused damage. All pertinent information for a specific applicant is stored under a unique registration identification (ID) within the National Emergency Management Information System (NEMIS). An inspection request occurs due to NEMIS-driven business rules (automatically), applicant request, or FEMA caseworker request. The scope of an inspection for owners includes noting real and personal property (furnishing and appliances) damages to the interior and exterior of the dwelling, addressing special needs, transportation, unmet needs, and miscellaneous purchases. Inspectors do not note real property specifications for renters.

Once the inspector validates the information provided by the applicant during registration intake, the inspector begins a physical assessment of real and/or personal property damages utilizing Automated Construction Estimator (ACE) software. The inspector then uploads this information back to FEMA via the NEMIS through use of a secure connection. The inspector only records observed disaster caused damages and does not determine eligibility or damage award levels. FEMA's policies and business rules determine eligibility and award levels based upon the damage assessment, and other available information.

Collection of Information

Title: FEMA Inspection and Claims Forms, formerly National Flood Insurance Program Claim Forms.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0005.

FEMA Forms: FEMA Form 086–0–6; Personal Property (Contents) Worksheet, FEMA Form 086–0–7; Building Property Worksheet, FEMA Form 086–0–9; Proof of Loss—Building & Contents (Policyholder-Prepared), FEMA Form 086–0–10; Proof of Loss—Increased Cost of Compliance (ICC), FEMA Form 086–0–11; First Notice of Loss, FEMA Form 086–0–17; Manufactured (Mobile) Home/Travel Trailer Worksheet, FEMA Form 086–0–22; Proof of Loss—Building & Contents (Adjuster-Prepared), FEMA Form 086–0–23; Advance Payment Request—Building & Contents, FEMA Form 086–0–24; Advance Payment Request—Increased Cost of Compliance (ICC), FEMA Form 086–0–25; Claim Appeal, FEMA Form 009–0–143; Onsite Housing Inspections, FEMA Form 009–0–144; Remote Voice Telephony Housing Inspections, FEMA Form 009–0–145; Remote Video Telephony Housing Inspections.

Abstract: The claims forms used for the National Flood Insurance Program are used by policyholders to collect the information needed to investigate, document, evaluate, and settle claims against National Flood Insurance Program policies for flood damage to their insured property or qualification for benefits under Increased Cost of Compliance coverage. The housing inspection instruments are used to collect and store damage assessment information in ACE to assist in the determination of Individuals and Households Program assistance for applicants with disaster caused damage to their primary residence.

Affected Public: Individuals, households, businesses, or other for-profit.

Estimated Number of Respondents: 312,026.

Estimated Number of Responses: 312,026.

Estimated Total Annual Burden Hours: 314,149.

Estimated Total Annual Respondent Cost: $11,796,263.

Estimated Respondents' Operation and Maintenance Costs: $0.00.

Estimated Respondents' Capital and Start-Up Costs: $0.00.

Estimated Total Annual Cost to the Federal Government: $103,715,613.

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. 2020–10374 Filed 5–13–20; 8:45 am]

BILLING CODE 9110–52–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2019–0023; OMB No. 1660–0113]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; FEMA Preparedness Grants: Tribal Homeland Security Grant Program (THSGP)

AGENCY: Federal Emergency Management Agency, 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 June 15, 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 Cornelius Jackson, Program Analyst, DHS FEMA, Grant Programs Directorate, (202) 786–9508.

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on January 22, 2020, at 85 FR 3711 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.

Collection of Information

Title: FEMA Preparedness Grants: Tribal Homeland Security Grant Program (THSGP).

Type of information collection: Extension, with change, of a currently approved information collection.

OMB Number: 1660–0113.

Form Titles and Numbers: FEMA Form 089–22, THSGP—Tribal Investment Justification Template.

Abstract: The THSGP provides supplemental funding to ''directly eligible tribes'' to help strengthen the nation against risks associated with potential terrorist attacks as authorized by sections 2004 and 2005 of the Homeland Security Act of 2002 (Pub. L. 107–296, as amended) (6 U.S.C. 605—606). ''Directly eligible tribes'' are defined in Section 2001 of the Homeland Security Act of 2002 (Pub. L. 107–296, as amended) (6 U.S.C. 601). This program provides funds to build capabilities at the tribal governmental level.

Affected Public: Tribal Governments.

Estimated Number of Respondents: 60.

Estimated Number of Responses: 60.

Estimated Total Annual Burden Hours: 18,010.

Estimated Total Annual Respondent Cost: $886,452.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $460,885.

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. 2020–10378 Filed 5–13–20; 8:45 am]

BILLING CODE 9111–27–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–FEMA–2020–0009; OMB No. 1660–0114]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; FEMA Preparedness Grants: Port Security Grant Program

AGENCY: Federal Emergency Management Agency, 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 June 15, 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: Duane Davis, Section Chief, FEMA, Grant Programs Directorate, 202–680–4060, *duane.davis@fema.dhs.gov.* You may contact the Records Management Division for copies of the proposed collection of information at email address: *FEMA-Information-Collections-Management@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: Section 102 of the Maritime Transportation Security Act of 2002, as amended (46 U.S.C. 70107), established the Port Security Grant System (PSGP) to provide for the establishment of a grant program for a risk-based allocation of funds to implement Area Maritime Transportation Security Plans and facility security plans among port authorities, facility operators, and State and local government agencies required to provide port security services. Before awarding a grant under the program, the Secretary shall provide for review and comment by the appropriate Federal Maritime Security Coordinators and the Maritime Administrator. In administering the grant program, the Secretary shall take into account national economic and strategic defense concerns based upon the most current risk assessments available. In addition, any information collected by FEMA for this program is in accordance with 46 U.S.C. 70107(g), as amended by section 112(c) of the Security and Accountability For Every (SAFE) Port Act of 2006 (Pub. L. 109–347), which states: ''Any entity subject to an Area Maritime Transportation Security Plan may submit an application for a grant under this section, at such time, in such form, and containing such information and assurances as the Secretary may require.'' This proposed information collection was previously published in the **Federal Register** on February 11, 2020, at 85 FR 7779 with a 60 day public comment period. FEMA received one (1) unrelated comment. 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.

Collection of Information

Title: FEMA Preparedness Grants: Port Security Grant Program (PSGP).

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0114.

Form Titles and Numbers: FEMA Form 089–5, PSGP Investment Justification.

Abstract: The previous version of FEMA Form 089–5 presented numerous editing and submission challenges for applicants, often leaving required information blank within the form. Additionally, numerous applicants annually fail to provide required content information within a detailed budget worksheet or provide no detailed budget worksheet at all. A detailed budget worksheet is required; however it is not currently in a required template. This update changes the format and software of Form 089–5 and incorporates the detailed budget worksheet to help ensure accurate project accounting. By broadening the form to include all required project information, applicants will have fewer documents to track and submit; and subsequent agency reviews will be streamlined and improve consistency among application format.

Affected Public: State, local and Tribal Governments; businesses or other for-profits and non-profits.

Estimated Number of Respondents: 893.

Estimated Number of Responses: 1,759.

Estimated Total Annual Burden Hours: 17,450 hours.

Estimated Total Annual Respondent Cost: $1,430,377.

Estimated Respondents' Operation and Maintenance Costs: 0.

Estimated Respondents' Capital and Start-Up Costs: 0.

Estimated Respondents' Operation and Maintenance Costs: 0.

Estimated Respondents' Capital and Start-Up Costs: 0.

Estimated Total Annual Cost to the Federal Government: $1,055,219.

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, such as 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. 2020–10379 Filed 5–13–20; 8:45 am]

BILLING CODE 9111–27–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Immigration and Customs Enforcement

[OMB Control Number 1653–0051]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Standards To Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities

AGENCY: U.S. Immigration and Customs Enforcement, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: In accordance with the Paperwork Reductions Act (PRA) of 1995 the Department of Homeland Security (DHS), U.S. Immigration and Customs Enforcement (ICE) will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance.

DATES: Comments are encouraged and will be accepted until July 13, 2020.

ADDRESSES: All submissions received must include the OMB Control Number 1653–0051 in the body of the letter, the agency name and Docket ID ICEB–2012–0003. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number ICEB–2012–0003;

(2) *Mail:* Submit written comments to DHS, ICE, Office of the Chief Information Officer (OCIO), PRA Clearance, Washington, DC 20536–5800.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Patricia Reiser (610.587.9123), *patricia.reiser@ice.dhs.gov,* U.S. Immigration and Customs Enforcement.

SUPPLEMENTARY INFORMATION:

Comments

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) 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;

(2) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Standards to Prevent, Detect, and Respond to Sexual Abuse and Assault in Confinement Facilities

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or households. DHS is setting standards for the prevention, detection, and response to sexual abuse in its confinement facilities. For DHS facilities and as incorporated in DHS contracts, these standards require covered facilities to retain and report to the agency certain specified information relating to sexual abuse prevention planning, responsive planning, education and training, and investigations, as well as to collect, retain, and report to the agency certain specified information relating to allegations of sexual abuse within the covered facility.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* 1,386,177 responses at 6 minutes (.1 hours) per response.

(6) *An estimate of the total public burden (in hours) associated with the collection:* 120,082 annual burden hours.

Dated: May 8, 2020.

Scott Elmore,

PRA Clearance Officer.

[FR Doc. 2020–10305 Filed 5–13–20; 8:45 am]

BILLING CODE 9111–28–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–WSFR–2020–N018; FVWF97820900000–XXX–FF09W13000 and FVWF54200900000–XXX–FFO9W13000; OMB Control Number 1018–0088]

Agency Information Collection Activities; National Survey of Fishing, Hunting, and Wildlife-Associated Recreation (FHWAR)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to reinstate a previously approved information collection with revisions.

DATES: Interested persons are invited to submit comments on or before July 13, 2020.

ADDRESSES: Send your comments on the information collection request by mail to the Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803; or by email to *Info_Coll@fws.gov.* Please reference OMB Control Number 1018–0088 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: Madonna L. Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the PRA and its implementing regulations at 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. 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 review, we cannot guarantee that we will be able to do so.

Abstract: The information collected for the National Survey of Fishing, Hunting and Wildlife-Associated Recreation (FHWAR) assists the Fish and Wildlife Service in administering the Wildlife and Sport Fish Restoration grant programs. The 2022 FHWAR survey will provide up-to-date information on the uses and demands for wildlife-related recreation resources and a basis for developing and evaluating programs and projects to meet existing and future needs.

We collect the information in conjunction with carrying out our responsibilities under the Dingell-Johnson Sport Fish Restoration Act (16 U.S.C. 777–777m) and the Pittman-Robertson Wildlife Restoration Act (16 U.S.C. 669–669i). Under these acts, as amended, we provide approximately $1 billion in grants annually to States for projects that support sport fish and wildlife management and restoration, including:

- Improvement of fish and wildlife habitats,
- Fishing and boating access,
- Fish stocking, and
- Hunting and fishing opportunities.

We also provide grants for aquatic education and hunter education, maintenance of completed projects, and research into problems affecting fish and wildlife resources. These projects help to ensure that the American people have adequate opportunities for fish and wildlife recreation. We conduct the survey about every 5 years. The 2022 FHWAR survey will be the 14th conducted since 1955. We sponsor the survey at the States' request, which is made through the Association of Fish and Wildlife Agencies. We contract with the National Opinion Research Center (NORC) at the University of Chicago, which collects the information using internet, telephone, or mail-in interviews. Respondents are invited to take the survey with a mailed letter. NORC will select a sample of sportspersons and wildlife watchers from a household screen and conduct three detailed interviews during the survey year. The survey collects information on the number of days of participation, species of animals sought, and expenditures for trips and equipment. Information on the characteristics of participants includes age, income, sex, education, race, and State of residence.

Federal and State agencies use information from the survey to make policy decisions related to fish and wildlife restoration and management. Participation patterns and trend information help identify present and future needs and demands. Land management agencies use the data on expenditures and participation to assess the value of wildlife-related recreational uses of natural resources. Wildlife-related recreation expenditure information is used to estimate the impact on the economy and to support the dedication of tax revenues for fish and wildlife restoration programs.

Title of Collection: National Survey of Fishing, Hunting, and Wildlife-Associated Recreation (FHWAR).

OMB Control Number: 1018–0088.

Form Number: None.

Type of Review: Reinstatement of a previously approved collection.

Respondents/Affected Public: Individuals/households.

Respondent's Obligation: Voluntary.

Frequency of Collection: Screener data collection will be conducted from January through March 2022. The first detailed sportsperson and wildlife-watcher interviews will be conducted in May 2022. The second detailed interviews will be conducted in September 2022. The third and final detailed interviews will be conducted in January 2023.

Total Estimated Annual Nonhour Burden Cost: None.

Activity	Estimated number of household responses	Median completion time per response (minutes)	Estimated burden hours *
National Survey			
Main: Screener	37,128	9	5,569
Main: Wave 1	40,850	13	8,851
Main: Wave 2	38,293	13	8,297
Main: Wave 3	35,114	20	11,705
Subtotal:	*151,385*		*34,422*
State-Level Survey			
Main: Screener	17,870	9	2,681
Main: Wave 1	10,722	10	1,787
Main: Wave 2	10,722	10	1,787
Main: Wave 3	10,722	10	1,787
Subtotal:	50,036		8,042
Grand Total:	*201,421*		*42,464*

* Rounded.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: May 11, 2020.

Madonna L. Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2020–10317 Filed 5–13–20; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[201A2100DD/AAKC001030/ A0A501010.999900]

Suspension of Preparation of Environmental Impact Statement for the Proposed Redding Rancheria Fee-to-Trust and Casino Project, Shasta County, California

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice announces that the Bureau of Indian Affairs (BIA) is suspending preparation of an environmental impact statement (EIS) for the Redding Rancheria's (Tribe's) application requesting that the United States acquire land in trust in Shasta County, California, for the construction and operation of a casino resort.

FOR FURTHER INFORMATION CONTACT: Mr. Chad Broussard, Environmental Protection Specialist, Bureau of Indian Affairs, Pacific Regional Office, 2800 Cottage Way, Room W–2820, Sacramento, California 95825; telephone: (916) 978–6165; email: *chad.broussard@bia.gov.* Information is also available online at *www.reddingeis.com.*

SUPPLEMENTARY INFORMATION: On November 29, 2016, the BIA published a Notice of Intent to Prepare an EIS in connection with the Tribe's application requesting that the United States acquire approximately 232 acres of land in trust in Shasta County, California, for the construction and operation of a casino resort. The proposed fee-to-trust property is located in an unincorporated part of Shasta County, California, approximately 1.6 miles northeast of the existing Redding Rancheria, and approximately two miles southeast from the downtown of the City of Redding. The proposed trust property includes seven parcels, bound by Bechelli Lane on the north, private properties to the south, the Sacramento River on the west, and Interstate 5 on the east. The Tribe is proposing to construct a casino resort that includes a casino, hotel, event/convention center, outdoor amphitheater, retail center, and associated parking/infrastructure. The new facility would replace the Tribe's existing casino, and the Tribe would convert the existing casino buildings to a different Tribal use.

On April 10, 2019, the BIA published a Notice of Availability in the **Federal Register** (84 FR 14391) for the Draft EIS for the Proposed Redding Rancheria Fee-to-Trust and Casino Project, Shasta County, California. On June 6, 2019, the BIA published a notice in the **Federal Register** (84 FR 26440) to extend the comment period for the Draft EIS to June 17, 2019.

By letter dated February 21, 2020, the Tribe notified the Department of the Interior (Department) that it would await a decision from the California Supreme Court in a case arising under State law and involving the Indian Gaming Regulatory Act, 25 U.S.C. 2719 *et. seq.,* before the Tribe decided how to proceed on its application. Therefore, the Department is suspending its review of the Tribe's application and preparation of the EIS. Since the Tribe's request involves action by the California Supreme Court, the Department does not have a definite time frame for how long the suspension will last; however, the Department will provide notice when it resumes the environmental review process.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

[FR Doc. 2020–10352 Filed 5–13–20; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[201A2100DD/AABB003600/ A0T902020.999900.253G]

Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie); Amendment to Liquor Ordinance

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice.

SUMMARY: This notice publishes the amendment to the Liquor Ordinance of the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie). The liquor ordinance regulates and controls the possession, sale, manufacture, and distribution of alcohol on Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie) trust lands in conformity with the laws of the State of Oklahoma where applicable and necessary. Although the amendment was adopted on October 30, 2019, it does not take effect until published in the **Federal Register**.

DATES: This ordinance takes effect on June 15, 2020.

FOR FURTHER INFORMATION CONTACT: Ms. Sherry Lovin, Tribal Government Officer, Southern Plains Regional Office, Bureau of Indian Affairs, Post Box 368, Anadarko, Oklahoma 73005, telephone: (405) 247–1534 or (405) 247–6673, fax: (405) 247–1534; or Ms. Laurel Iron Cloud, Chief, Division of Tribal Government Services, Office of Indian Services, Bureau of Indian Affairs, 1849 C Street NW, MS–4513–MIB, Washington, DC 20240, telephone: (202) 513–7641.

SUPPLEMENTARY INFORMATION: Pursuant to the Act of August 15, 1953, Public Law 83–277, 67 Stat. 5886, 18 U.S.C. 1161, as interpreted by the Supreme Court in *Rice* v. *Rehner,* 463 U.S. 713 (1983), the Secretary of the Interior shall certify and publish in the **Federal Register** notice of adopted liquor control ordinances for the purpose of regulating liquor transactions in Indian country. On May 14, 2010, the Wichita and Affiliated Tribes Executive Committee duly adopted the Liquor Ordinance of the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie). The Liquor Ordinance of the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie) was published in the **Federal Register** on July 27, 2010, at 75 FR 44011 and a correction was published on August 18, 2010, at 75 FR 51102.

This notice is published in accordance with the delegated authority by the Secretary of the Interior to the Assistant Secretary—Indian Affairs. I certify that the Wichita and Affiliated Tribes Executive Committee duly adopted the amendment to the Liquor Ordinance of the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie) by Resolution Number WT–20–014 on October 30, 2019.

Tara Sweeney,

Assistant Secretary—Indian Affairs.

The Liquor Ordinance of the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Section 215, as amended, shall read as follows:

215. ''Tribal Lands'' means the 5.0574 acres of land held in trust by the United States for the benefit of the Wichita and Affiliated Tribes upon which a gaming facility of the Tribe known as Sugar Creek Casino exists, whose address is 4200 North Broadway, Hinton, Oklahoma 73047, described as:

All Interest in Surface and Surface Rights Only in and to a tract of land lying in the Southwest Quarter (SW/4) of Section Ten (10), Township Twelve (12) North, Range Eleven (11) West of the Indian Meridian, Caddo County, Oklahoma, being particularly described as follows:

COMMENCING at a Railroad Spike found for corner of the Southeast corner of said Southwest Quarter (SW/4);

THENCE North 00°15′47″ West, along the East line of said Southwest Quarter (SW/4), a distance of 227.41 feet;

THENCE South 89°44′13″ West, a distance of 70.03 feet to the POINT OF BEGINNING, said point being on the West Right of Way line of U.S. Highway 281 located 75.00 feet West of the centerline of said Highway as set forth by the Easement to the State of Oklahoma recorded at Book 79, Page 185;

THENCE South 89°40′46″ West, perpendicular to said Right of Way line, a distance of 208.00 feet;

THENCE South 00°19′14″ East, parallel to said Right of Way line, a distance of 143.29 feet;

THENCE South 89°44′13″ West, perpendicular to the East line of said Southwest Quarter (SW/4), a distance of 292.50 feet;

THENCE North 00°15′47″ West, parallel to said East line, a distance of 500.00 feet;

THENCE North 89°44′13″ East, a distance of 500.00 feet to a point on said West Right of Way line;

THENCE South 00°19′14″ East, along said West Right of Way line, a distance of 356.50 feet to the POINT OF BEGINNING.

Said tract of land containing 220,299 square feet or 5.0574 acres, more or less; and any lands the Tribe has been granted permanent use.

[FR Doc. 2020–10368 Filed 5–13–20; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[19XL.LLIDB03000.LF3100000. DF0000.LFHFFR650000.241A.4500136018]

Notice of Availability for the Tri-State Fuel Breaks Project Record of Decision, Idaho

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: In accordance with the National Environmental Policy Act of 1969, as amended, and the Federal Land Policy and Management Act of 1976, as amended, the Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Idaho BLM portion of the Tri-state Fuel Breaks Project Environmental Impact Statement (EIS).

ADDRESSES: Interested persons may review the ROD and accompanying background documents on the project website: *https://go.usa.gov/xPruu.* Copies of the ROD are available upon request from the BLM Boise District Office, 3948 S Development Ave., Boise, Idaho.

FOR FURTHER INFORMATION CONTACT: Lance Okeson, Project Lead, 208–384–3300; 3948 South Development Ave., Boise, ID 83705; *blm_id_tristate@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. FRS is available 24 hours a day, seven days a week, to leave a message or a question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The Tri-state Fuel Breaks Project envisions a strategic fuel break network along established roads over a 3.6 million-acre project area spanning southeastern Oregon and southwestern Idaho crossing district and state boundaries and connecting to an existing network of fuel breaks in the BLM's Winnemucca and Elko Districts in Nevada. Strategically placed fuel breaks in the Tri-state area will improve firefighter safety and expand opportunities to catch rapidly moving fires, potentially reducing fire size. Fuel breaks will provide greater protection of human life

and property, sagebrush communities, and habitat restoration investments. Reducing fire size will help limit the expansion of invasive plants such as cheatgrass and medusahead.

This ROD approves implementation of the preferred alternative (Alternative 5 of the FEIS) in Idaho. The BLM Boise District will create and maintain a fuel break network of 20,629 acres along 435 miles of roads through mechanical, chemical, and/or biological (*i.e.,* targeted grazing) treatments. BLM Oregon will issue a decision for their portion of the project at a future date.

The BLM published the Draft EIS on October 11, 2019, initiating a 45-day public comment period. During the comment period, the BLM received 40 letters and emails from the public and held three public meetings. The BLM took into account all comments in the preparation of the Final EIS released on April 3, 2020.

The BLM published the NOA for the Final EIS on April 3, 2020, initiating a 30-day availability period. On May 7, 2020, Department of the Interior Acting Assistant Secretary for Land and Minerals Management Casey Hammond signed a Record of Decision selecting the preferred alternative (Alternative 5) for implementation in the Idaho portion of the project area using a phased approach to prioritize well-maintained and strategically connected routes. That approval constitutes the final decision of the Department and, in accordance with the regulations at 43 CFR 4.410, is not subject to appeal under Departmental regulations found in 43 CFR part 4. Any challenge to this decision must be brought in the Federal District Court and is subject to 42 U.S.C. 4370m–6.

Authority: 40 CFR 1506.6, 40 CFR 1506.10.

Casey Hammond,

Principal Deputy Assistant Secretary, Exercising the authority of the Assistant Secretary, Land and Minerals Management.

[FR Doc. 2020–10298 Filed 5–13–20; 8:45 am]

BILLING CODE 4310–GG–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLAK940000.L14100000.BX0000.20X. LXSS001L0100]

Filing of Plats of Survey: Alaska

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of lands described in this notice are scheduled to be officially filed in the Bureau of Land Management (BLM), Alaska State Office, Anchorage, Alaska. This survey was executed at the request of Sealaska, Corporation and is necessary for the management of these lands.

DATES: The BLM must receive protests by June 15, 2020.

ADDRESSES: You may buy a copy of the plats from the BLM Alaska Public Information Center, 222 W 7th Avenue, Mailstop 13, Anchorage, AK 99513. Please use this address when filing written protests. You may also view the plats at the BLM Alaska Public Information Center, Fitzgerald Federal Building, 222 W 8th Avenue, Anchorage, Alaska, at no cost.

FOR FURTHER INFORMATION CONTACT: Douglas N. Haywood, Chief, Branch of Cadastral Survey, Alaska State Office, Bureau of Land Management, 222 W 7th Avenue, Anchorage, AK 99513; 907–271–5481; *dhaywood@blm.gov.* People who use a telecommunications device for the deaf may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the BLM 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:

Copper River Meridian, Alaska

U.S. Survey No. 11766, accepted May 8, 2020, situated within: T. 56 S., R. 72 E.

A person or party who wishes to protest one or more plats of survey identified above must file a written notice of protest with the State Director for the BLM in Alaska. The notice of protest must identify the plat(s) of survey that the person or party wishes to protest. You must file the notice of protest before the scheduled date of official filing for the plat(s) of survey being protested. The BLM will not consider any notice of protest filed after the scheduled date of official filing. A notice of protest is considered filed on the date it is received by the State Director for the BLM in Alaska during regular business hours; 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 a protest, if not filed with the notice of protest, must be filed with the State Director for the BLM in Alaska within 30 calendar days after the notice of protest is filed.

If a notice of protest against a plat of survey is received prior to the scheduled date of official filing, the official filing of the plat 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 dismissal or resolution of all protests of the plat.

Before including your address, phone number, email address, or other personally identifiable information in a notice of protest or statement of reasons, you should be aware that the documents you submit, including your personally identifiable information, may be made publicly available in their entirety at any time. While you can ask the BLM to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. Chap. 3.

Douglas N. Haywood,

Chief Cadastral Surveyor, Alaska.

[FR Doc. 2020–10370 Filed 5–13–20; 8:45 am]

BILLING CODE 4310–HC–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030131; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Department of Anthropology, Southern Methodist University, Dallas, TX

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Department of Anthropology, Southern Methodist University has completed an inventory of human remains and associated funerary objects in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Department of Anthropology, Southern Methodist University. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or

Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Department of Anthropology, Southern Methodist University at the address in this notice by June 15, 2020.

ADDRESSES: B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (2114) 768–2915, email *seiselt@smu.edu.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Department of Anthropology, Southern Methodist University, Dallas, TX. The human remains and associated funerary objects were removed from Freestone County and Navarro County, TX.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Department of Anthropology, Southern Methodist University professional staff in consultation with representatives of the Caddo Nation of Oklahoma and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma.

History and Description of the Remains

The Richland Creek Archaeological Project (RCAP) was conducted by Southern Methodist University (SMU) at the request of the Tarrant County Water Control and Improvement District Number One in an attempt to prepare a cultural resources management plan prior to construction of the Richland/Chambers Reservoir, and to explore the archeology of this region of TX.

Between 1980 and 1981, human remains representing, at minimum, four individuals were removed from site 41FT161B in Freestone County, TX, during the RCAP. Burial 1 is an adult individual of unknown sex, although possibly female based on the gracile nature of the human remains. Burial 2 is a 50–60 year old female, who was buried semi-flexed on the right side, with the head to the north. Burial 3 is an adult individual of unknown sex, although possibly female. (That Burial 3 is actually a portion of Burial 1 due to its location downslope of Burial 1, as indicated by the field notes, cannot be confirmed.) Burial 4 is an adult individual of unknown sex, although possibly female, who was buried semi-flexed on the left side, with the hands clasped and placed beneath the head, oriented in an east-west direction. No known individuals were identified. The three associated funerary objects are one Gary point, one chert blade, and one Steiner point.

Archeologists William A. Martin and Daniel E. McGregor dated the major occupation of the site to A.D. 600–900 based on radiocarbon, lithic, and ceramic evidence. The Gary dart and arrow points, as well as the coarse-grained sandy paste sherds, suggest Late Prehistoric (A.D. 700–1650) occupation.

Between 1980 and 1981, human remains representing, at minimum, five individuals were recovered from site 41NV179 in Navarro County, TX, during the RCAP. Burial A is an individual of unknown age and sex, due to the fragmentary nature of the remains. Burial B is an individual of unknown age and sex, who was buried flexed on the back with the arms crossed in front of the chest at the forearms. Burial C is an individual of unknown age and sex, who was buried on the back with the feet flexed beneath the body, the knees tucked in to the chest and the arms extended. Burial D is an individual of unknown age and sex. Burial E is an individual of unknown age and sex who does not appear in any of the official reports or field documentation. No known individuals were identified. No associated funerary objects are present. Major occupation of the site is dated to A.D. 600–900 based on lithic and ceramic evidence.

Between 1980 and 1984, human remains representing, at minimum, one individual were removed from the Hardy site (41FT200) in Freestone County, TX, during the RCAP. Burial 1 is an adult male less than 30 years old, whose fragmentary remains were recovered from the slough trench of the site. No known individuals were identified. No associated funerary objects are present.

Archeologist Daniel E. McGregor dated the major occupation of the site to the Middle Archaic to Late Prehistoric periods, based on ceramic evidence together with expanding and contracting stem projectile points.

Between 1980 and 1981, human remains representing, at minimum, one individual were removed from the Oxbow site (41NV243) in Navarro County, TX, during the RCAP. Burial 1 is a 35–45 year old male, who was buried semi-flexed on the right side, with the head to the southeast and facing downslope. No known individuals were identified. The 21 associated funerary objects are two lots of chips, two lots of broken flakes, four lots of shell, one lot of baked clay, three bifaces, two projectile points, three lots of whole flakes, two lots of unifaces, and two ground stones.

Between 1980 and 1984, human remains representing, at minimum, seven individuals were removed from the Irvine site (41NV182) in Navarro County, TX, during the RCAP. Burial 1 is a 25–35 year old individual of indeterminate sex. Burial 2 contains three individuals: One is a 35–45 year old male, a second is an adult individual of indeterminate sex who is represented only by a single tibia fragment, and the third is a child of indeterminate sex who is represented only by the cranium. Burial 3 is a 6–10 year old individual of unknown sex, although possibly female. Burial 9 is a 25–35 year old female, who was buried flexed and on the right side, with the head to the north. The seventh individual is of unknown age and sex. Lack of accompanying provenience information precludes a determination as to whether the remains of this individual are portions of an existing or missing burial from the site, or belong to a separate individual altogether. No known individuals were identified. The 43 associated funerary objects are four Gary dart points, one Dawson dart point, one Yarbrough dart point, one untyped straight stem point, one dart point tip fragment, one dart point base fragment, one sherd, one uniface, three bifaces, five biface fragments, five lot of baked clay, five lots of flakes, two lot of cobbles, two spalls, one mano, one core fragment, one lot of shatter, two lots of shell, one lot of fire cracked rock, two lots of unsorted material, one lot of mixed faunal remains, and one faunal bone (perhaps belonging to a bird).

Archeologists Daniel E. McGregor and Jeffery Bohlin dated the major occupation of the site to A.D. 700–900, based on the lithic evidence (contracting stem Gary dart and arrow points), ceramic materials (coarse-grained, sandy paste sherds), and the presence of large roasting and trash pits. There were two additional minor occupations of the site during the Late Archaic (as evidenced by expanding and straight stem dart points) and the Late Prehistoric (as

shown by radiocarbon dated materials from A.D. 1140 ± 50).

Between 1980 and 1984, human remains representing, at minimum, nine individuals were removed from the Adams Ranch site (41NV177) in Navarro County, TX, during the RCAP. Burial 1 is a 35–45+ year old female dating to the A.D. 200–700 component of the site. Burial 2 is a 6–8 year old child of unknown sex dating to the A.D. 800–1000 component of the site. Burial 3 is an adult individual of unknown sex (represented only by the left temporal bone) dating to the A.D. 200–700 component of the site. Burial 4 is a 7–9 year old child represented by cranial and long bone fragments. Burial 5 is an adult male. Burial 6 is a 30–40 year old male dating to the A.D. 200–700 component of the site. Burial 7 is an 18–24 month old child dating to the A.D. 200–700 component of the site. Burial 8 is an adult individual of unknown sex, who was found alongside Burial 2, and is represented only by a right parietal fragment. The ninth individual is represented by unidentified, miscellaneous skeletal remains provenienced to Trench 17 of the site. No known individuals were identified. The six associated funerary objects are one bag of shell fragments, one Gary point, one small arrow point (possibly Bonham type), one ceramic sherd, and two shells.

Archeologist William A. Martin identified three major occupations of Adams Ranch, and believed it to have functioned as a hunting/collecting camp. The three periods of occupation were the Late Archaic (A.D. 200–700), Early Round Prairie Phase (A.D. 800–1000), and the St. Elmo Phase (post A.D. 1000). One feature of interest at the site was a large central pit believed to be a Wylie Focus pit used for roasting, trash disposal, and burial.

Between 1980 and 1984, human remains representing, at minimum, 22 individuals were removed from the Bird Point Island site (41FT201) in Freestone County, TX, during the RCAP. These individuals were recovered from formal burials and as fragments or cremations within non-burial contexts. Burial 1 is an adult individual of unknown sex dating to the A.D. 1000–1200 occupation of the site. Burial 2 is an adult male dating to the A.D. 580–860 occupation of the site. Burial 3 is an adult male dating to the 170 B.C. to A.D. 130 occupation of the site. Burial 8 is a 25–30 year old male dating to the A.D. 1300–1650 occupation of the site, who was buried extended and prone, with the left arm positioned under the chest, clasping the right wrist, and the head oriented in an east-west direction. Burial 9/11 is a 25–30 year old male, whose skeleton is complete and well-preserved except for the hand, foot, and upper facial bones. Burial 10 is an adult female found alongside Burial 9/11, who is represented by fragmentary remains of a right radius, lower ribs, and calcaneus. Burial 12 is a post-adolescent individual of unknown sex represented by occipital, parietal, and long bone fragments. Burial 13 is an adult female, who was buried tightly flexed and with the head to the west. Burial 14 is an infant of unknown sex, who is represented by craniofacial and upper thoracic remains. Burial 15 is an adult female represented by cranial and lower axial skeletal remains, who was buried semi-flexed on the right side and with the face to the north. Burial 16 is an adult female dating to the A.D. 1300–1650 occupation of the site, who was buried semi-flexed on the right side, with the forearms brought forward toward the face. Feature 91 contained a possible cremation dating to the A.D. 1000–1200 occupation of the site, represented by burned bone fragments recovered from flotation. Features 65, 77, 90, 92, 93, 107, and 110 also contained burned bone fragments believed to represent cremations due to the fact that these feature numbers are absent from the feature inventory, and the official report states that any features later determined to be cremations were re-designated as burials and removed from the inventory. Finally human remains belonging to three individuals (41FT201.403.14, 41FT201.401.9.1, and 41FT201.403.10.8) are represented by bone fragments. The provenience information for these human remains is insufficient to conclusively determine whether they are portions of existing or missing burials in the collection, or separate individuals entirely. No known individuals were identified. The 10 associated funerary objects are two lots of assorted faunal remains; two lots of assorted shell, bone, and rock; three shells; one lot of wood; one lot of lithic debris; and one lot of shell, charcoal, and flakes.

The Bird Point Island Site was occupied substantially over four periods of time: 170 B.C. to A.D. 130, A.D. 580–860, A.D. 1000–1200, and A.D. 1300–1650. Bird Point Island contained a large central pit similar to the one at Adams Ranch, and was believed to be a Wylie Focus pit. Analysis of the cultural features, structures, and artifacts of the site suggests cultural relationships between the inhabitants of the site and the Caddo.

All seven of these Richland Creek sites fall within historic Caddo territory, and finds from Wylie Focus sites (*i.e.* Bird Point Island and Adams Ranch) show influence of Caddo culture.

Determinations Made by the Department of Anthropology, Southern Methodist University

Officials of the Department of Anthropology, Southern Methodist University have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 49 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 83 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Caddo Nation of Oklahoma and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco, & Tawakonie) hereafter referred to as The Tribes.

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to B. Sunday Eiselt, Department of Anthropology, Southern Methodist University, 3225 Daniel Avenue, Heroy Hall #450, Dallas, TX 75205, telephone (214) 768–2915, email *seiselt@smu.edu,* by June 15, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Department of Anthropology, Southern Methodist University is responsible for The Tribes that this notice has been published.

Dated: April 3, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–10345 Filed 5–13–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0030085; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Arizona Museum of Natural History, Mesa, AZ

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The Arizona Museum of Natural History has completed an inventory of human remains and associated funerary objects, in consultation with the appropriate Indian Tribes or Native Hawaiian organizations, and has determined that there is a cultural affiliation between the human remains and associated funerary objects and present-day Indian Tribes or Native Hawaiian organizations. Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request to the Arizona Museum of Natural History. If no additional requestors come forward, transfer of control of the human remains and associated funerary objects to the lineal descendants, Indian Tribes, or Native Hawaiian organizations stated in this notice may proceed.

DATES: Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to the Arizona Museum of Natural History at the address in this notice by June 15, 2020.

ADDRESSES: Melanie Deer, Arizona Museum of Natural History, 53 N MacDonald, Mesa, AZ 85201, telephone (480) 644–4381, email *melanie.deer@mesaaz.gov.*

SUPPLEMENTARY INFORMATION: Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, of the completion of an inventory of human remains and associated funerary objects under the control of the Arizona Museum of Natural History, Mesa, AZ. The human remains and associated funerary objects were removed from various locations in AZ.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003(d)(3). The determinations in this notice are the sole responsibility of the museum, institution, or Federal agency that has control of the Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations in this notice.

Consultation

A detailed assessment of the human remains was made by the Arizona Museum of Natural History professional staff in consultation with representatives of the Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; and the Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona.

History and Description of the Remains

In 1979, human remains representing, at minimum, one individual were removed near Florence, Pinal County, AZ. On August 4, 1984 they were donated to the Arizona Museum of Natural History by Al Heimer (presumably the person who excavated them). No known individual was identified. No associated funerary objects are present.

Based on current archeological evidence, the region where these human remains were collected was occupied in prehistoric times by people belonging to the Hohokam Material Culture. Based on current archeological and ethnographic evidence, these people are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. The Four Southern Tribes of Arizona divide their ancestral lands such that each Tribe oversees those portions closest to their reservations. The Florence area is primarily Gila River Indian Community ancestral land.

Sometime prior to December 29, 1984, human remains representing, at minimum, one individual were removed from land in AZ. This individual was donated to the Arizona Museum of Natural History on December 29, 1984 by Gregory Brooks, a resident of Chandler, Maricopa County, AZ. No known individual was identified. The one associated funerary object is one lot of ceramic sherds.

Based on the style of the ceramics, the human remains and object are related to people belonging to the prehistoric Hohokam Material Culture, who are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. Maricopa County is primarily Gila River Indian Community and Salt River Pima-Maricopa Indian Community ancestral land, and the Chandler area is primarily Gila River Indian Community ancestral land.

Sometime prior to November 20, 1980, human remains representing, at minimum, two individuals were removed from land in AZ. On November 20, 1980, William Chesley facilitated the anonymous donation of the human remains to the Arizona Museum of Natural History. No known individuals were identified. The four associated funerary objects are three ceramic jars and one ceramic bowl.

Based on the style of the ceramics, the human remains and objects are related to people belonging to the prehistoric Hohokam Material Culture. Based on archeological and ethnographic evidence, these people are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. As the facilitator (Chesley) also made a donation to the museum that originated from the Pettijohn Site in Stanfield, Pinal County, AZ, which is on Gila River Indian Community ancestral land, the Gila River Indian Community and Salt River Pima-Maricopa Indian Community have decided that the Gila River Indian Community would take the lead with respect to these human remains and objects.

Sometime prior to November 17, 1977, human remains representing, at minimum, one individual were removed from the Pettijohn Site in Stanfield, Pinal County, AZ. On November 17, 1977, the human remains were donated to the Arizona Museum of Natural History by William Chesley. No known individual was identified. The one associated funerary object is a ceramic jar.

Although no information is known about the Pettijohn Site itself, based on the style of the ceramic jar and the location of the site, the human remains and object are related to people belonging to the prehistoric Hohokam Material Culture, who are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. The Pettijohn Site is primarily Gila River Indian Community ancestral land.

On November 30, 1983, human remains representing, at minimum, two individuals were removed from a house in Mesa, Maricopa County, AZ. These individuals were found by a construction crew, who alerted the Mesa Police Department. The human remains were determined to be associated with a prehistoric site. Subsequently, they were donated to the Arizona Museum of Natural History. No known individuals were identified. The one associated funerary object is a shell bracelet.

Based on current archeological evidence, the region where these human remains were collected was occupied in prehistoric times by people belonging to the Hohokam Material Culture. Based on archeological and ethnographic evidence, these people are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. The Mesa area is primarily Salt River Pima-Maricopa Indian Community ancestral land.

From 1979 to 1991, human remains representing, at minimum, 75 individuals were removed from Park of the Canals in Mesa, Maricopa County, AZ. This portion of the site was excavated by the Southwest Archaeological Team, led by Sam Baar. No known individuals were identified. The eight associated funerary objects are ceramic vessels.

Based on the style of the ceramics and the location of the site, the human remains and objects are related to people belonging to the Hohokam Material Culture. Based on current archeological and ethnographic evidence, these people are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. The Mesa area is primarily Salt River Pima-Maricopa Indian Community ancestral land.

In 2005, 2010, and 2011, human remains representing, at minimum, four individuals were removed from the Riverview site in Mesa, Maricopa County, AZ. No known individuals were identified. The two associated funerary objects are one ceramic bowl and one lot of sherds.

Based on the style of the ceramics and the location of the site, the human remains and objects are related to people belonging to the Hohokam Material Culture. Based on current archeological and ethnographic evidence, these people are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. The Mesa area is primarily Salt River Pima-Maricopa Indian Community ancestral land.

Prior to 2018, human remains representing, at minimum, 11 individuals were removed from AZ. The human remains were found during the cleaning of an archeological lab at the Arizona Museum of Natural History used for studying prehistoric Hohokam Material Culture. No known individuals were identified. The nine associated funerary objects are one lot of corn, one lot of beans, two lots of stones, one lot of possible asbestos, one ceramic bowl, two lots of sherds, and one lot of soil associated with cremation.

Based on the lab's use, the human remains and objects are related to people belonging to the prehistoric Hohokam Material Culture. Based on archeological and ethnographic evidence, these people are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe.

Sometime prior to 1982, human remains representing, at minimum, one individual were removed from Mesa Grande in Mesa, Maricopa County, AZ. The human remains were excavated by Midvale and donated to the Arizona Museum of Natural History in 1982. No known individual was identified. The two associated funerary objects are one burn corn and one lot of ceramic sherds.

Based on the style of the ceramics and location of the site, the human remains and objects are related to people belonging to the prehistoric Hohokam Material Culture. Based on current archeological and ethnographic evidence, theses people are ancestral to the Four Southern Tribes of Arizona (*i.e.,* the Tohono O'odham Nation, Gila River Indian Community, Salt River-Pima Maricopa Indian Community, and Ak-Chin Indian Community) and the Hopi Tribe. The Mesa Grande site is primarily Salt River Pima-Maricopa Indian Community ancestral land.

Determinations Made by the Arizona Museum of Natural History

Officials of the Arizona Museum of Natural History have determined that:

- Pursuant to 25 U.S.C. 3001(9), the human remains described in this notice represent the physical remains of 98 individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(3)(A), the 28 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American human remains and associated funerary objects and the Ak-Chin Indian Community (previously listed as Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona); Gila River Indian Community of the Gila River Indian Reservation, Arizona; Hopi Tribe of Arizona; Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona; and the Tohono O'odham Nation of Arizona (hereafter referred to as ''The Tribes'').

Additional Requestors and Disposition

Lineal descendants or representatives of any Indian Tribe or Native Hawaiian organization not identified in this notice that wish to request transfer of control of these human remains and associated funerary objects should submit a written request with information in support of the request to Melanie Deer, Arizona Museum of Natural History, 53 N MacDonald, Mesa, AZ 85201, telephone (480) 644–4381, email *melanie.deer@mesaaz.gov,* by June 15, 2020. After that date, if no additional requestors have come forward, transfer of control of the human remains and associated funerary objects to The Tribes may proceed.

The Arizona Museum of Natural History is responsible for notifying The Tribes that this notice has been published.

Dated: March 25, 2020.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2020–10344 Filed 5–13–20; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR02910000, XXXR0680R1, RR.17529652.2900012]

Notice of Intent To Prepare a Supplemental Environmental Impact Statement for the B.F. Sisk Dam Raise and Reservoir Expansion Project, Merced County, California

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of intent; request for comments.

SUMMARY: The Bureau of Reclamation (Reclamation) intends to prepare a Supplemental Environmental Impact Statement (SEIS) for the B.F. Sisk Dam Raise and Reservoir Expansion Project. Reclamation is requesting public and agency comment to identify significant issues or other alternatives to be addressed in the SEIS.

DATES: Submit written comments on the scope of the SEIS on or before June 15, 2020.

ADDRESSES: Provide written scoping comments, requests to be added to the mailing list, or requests for other special assistance needs to Ms. Casey Arthur, Project Manager, Bureau of Reclamation, Willows Construction Office, 1140 W. Wood Street Willows, CA, 95988.

FOR FURTHER INFORMATION CONTACT: Ms. Casey Arthur, Project Manager, Bureau of Reclamation, Willows Construction Office, 1140 W. Wood Street Willows, CA, 95988.; telephone (530) 892–6202; facsimile (530) 934–7679; email *carthur@usbr.gov.* Persons who use a telecommunications device for the deaf may call the Federal Relay Service (FedRelay) at 1–800–877–8339 TTY/ASCII to contact the above individual during normal business hours or to leave a message or question after hours. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: Reclamation is issuing this notice pursuant to the National Environmental Policy Act of 1969, as amended (NEPA), 42 U.S.C. 4321 *et seq.;* the Council on Environmental Quality's (CEQ) regulations for implementing NEPA, 43 CFR parts 1500 through 1508; and the Department of the Interior's NEPA regulations, 43 CFR part 46.

Background

B.F. Sisk Dam is an earth-filled gravity embankment dam with a crest height of 382 feet and an overall length of about 3.5 miles, impounding San Luis Reservoir with a capacity of 2,041,000 acre-feet (AF). The dam is located near Santa Nella, California, along Pacheco Pass. Although the dam was constructed and is owned by Reclamation, the California Department of Water Resources (DWR) operates the facilities, and the California Department of Parks and Recreation manages the recreational resources associated with San Luis Reservoir. San Luis Reservoir is an off-stream reservoir within Reclamation's Central Valley Project (CVP) and DWR's State Water Project.

Reclamation's Safety of Dams Office completed a risk analysis of B.F. Sisk Dam that evaluated dam stability in the event of seismic activity that proposed a structural solution, which included a crest raise. Reclamation and DWR prepared an environmental impact statement (EIS)/environmental impact report (EIR) analyzing the effects from a No Action Alternative, Operational Alternative, and Crest Raise Alternative, and noticed the availability of the Final EIS/EIR to the public via the **Federal Register** on August 23, 2019 (84 FR 44295). In December 2019, Reclamation signed a Record of Decision providing the rationale for choosing the Crest Raise Alternative (*https://www.usbr.gov/mp/nepa/nepa_project_details.php?Project_ID=34281*). Reclamation is currently designing the Crest Raise Alternative under the B.F. Sisk Safety of Dams (SOD) Modification Project.

As a connected action to the B.F. Sisk SOD Modification Project, Reclamation and San Luis and Delta Mendota Water Authority (SLDMWA) seek to evaluate an increase in storage capacity of the San Luis Reservoir. The increased storage capacity would be achieved by an additional 10-foot raise of the B.F. Sisk Dam embankment across the entire dam crest above the level proposed for dam safety purposes (Proposed Action). This additional 10 feet of dam embankment could add approximately 120,000 AF of water storage to San Luis Reservoir. SLDMWA, in coordination with Reclamation, is conducting a feasibility study to evaluate the Proposed Action and a potential cost-share in accordance with the Reclamation SOD Act (43 U.S.C. 506 *et seq.*), as amended by Public Law 114–113, and Section 4007 of the Water Infrastructure Improvements for the Nation (WIIN) Act (Pub. L. 114–322).

The Reclamation SOD Act of November 2, 1978, was amended to include authority for Reclamation to develop additional project benefits in conjunction with a SOD modification. Pursuant to Section 5.B. of the SOD Act, as amended, Reclamation must determine that additional project benefits are necessary and in the interest of the United States prior to developing any additional project benefits, consistent with Reclamation law. Furthermore, it must be determined that the development of additional project benefits will not negatively impact the SOD Modification Project.

As a potential funder for the Proposed Action under the WIIN Act, and in accordance with the amended SOD Act, Reclamation's preliminary purpose and need is to evaluate the feasibility report and determine if SLDMWA's request to increase storage capacity as an additional benefit in conjunction with the current SOD Modification Project is consistent with Reclamation Law, can support a Secretary of the Interior's finding of feasibility, has Federal benefits pursuant to the WIIN Act, and can be accomplished without negatively impacting the SOD Modification Project.

In addition to a feasibility study, Reclamation intends to complete a SEIS pursuant to NEPA to consider potential environmental effects from implementing the Proposed Action. This environmental document is supplemental to the Final EIS/EIR previously developed for the SOD Modification Project entitled B.F. Sisk Dam Safety of Dams Modification Project (84 FR 44295). Reclamation will focus the SEIS on analyzing effects to resources where a potentially significant impact exists. The resources intended to be discussed include: Water quality, surface water supply, geology and soils, air quality, greenhouse gas emissions, visual resources, noise, traffic and transportation, hazards and hazardous materials, terrestrial resources, recreation, and cultural resources including tribal cultural resources. Agencies and the public are encouraged to provide input regarding potentially significant issues to be addressed in the SEIS, or to identify potential alternatives that would meet the purpose of the Proposed Action.

Public Disclosure

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 may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Richard Welsh,

Principal Deputy Regional Director, Bureau of Reclamation, Interior Region 10—California-Great Basin.

[FR Doc. 2020–10296 Filed 5–13–20; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR06450000, 19XR0680A4, RX.08254998.0010010]

Off-Road Vehicle Designation for the San Angelo Project, Texas

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of off-road vehicle designation.

SUMMARY: This notice announces the Bureau of Reclamation's designation of areas for authorized off-road vehicle (ORV) use on Federal lands surrounding Twin Buttes Reservoir, which is part of the Bureau of Reclamation's San Angelo Project in Tom Green County, Texas.

DATES: This ORV designation is effective immediately and is permanent until canceled, amended, or replaced by the Bureau of Reclamation.

ADDRESSES: A copy of the off-road designation, including the Environmental Assessment and Finding of No Significant Impact, is available at *https://www.usbr.gov/gp/otao/.*

FOR FURTHER INFORMATION CONTACT: Mr. Trent Parish, Bureau of Reclamation, Oklahoma-Texas Area Office, 5316 Highway 290 West, Suite 110, Austin, TX 78735; (512) 899–4150; or email *jparish@usbr.gov.*

SUPPLEMENTARY INFORMATION: The use of off-road vehicles on public lands associated with Twin Buttes Reservoir, TX must be designated in accordance with 43 CFR 420 and other applicable Federal rules and regulations. In recognition of this, and with the prerequisite to ensure compliance with such Federal regulations, Reclamation, Texas Parks Wildlife Department, and the City of San Angelo completed a comprehensive inventory and condition assessment of existing resources, and coordinated extensively with local stakeholders to seek input from the public on preferred ORV uses, as well on overall recreation priorities. Federal lands were evaluated according to criteria outlined in 43 CFR 420.22 to determine their suitability for ORV use. This included all Federal lands associated with the San Angelo Project and Twin Buttes Reservoir located within Tom Green County, Texas. The assessment resulted in the proposed designation of 73 miles of trails and three ORV areas. This designation is the culmination of resource considerations and public involvement integrated into an Environmental Assessment and Finding of No Significant Impact (19–18–TX–SA) that were completed in accordance with the National Environmental Protection Act of 1969.

The ORV designation includes:

(a) Approximately 56 miles of designated access routes. Access routes provide reasonable access to lands surrounding Twin Buttes Reservoir's North and South Pools.

(b) Approximately 17 miles of Motorcycle/All-Terrain Vehicle (Moto/ATV) routes. Moto/ATV routes are a network of one-directional trails designated for motorized use by motorcycles and small ATVs

(c) Approximately 338 acres of ORV areas. The ORV areas are comprised of three separate tracts of land with variable terrain requiring more diverse ORV skill levels.

Mark A. Treviño,

Oklahoma—Texas Area Manager, Bureau of Reclamation, Arkansas-Rio Grande-Texas-Gulf—Interior Region 6.

[FR Doc. 2020–10349 Filed 5–13–20; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1012 (Third Review)]

Frozen Fish Fillets From Vietnam; Scheduling of a Full Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of a full review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on frozen fish fillets from Vietnam would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. The Commission has determined to exercise its authority to extend the review period by up to 90 days.

DATES: May 11, 2020.

FOR FURTHER INFORMATION CONTACT: Stamen Borisson ((202) 205–3125), 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 this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On January 6, 2020, the Commission determined that responses to its notice of institution of the subject five-year review were such that a full review should proceed (85 FR 3417, January 21, 2020); accordingly, a full review is being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in the review 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 this review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

For further information concerning the conduct of this review 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, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings at 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 section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission's notice of institution of the review 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 review will be placed in the nonpublic record on August 24, 2020, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold a hearing in connection with the review beginning at 9:30 a.m. on Tuesday, September 15, 2020, at the U.S. International Trade Commission Building. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before September 4, 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 September 9, 2020, at the U.S. International Trade Commission Building, if deemed necessary. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), 207.24, and 207.66 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 to the review may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is September 2, 2020. Parties may also file written testimony in connection with their presentation at the hearing, as provided in section 207.24 of the Commission's rules, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is September 22, 2020. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review on or before September 22, 2020. On October 20, 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 October 22, 2020, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 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 section 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 sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (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.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C.1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.
Issued: May 11, 2020.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2020–10358 Filed 5–13–20; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0076]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Application for Restoration of Explosives Privileges—ATF Form 5400.29

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-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. The proposed information collection (IC) OMB 1140–0076 (Application for Restoration of Explosives Privileges—ATF Form 5400.29), is being revised to include multiple material and formatting changes. The proposed IC is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 13, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Laura O'Lena, NCETR/Explosives Enforcement and Training Division, Explosives Enforcement Branch, either by mail at 3750 Corporal Road, Huntsville, Alabama 35898, by email at *EROD@atf.gov,* or by telephone at 256–261–7640.

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 (check justification or form 83):*

Revision of a currently approved collection.

2. *The Title of the Form/Collection:* Application for Restoration of Explosives Privileges.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 5400.29.

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 (if applicable): Business or other for-profit.

Abstract: Persons who wish to ship, transport, receive, or possess explosive materials, but are prohibited from doing so, must complete the Application for Restoration of Explosives Privileges—ATF Form 5400.29. The completed form must be submitted to ATF, to determine if the applicant is likely to act in a manner that endangers public safety, and that granting relief is not contrary to the public interest.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 300 respondents will utilize the form annually, and it will take each respondent approximately 30 minutes to complete the form.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 150 hours, which is equal to 300 (# of respondents) * 1 (# responses per respondents) * .5 (30 minutes or the total time to complete each response).

7. *An Explanation of the Change in Estimates:* The adjustment to this IC include an increase in the public burden cost to $ 9,765, which is due to inclusion of the cost to conduct ATF in-person interviews with both the respondent's supervisor and a coworker, as well as mailing costs.

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: May 11, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–10366 Filed 5–13–20; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0013]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension With Change of a Currently Approved Collection; Application for Tax-Exempt Transfer of Firearm and Registration to Special Occupational Taxpayer—ATF Form 3 (5320.3)

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-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. The proposed information collection (IC) is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 13, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: James Chancey, National Firearms Act Division, either by mail at 244 Needy Road, Martinsburg, WV 25405, by email at *nfaombcomments@atf.gov,* or by telephone at 304–616–4500.

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 (check justification or form 83):* Extension with or without change of a currently approved collection.

2. *The Title of the Form/Collection:* Application for Tax-Exempt Transfer of Firearm and Registration to Special Occupational Taxpayer.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number (if applicable): ATF Form 3 (5320.3).

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: Business or other for-profit.

Other (if applicable): Federal Government.

Abstract: The Application for Tax-Exempt Transfer of Firearm and Registration to Special Occupational Taxpayer—ATF Form 3 (5320.3) form is used by Federal firearms licensees, to apply for the transfer and registration of a National Firearms Act (NFA) firearm that is subject to exemption from transfer tax, as provided by 26 U.S.C. 5852(d).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 130, 289 respondents will utilize the form annually, and it will take each respondent approximately 30 minutes 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 65,145 hours, which is equal to 130, 289 (# of respondents) * 1 (# of responses per respondent) * .5 (30 minutes or the total time taken to complete each response).

7. *An Explanation of the Change in Estimates:* The adjustments to this information collection include a decrease in the total responses by 47,211. Consequently, the annual burden hours has also reduced by 23,605. However, the public cost

increased to $ 4,292, because some respondents completed and mailed their applications to ATF for processing, although this collection can be electronically submitted.

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: May 11, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–10362 Filed 5–13–20; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Bureau of Alcohol, Tobacco, Firearms and Explosives

[OMB Number 1140–0049]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change of a Currently Approved Collection Application for National Firearms Examiner Academy—ATF Form 6330.1

AGENCY: Bureau of Alcohol, Tobacco, Firearms and Explosives, Department of Justice.

ACTION: 60-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. The proposed information collection (IC) is also being published to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and will be accepted for 60 days until July 13, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments, regarding the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions, or additional information, please contact: Sheila Hopkins, Office of Science and Technology, Laboratory Services, either by mail at National Laboratory Center, 6000 Ammendale Rd., Ammendale, MD 20705, by email at *Sheila.hopkins@atf.gov,* or by telephone at 202–648–6061.

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* (check justification or form 83): Extension without change of a currently approved collection.

2. *The Title of the Form/Collection:* Application for National Firearms Examiner Academy.

3. *The agency form number, if any, and the applicable component of the Department* sponsoring the collection:

Form number (if applicable): ATF Form 6330.1.

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: State, Local or Tribal Government.

Other (if applicable): Federal Government.

Abstract: The information requested on the Application for National Firearms Examiner Academy—ATF Form 6330.1 must be provided by all prospective students of the ATF National Firearms Examiner Academy (NFEA). The collected information will be used to determine the applicant's eligibility to acquire firearms and toolmark examiner training at the NFEA.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 75 respondents will utilize the form annually, and it will take each respondent approximately 12 minutes 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 15 hours, which is equal to 75 (# of respondents) * 1 (# of responses per respondent) * .20 (12 minutes or the time taken to prepare each 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: May 11, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–10360 Filed 5–13–20; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Modification of Consent Decree Under the Clean Water Act and Oil Pollution Act

On May 7, 2020, the Department of Justice lodged with the United States District Court for the Western District of Michigan a proposed Fifth Modification of Consent Decree in the lawsuit entitled *United States* v. *Enbridge Energy, Limited Partnership, et al.,* Civil Action No. 1:16–cv–914.

On May 23, 2017, the United States District Court for the Western District of Michigan approved and entered a Consent Decree that resolved specified claims asserted by the United States against Enbridge Energy, Limited Partnership and eight affiliated entities (''Enbridge'') under the Clean Water Act and Oil Pollution Act arising from two separate 2010 oil spills resulting from failures of Enbridge oil transmission pipelines near Marshall, Michigan and Romeoville, Illinois. The complaint filed by the United States alleged that Enbridge's pipelines had unlawfully discharged oil into waters of the United States and sought civil penalties, recovery of removal costs, and injunctive relief. The Consent Decree established various requirements applicable to a network of 14 pipelines that comprise Enbridge's Lakehead

System—including requirements governing excavation, repair or mitigation, and imposition of interim pressure restrictions for various features, such as dents, corrosion and cracks, that are detected through In-Line Inspections (''ILI'') of such pipelines.

The proposed Fifth Modification of Consent Decree (''Modification'') revises several different provisions of the Consent Decree. A major focus of the proposed Modification is to clarify and revise requirements applicable to one specific type of feature detected on Lakehead System pipelines—dent features that intersect or interact with corrosion features (''dent/corrosion features''). The Modification clarifies that Enbridge must identify all dent features, regardless of the dent depth, and determine whether detected dent features intersect with corrosion features. The Modification establishes requirements for evaluation of dent/corrosion features applying new analytical techniques that would be used to determine whether such features require excavation, repair or mitigation, or interim pressure restrictions. In addition to requiring use of the new methodologies going forward, the Modification includes requirements for re-examining certain previously collected ILI data to identify shallow dent features that Enbridge had not evaluated in the period prior to March 31, 2019, as well as requirements to apply the new analytical methodologies to any additional dent/corrosion features identified based on the re-examination of old data.

In addition to revisions that support new requirements governing the evaluation of dent/corrosion features, the proposed Modification revises the definition of Established Maximum Operating Pressure (''MOP'') to incorporate revised MOP values for Enbridge's Line 61. The revised MOP values reflect corrected information on pipe wall thickness obtained during a data quality review of Enbridge's pipeline information. The proposed Modification also revises and clarifies provisions of the Consent Decree relating to Priority Feature notifications. In the proposed revision of Appendix A, features referred to as ''ovalities'' would be subject to a separate Priority Feature notification criterion from the criterion applicable to other geometric features. Finally, the proposed Modification would revise Table 4 of the Consent Decree to clarify that a dig selection criterion applicable to dents on portions of Line 61 is intended to apply only to dents with depths greater than a specified depth.

The publication of this notice opens a period for public comment on the proposed Fifth Modification of Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Enbridge Energy, Limited Partnership, et al.,* D.J. Ref. No. 90–5–1–1–10099. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed Fifth Modification of Consent Decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* The Justice Department will provide a paper copy of the proposed Fifth Modification of Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

In requesting a paper copy, please enclose a check or money order for $7.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Patricia A. McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2020–10306 Filed 5–13–20; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0330]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection; Law Enforcement Congressional Badge of Bravery

AGENCY: Bureau of Justice Assistance, Department of Justice.

ACTION: 30-day notice.

SUMMARY: BJA's CBOB Office will use the CBOB application information to confirm the eligibility of applicants to be considered for the CBOB, and forward the application as appropriate to the Federal or the State and Local CBOB Board for their further consideration. This proposed information collection was previously published in the **Federal Register** allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 60 days until June 15, 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 Bureau of Justice Statistics, 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:* Extension of a currently approved collection.

2. *The Title of the Form/Collection:* Law Enforcement Congressional Badge of Bravery

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* None.

4. *Affected public who will be asked or required to respond, as well as a brief*

abstract: Law Enforcement Agencies. Under Public Law No: 110–298 The US Department of Justice Attorney General may request voluntary nominations from an appointed Federal Board, for the names of law enforcement officers cited as performing an act of bravery while in the line of duty, for a Federal Law Enforcement Congressional Badge of Bravery award.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 184 applicants annually.

6. *An estimate of the total public burden (in hours) associated with the collection:* The estimated public burden associated with this collection is 61 hours.

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: May 11, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–10364 Filed 5–13–20; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0243]

Agency Information Collection Activities; Proposed eCollection; eComments Requested; Revision of a Currently Approved Collection: Office of Justice Programs' Justice Grants System/JustGrants (formerly Community Partnership Grants Management System)

AGENCY: Office of Audit, Assessment, and Management, Office of Justice Programs.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs (OJP), will be submitting 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. The proposed information collection is published to obtain comments from the public and affected agencies.

DATES: The purpose of this notice is to allow for an additional 60 days for public comment until July 13, 2020.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions for information, please contact please contact: Maria Swineford, (202) 616–0109, Office of Audit, Assessment, and Management, Office of Justice Programs, U.S. Department of Justice, 810 Seventh Street NW, Washington, DC 20531 or *maria.swineford@usdoj.gov.*

SUPPLEMENTARY INFORMATION: This process is conducted in accordance with 5 CFR 1320.10. 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;

—Enhance the quality, utility, and clarity of the information to be collected; 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:

(1) *Type of Information Collection:* Renewal of a currently approved collection (1121–0243).

(2) *The Title of the Form/Collection:* Justice Grants System (JustGrants).

(3) *The Agency Form Number, if any, and the Applicable Component of the Department Sponsoring the Collection:*

Form Number: None.

Component: Office of Justice Programs, Department of Justice.

(4) *Affected Public Who Will be Asked or Required to Respond, as well as a Brief Abstract:*

Primary: State, Local or Tribal Governments, Organizations, and Institutes of Higher Education, and other applicants, applying for grants.

Other: None.

Abstract: JustGrants is a replacement for a collection of legacy systems currently used by the COPS Office, OJP, and OVW. Functionality of JustGrants includes online application submission; peer review; and grant award and award management which includes: award notification and acceptance, grant adjustment modification (GAM); draw down of funds (via the Department of Treasury-managed Automated Standard Application for Payments (ASAP) system system); post-award programmatic progress reports, special reports financial reports, monitoring and audit, performance measures, and subaward reports; closeouts and compliance. JustGrants facilitates reporting to Congress and other interested agencies. The system provides essential information required to comply with the Federal Funding Accountability and Transparency Act of 2006 (FFATA). JustGrants has also been designated the OJP official system of record for grants activities by the National Archives and Records Administration (NARA).

(5) *An Estimate of the Total Number of Respondents and the Amount of Time Estimated for an Average Respondent to Respond:* An estimated 6,402 organizations will respond to JustGrants and on average it will take each of them up to 10 hours to complete various award lifecycle processes within the system varying from application submission, award management and reporting, and award closeout.

(6) *An Estimate of the Total Public Burden (in hours) Associated with the collection:* The estimated public burden associated with this application is 64,118 hours.

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: May 11, 2020.

Melody Braswell,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2020–10365 Filed 5–13–20; 8:45 am]

BILLING CODE 4410–02–P

NATIONAL FOUNDATION OF THE ARTS AND THE HUMANITIES

Institute of Museum and Library Services

41st Meeting of the National Museum and Library Services Board

AGENCY: Institute of Museum and Library Services (IMLS), National

Foundation of the Arts and the Humanities (NFAH).

ACTION: Notice of meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the National Museum and Library Services Board will meet to advise the Director of the Institute of Museum and Library Services (IMLS) with respect to duties, powers, and authority of IMLS relating to museum, library, and information services, as well as coordination of activities for the improvement of these services.

DATES: The meeting will be held on June 11, 2020, from 11:00 a.m. Eastern Time until adjourned.

ADDRESSES: The meeting will convene virtually. In order to enhance openness and public participation, virtual meeting and audio conference technology will be used during the meeting. Instructions will be sent to all public registrants.

FOR FURTHER INFORMATION CONTACT: Katherine Maas, Project Specialist and Alternate Designated Federal Officer, Institute of Museum and Library Services, Suite 4000, 955 L'Enfant Plaza North SW, Washington, DC 20024; (202) 653–4798; *kmaas@imls.gov* (*mailto:kmaas@imls.gov*).

SUPPLEMENTARY INFORMATION: The National Museum and Library Services Board is meeting pursuant to the National Museum and Library Service Act, 20 U.S.C. 9105a, and the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.

The 41st Meeting of the National Museum and Library Services Board will be held on June 11, 2020. A plenary session (open to the public) will convene online at 11:00 a.m. Eastern Time, followed by an Executive Session (closed to the public).

The agenda for the plenary session of the National Museum and Library Services Board will be as follows:

I. Call to Order and Welcome
II. Approval of Minutes
  Board Program: Museums, Libraries, and COVID–19 Response
III. Introduction
IV. Legislative Framework
V. Office of Library Services Report
VI. Office of Museum Services Report
VII. REALM (REopening Archives, Libraries and Museums) Project Report
  Operational Reports
VIII. Financial and Operations Report
IX. Communications Report
X. Office of the Chief Information Officer Report
XI. Board Discussion

As identified above, portions of the meeting of the National Museum and Library Services Board will be closed to the public pursuant to subsections (c)(4), (c)(6) and (c)(9) of section 552b of Title 5, United States Code, as amended. The closed session will consider information that may disclose: Trade secrets and commercial or financial information obtained from a person and privileged or confidential; and information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action.

If you wish to attend the virtual public session of the meeting, please inform IMLS as soon as possible, but no later than close of business on June 8, 2020, by contacting Katherine Maas at *kmaas@imls.gov* (*mailto:kmaas@imls.gov*). Virtual meeting and audio instructions will be sent to all public registrants. Please provide notice of any special needs or accommodations by May 28, 2020.

Dated: May 8, 2020.

Kim Miller,

Senior Grants Management Specialist, Institute of Museum and Library Services.

[FR Doc. 2020–10302 Filed 5–13–20; 8:45 am]

BILLING CODE 7036–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995. This is the second notice for public comment; the first was published in the **Federal Register**, and no comments were received. NSF is forwarding the proposed submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice.

DATES: 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: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314, or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

Copies of the submission may be obtained by calling 703–292–7556.

SUPPLEMENTARY INFORMATION: NSF may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Comments regarding (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility and clarity of the information to be collected; (d) ways to 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 should be addressed to the points of contact in the **FOR FURTHER INFORMATION CONTACT** section.

Title of Collection: Grantee Reporting Requirements for the Emerging Frontiers in Research and Innovation Program.

OMB Number: 3145–0233.

Type of Request: Revision to and extension of approval of an information collection.

Proposed Project: The Emerging Frontiers in Research and Innovation (EFRI) program recommends, prioritizes, and funds interdisciplinary initiatives at the emerging frontier of engineering research and education. These investments represent transformative opportunities, potentially leading to: New research areas for NSF, ENG, and other agencies; new industries or capabilities that result in a leadership position for the country; and/or significant progress on a recognized national need or grand challenge.

Established in 2007, EFRI supports cutting-edge research that is difficult to fund through other NSF programs, such

as single-investigator grants or large research centers. EFRI seeks high-risk opportunities with the potential for a large payoff where researchers are encouraged to stretch beyond their ongoing activities. Based on input from workshops, advisory committees, technical meetings, professional societies, research proposals, and suggestions from the research community, the EFRI program identifies those emerging opportunities and manages a formal process for funding their research. The emerging ideas tackled by EFRI are ''frontier'' because they not only push the understood limits of engineering but actually overlap multiple fields. The EFRI funding process inspires investigators with different expertise to work together on one emerging concept.

EFRI awards require multi-disciplinary teams of at least one Principal Investigator and two Co-Principal Investigators. The anticipated duration of all awards is 4-years. With respect to the anticipated funding level, each project team may receive support of up to a total of $2,000,000 spread over four years, pending the availability of funds. In this respect, EFRI awards are above the average single-investigator award amounts.

EFRI-funded projects could include research opportunities and mentoring for educators, scholars, and university students, as well as outreach programs that help stir the imagination of K–12 students, often with a focus on groups underrepresented in science and engineering.

We are seeking to collect additional information from the grantees about the outcomes of their research that goes above and beyond the standard reporting requirements used by the NSF and spans over a period of 5 years after the award. This data collection effort will enable program officers to longitudinally monitor outputs and outcomes given the unique goals and purpose of the program. This is very important to enable appropriate and accurate evidence-based management of the program and to determine whether or not the specific goals of the program are being met.

Grantees will be requested to submit this information on an annual basis to support performance review and the management of EFRI grants by EFRI officers. EFRI grantees will be requested to submit these indicators to NSF via a data collection website that will be embedded in NSF's IT infrastructure. These indicators are both quantitative and descriptive and may include, for example, the characteristics of project personnel and students; sources of complementary funding and in-kind support to the EFRI project; characteristics of industrial and/or other sector participation; research activities; education activities; knowledge transfer activities; patents, licenses; publications; descriptions of significant advances and other outcomes of the EFRI effort.

Each submission will address the following major categories of activities: (1) Knowledge transfer across disciplines, (2) innovation of ideas in areas of great opportunity, (3) potential for translational research, (4) project results that advance the frontier/creation of new fields of study, (5) introduction to the classroom of innovative research methods or discoveries, (6) fostering participation of underrepresented groups in science, and (7) impacting student career trajectory. For each of the categories, the report will enumerate specific outputs and outcomes.

Use of the Information: The data collected will be used for NSF internal reports, historical data, and performance review by peer site visit teams, program level studies and evaluations, and for securing future funding for continued EFRI program maintenance and growth.

Estimate of Burden: Approximately 7 hours per grant for approximately 100 grants per year for a total of 700 hours per year.

Respondents: Principal Investigators who lead the EFRI grants, and co-Principal Investigators and students involved in EFRI-funded research.

Estimated Number of Responses per Report: One report collected for each of the approximately 100 grantees every year, including sub-reports from co-PIs and student researchers.

Dated: May 8, 2020.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2020–10299 Filed 5–13–20; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–346; NRC–2020–0111]

Energy Harbor Nuclear Corp.; Energy Harbor Nuclear Generation LLC; Davis-Besse Nuclear Power Station, Unit No. 1

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has issued a temporary exemption from certain periodic training and requalification requirements for security personnel at the Davis-Besse Nuclear Power Station, Unit No. 1, in response to an April 23, 2020, request, as supplemented on May 6, 2020, from Energy Harbor Nuclear Corp.

DATES: The temporary exemption was issued on May 8, 2020.

ADDRESSES: Please refer to Docket ID NRC–2020–0111. 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–2020–0111. 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 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.* 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. The NRC staff's approval is available in ADAMS under Accession No. ML20119B072.

FOR FURTHER INFORMATION CONTACT: Blake A. Purnell, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1380, email: *Blake.Purnell@nrc.gov.*

SUPPLEMENTARY INFORMATION: The text of the exemption is attached.

Dated: May 11, 2020.

For the Nuclear Regulatory Commission.

Blake A. Purnell,

Project Manager, Plant Licensing Branch III, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

Attachment—Exemption

NUCLEAR REGULATORY COMMISSION

Docket No. 50–346

Energy Harbor Nuclear Corp.

Energy Harbor Nuclear Generation LLC; Davis-Besse Nuclear Power Station, Unit No. 1; Exemption

I. Background

Energy Harbor Nuclear Corp. (EHNC) and Energy Harbor Nuclear Generation LLC (collectively, the licensees) are the holders of the Renewed Facility Operating License No. NPF–3 for Davis-Besse Nuclear Power Station, Unit No. 1 (Davis-Besse), which consists of a pressurized-water reactor (PWR) located in Ottawa County, Ohio. The license provides, among other things, that the facility is subject to all the rules, regulations, and orders of the U.S. Nuclear Regulatory Commission (NRC, Commission) now or hereafter in effect.

II. Request/Action

By letter dated April 23, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20114E221), as supplemented by letter dated May 6, 2020 (ADAMS Accession No. ML20128J218), EHNC requested a temporary exemption from certain periodic requalification requirements for security personnel in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 73, Appendix B, Section VI, ''Nuclear Power Reactor Training and Qualification Plan for Personnel Performing Security Program Duties,'' pursuant to 10 CFR 73.5, ''Specific exemptions.'' Specifically, due to the Coronavirus Disease 2019 (COVID–19) public health emergency (PHE) currently affecting the United States and the state of emergency declared by the State of Ohio on March 9, 2020, EHNC requests a temporary exemption from the following requirements in 10 CFR part 73, Appendix B, Section VI, related to periodic training and requalification of security personnel at Davis-Besse:

- *Paragraph B.5.(a):* ''At least annually, armed and unarmed individuals shall be required to demonstrate the capability to meet the physical requirements of this appendix [10 CFR part 73, Appendix B] and the licensee training and qualification plan.''
- *Paragraph C.3.(l)(1) in part:* ''Each member of each shift who is assigned duties and responsibilities required to implement the safeguards contingency plan and licensee protective strategy participates in at least one (1) tactical response drill on a quarterly basis and one (1) force-on-force exercise on an annual basis.''
- *Paragraph D.1.(b)(3) in part:* ''Armed individuals shall be administered an annual written exam that demonstrates the required knowledge, skills, and abilities to carry out assigned duties and responsibilities as an armed member of the security organization.''
- *Paragraph D.2.(a):* ''Armed and unarmed individuals shall be requalified at least annually in accordance with the requirements of this appendix [10 CFR part 73, Appendix B] and the Commission-approved training and qualification plan.''
- *Paragraph E.1.(c):* ''The licensee shall conduct annual firearms familiarization training in accordance with the Commission-approved training and qualification plan.''
- *Paragraph E.1.(f) in part:* ''Armed members of the security organization shall participate in weapons range activities on a nominal four (4) month periodicity.''
- *Paragraph F.5.(a):* ''Armed members of the security organization shall be re-qualified for each assigned weapon at least annually in accordance with Commission requirements and the Commission-approved training and qualification plan, and the results documented and retained as a record.''

EHNC requested that this temporary exemption expire 90 days after the end of the COVID–19 PHE, or December 31, 2020, whichever occurs first.

III. Discussion

On January 31, 2020, the U.S. Department of Health and Human Services declared a PHE for the United States to aid the nation's healthcare community in responding to COVID–19. On March 11, 2020, the COVID–19 outbreak was characterized as a pandemic by the World Health Organization.

Pursuant to 10 CFR 73.5, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 73 when the exemptions are authorized by law, will not endanger life or property or the common defense and security, and are otherwise in the public interest.

EHNC is requesting a temporary exemption from the requirements in paragraphs B.5.(a), C.3.(l)(1), D.1.(b)(3), D.2.(a), E.1.(c), E.1.(f), and F.5.(a) of 10 CFR part 73, Appendix B, Section VI, related to the periodic training and requalification of security personnel, pursuant to 10 CFR 73.5. EHNC is requesting this temporary exemption to support licensee isolation activities (*e.g.,* social distancing, group size limitations, and self-quarantining) to help protect required site personnel from COVID–19 and ensure personnel remain capable of maintaining plant security. EHNC stated that these ''isolation activities restrict certain training activities.'' Notably, EHNC stated that: ''Range activities are challenged by current social distancing and safety guidelines relevant to COVID–19 response standards. Weapons range activities require significant staff support that potentially places armed individuals in the Energy Harbor Nuclear Corp. security organization and other security staff in close proximity to one another, increasing the likelihood of staff and officer exposure to COVID–19. Range activities present additional hygiene issues relevant to range facilities during the PHE.''

EHNC also stated that the requested exemption does not change physical security plans or defensive strategy. More specifically, EHNC stated that security personnel impacted by this exemption are currently satisfactorily qualified on all required tasks and are monitored regularly by supervisory personnel.

Licensee Provided Controls To Maintain the Knowledge, Skills, and Abilities of Security Personnel

EHNC has identified controls that have been or will be implemented at Davis-Besse to ensure impacted security personnel maintain the knowledge, skills, and abilities required to effectively perform assigned duties and responsibilities during the period of this temporary exemption (*i.e.,* up to 90 days after the end of the COVID–19 PHE, or December 31, 2020, whichever occurs first). A discussion of how these controls relate to the current requirements is provided below:

1. *Paragraph B.5.(a) of 10 CFR 73, Appendix B, Section VI:* The purpose of the annual physical requirements in paragraph B.5.(a) is to ensure armed and unarmed members of the licensee's security organization are capable of performing their assigned duties necessary for implementing the licensee's Commission-approved security plans, protective strategy, and implementing procedures. To help ensure impacted security personnel

maintain the knowledge, skills, and abilities required to effectively perform assigned duties and responsibilities at Davis-Besse, EHNC has established measures ''to ensure security personnel self-report and notify supervision or medical personnel, as appropriate, of changes related to their physical fitness that could impact their ability to perform their respective job function.''

2. *Paragraph C.3.(l)(1) of 10 CFR 73, Appendix B, Section VI:* The purpose of the quarterly tactical drills and the annual licensee conducted force-on-force exercises is to ensure that the site security force maintains its contingency response readiness. Participation in these drills and exercises also supports the requalification of security force members. To help ensure impacted security personnel maintain the knowledge, skills, and abilities required to effectively perform assigned duties and responsibilities at Davis-Besse, EHNC described the measures it is taking to ensure contingency response readiness. These measures are: Conducting individual table top discussions during the shift and review of response locations with adherence to social distancing standards; providing officers with shift discussion topics utilizing lessons learned from previous exercises and based on training lesson plans/material objectives; and providing for officer follow up questions and answers relevant to the focus topics with adherence to social distancing standards.

3. *Paragraphs D.1.(b)(3), D.2.(a), E.1.(c), and F.5.(a) of 10 CFR 73, Appendix B, Section VI:* The purpose of the annual requalification requirements is to ensure the licensee's armed and unarmed individuals possess the requisite knowledge, skills, and abilities to effectively perform assigned duties in accordance with the Commission-approved security plans, protective strategy, and implementing procedures for the site. To help ensure impacted security personnel maintain the knowledge, skills, and abilities required to effectively perform assigned duties and responsibilities at Davis-Besse, EHNC stated that it ''has established measures to ensure that individuals maintain performance capability despite not completing the annual requalification for the annual written exam, firearms familiarization and weapons requalification.'' These measures include lesson plan objective-based discussions topics regarding critical tasks necessary for performance of security duties and regarding the fundamentals of marksmanship.

4. *Paragraph E.1.(f) of 10 CFR 73, Appendix B, Section VI:* The purpose of the weapons range activity is to ensure that armed individuals in the licensee's security organization maintain weapons proficiency in support of the licensee's physical protection program. To help ensure impacted security personnel maintain the knowledge, skills, and abilities required to effectively perform assigned duties and responsibilities at Davis-Besse, EHNC stated that it ''will establish measures to ensure that individuals maintain performance capability despite not completing weapons range activities on a nominal four-month periodicity. Those measures include discussion topics regarding relevant range activities and are based on range training lesson plan objectives to maintain knowledge of weapon performance requirements.''

Restoring Compliance With 10 CFR 73, Appendix B, Section VI

EHNC requested that this exemption expire 90 days after the end of the COVID–19 PHE, or December 31, 2020, whichever occurs first. EHNC indicates that the additional time period after the end of the COVID–19 PHE will be used to restore compliance with the periodic security training and requalification requirements at Davis-Besse. To support restoring compliance with these requirements, EHNC stated that it will maintain a list with the names of the individuals that do not meet the periodic security requalification requirements, including the date(s) when each individual exceeds the required training periodicities. It is the NRC's expectation that any annual licensee-conducted force-on-force exercises that are delayed will be rescheduled so that they are completed after the PHE ends. Security personnel that miss one or more quarterly tactical drills during the period of the exemption would need to resume participation in those drills after the exemption expires.

A. The Exemption Is Authorized by Law

EHNC is requesting an exemption from the requirements related to periodic training and requalification of security personnel in paragraphs B.5.(a), C.3.(l)(1), D.1.(b)(3), D.2.(a), E.1.(c), E.1.(f), and F.5.(a) of 10 CFR part 73, Appendix B, Section VI. In accordance with 10 CFR 73.5, the Commission may grant exemptions from the regulations in 10 CFR part 73, as authorized by law. The NRC staff finds that granting the proposed exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, or other laws, and is, thus, authorized by law.

B. The Exemption Will Not Endanger Life or Property or the Common Defense and Security

EHNC stated that the requested exemption will not endanger life or property or the common defense and security. The requested exemption would temporarily allow the identified security training and requalification requirements to be deferred for security personnel currently satisfactorily qualified at Davis-Besse. EHNC indicated that although it had scheduled these requalification activities to comply with the regulation, these activities must be rescheduled to allow implementation of the EHNC pandemic response plan mitigation strategies. EHNC asserts that these strategies serve the public interest by ensuring adequate staff isolation and maintaining staff health to perform their job function actions during the COVID–19 PHE.

EHNC stated that the requested exemption is related to training requalification and does not change physical security plans or defensive strategy. EHNC stated that security personnel impacted by the requested exemption are currently satisfactorily qualified on all required tasks. EHNC also stated that security personnel are monitored regularly by supervisory personnel. As discussed above, EHNC identified controls that have been or will be implemented at Davis-Besse to ensure impacted security personnel maintain the knowledge, skills, and abilities required to effectively perform assigned duties and responsibilities. Therefore, EHNC stated that granting the requested temporary exemption will not endanger or compromise the common defense or security or the safeguarding of Davis-Besse. EHNC requested that the exemption expire 90 days after the end of the COVID–19 PHE, or December 31, 2020, whichever occurs first. EHNC stated that this timeframe is needed for it to restore compliance with the periodic security training and requalification requirements at Davis-Besse.

The NRC staff finds that the controls EHNC has or will establish for the duration of the exemption are adequate to ensure that the required security posture at Davis-Besse is maintained. These controls are adequate because they include a variety of mechanisms to help ensure impacted security personnel continue to maintain the knowledge, skills, and abilities required to perform assigned duties and responsibilities, and as a result, will continue to ensure adequate security of Davis-Besse. In addition, the requested duration of the exemption would allow

EHNC time to restore normal requalification processes at Davis-Besse in a systematic manner. For example, it may take time after the PHE has ended for security personnel affected by COVID–19 to fully recover and return to duty status. Based on the above, the NRC staff concludes that the proposed exemption would not endanger life or property or the common defense and security.

C. Otherwise in the Public Interest

On April 17, 2020, the Cybersecurity & Infrastructure Security Agency (CISA) within the U.S. Department of Homeland Security (DHS) published Version 3.0 of its ''Guidance on the Essential Critical Infrastructure Workforce: Ensuring Community and National Resilience in COVID–19 Response.'' Although that guidance is advisory in nature, it is designed to ensure ''continuity of functions critical to public health and safety, as well as economic and national security.'' In addition, the Centers for Disease Control and Prevention (CDC) has issued recommendations (*e.g.,* social distancing, limiting assemblies) to limit the spread of COVID–19.

EHNC stated, in part, that:

The Energy Harbor Nuclear Corp. pandemic response plan is based on [the Nuclear Energy Institute (NEI) guidance document] NEI 06–03, *Pandemic Threat Planning, Preparation, and Response Reference Guide* (Reference 4), which recommends isolation strategies such as sequestering, use of super crews or minimum staffing as well as social distancing, group size limitations and self-quarantining, in the event of a pandemic, to prevent the spread of the virus to the plant. NEI 06–03 provides other mitigation strategies that serve the public interest during a pandemic by ensuring adequate staff is isolated from the pandemic and remains healthy to perform their job function.

Keeping [Davis-Besse] in operation during the pandemic will help to support the public need for reliable electricity supply to cope with the pandemic. As the US Departments of Homeland Security and Energy have stated in their guidance, the electric grid and nuclear plant operation make up the nation's critical infrastructure similar to the medical, food, communications, and other critical industries. If the plant operation is impacted because it cannot comply with the security training requalification requirements while isolation activities are in effect for essential crew members, the area electrical grid would lose this reliable source of baseload power. In addition, [Davis-Besse] personnel could face the added transient challenge of shutting down their respective plant and possibly not restarting it until the pandemic passes. This does not serve the public interest in maintaining a safe and reliable supply of electricity.

EHNC stated that the requalification activities for security personnel at Davis-Besse must be rescheduled to allow implementation of the EHNC pandemic response plan mitigation strategies. In addition, EHNC indicated that this exemption would support the licensee's implementation of isolation activities (*e.g.,* social distancing, group size limitations, and self-quarantining) at Davis-Besse. EHNC stated these actions serve the public interest by ensuring adequate staff isolation and maintaining staff health to perform their job function during the COVID–19 PHE.

Based on the above and the NRC staff's aforementioned findings, the NRC staff concludes that granting the temporary exemption is in the public interest because it allows EHNC to maintain the required security posture at Davis-Besse while the facility continues to provide electrical power. The exemption also enables EHNC to reduce the risk of exposing essential security personnel at Davis-Besse to COVID–19.

D. Environmental Considerations

NRC approval of this exemption request is categorically excluded under 10 CFR 51.22(c)(25), and there are no special circumstances present that would preclude reliance on this exclusion. The NRC staff determined, per 10 CFR 51.22(c)(25)(vi)(E), that the requirements from which the exemption is sought involve education, training, experience, qualification, requalification, or other employment suitability requirements. The NRC staff also determined that approval of this exemption request involves no significant hazards consideration because it does not authorize any physical changes to the facility or any of its safety systems, nor does it change any of the assumptions or limits used in the facility licensee's safety analyses or introduce any new failure modes; no significant change in the types or significant increase in the amounts of any effluents that may be released offsite because this exemption does not affect any effluent release limits as provided in the facility licensee's technical specifications or by the regulations in 10 CFR part 20, ''Standards for Protection Against Radiation''; no significant increase in individual or cumulative public or occupational radiation exposure because this exemption does not affect limits on the release of any radioactive material or the limits provided in 10 CFR part 20 for radiation exposure to workers or members of the public; no significant construction impact because this exemption does not involve any changes to a construction permit; and no significant increase in the potential for or consequences from radiological accidents because this exemption does not alter any of the assumptions or limits in the facility licensee's safety analysis. In addition, the NRC staff determined that there would be no significant impacts to biota, water resources, historic properties, cultural resources, or socioeconomic conditions in the region. As such, there are no extraordinary circumstances present that would preclude reliance on this categorical exclusion. Therefore, pursuant to 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the approval of this exemption request.

IV. Conclusions

Accordingly, the NRC has determined that pursuant to 10 CFR part 73.5, the exemption is authorized by law, will not endanger life or property or the common defense and security, and is otherwise in the public interest. Therefore, the Commission hereby grants EHNC's request to exempt Davis-Besse from the requirements for periodic requalification of security personnel in paragraphs B.5.(a), C.3.(l)(1), D.1.(b)(3), D.2.(a), E.1.(c), E.1.(f), and F.5.(a) of 10 CFR part 73, Appendix B, Section VI. This exemption expires 90 days after the end of the COVID–19 PHE, or December 31, 2020, whichever occurs first.

Dated: May 8, 2020.

For the Nuclear Regulatory Commission.

Craig G. Erlanger,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2020–10369 Filed 5–13–20; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. C2020–1; Presiding Officer's Ruling No. 4]

Complaint of Randall Ehrlich

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is revising the procedural schedule for the Complaint of Randall Ehrlich v. United States Postal Service, which relates to alleged discrimination by Postal Service management in continuing a suspension of mail service due to a dog hold on the Complainant's residence. This notice informs the public of the revised procedural schedule.

DATES: *Prehearing Conference:* September 1, 2020 at 1:00 p.m. Eastern Daylight Time (10:00 a.m. Pacific Daylight Time) by telephone; *Hearing of evidence to begin:* October 5, 2020; *Deadline for requests to hold a hearing before the Presiding Officer for oral presentation of evidence:* no later than 7 days before the prehearing conference.

ADDRESSES: For additional information, Presiding Officer's Ruling No. 4 can be accessed electronically through the Commission's website at *https://www.prc.gov.*

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Revised Procedural Schedule

I. Introduction

Pursuant to 39 CFR 3001.19 and 39 CFR 3001.17, the Commission gives notice that the procedural schedule has been adjusted for the Complaint of Randall Ehrlich v. United States Postal Service, which relates to alleged discrimination by Postal Service management in continuing a suspension of mail service due to a dog hold on the Complainant's residence, potentially violating 39 U.S.C. 403(c).[1] This notice informs the public of the revised procedural schedule established in Presiding Officer's Ruling No. 4.[2]

II. Revised Procedural Schedule

1. A prehearing conference is scheduled to be conducted before the Presiding Officer on September 1, 2020 at 1:00 p.m. Eastern Daylight Time (10:00 a.m. Pacific Daylight Time) by telephone.

2. The hearing of evidence in this case shall begin October 5, 2020.

3. A request to hold a hearing before the Presiding Officer for the oral presentation of evidence (including any testimony) shall be filed no later than 7 days before the prehearing conference and shall specify each witness for which oral testimony is proposed.

Erica A. Barker,

Secretary.

[FR Doc. 2020–10354 Filed 5–13–20; 8:45 am]

BILLING CODE 7710–FW–P

[1] Complaint of Randall Ehrlich, December 23, 2019.

[2] *See* Presiding Officer's Ruling Adjusting Procedural Schedule, May 8, 2020.

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2020–130 and CP2020–137]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* May 18, 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. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the market dominant or the competitive product list, or the modification of an existing product currently appearing on the market dominant or the competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern market dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2020–130 and CP2020–137; *Filing Title:* USPS Request to Add Priority Mail Contract 614 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* May 8, 2020; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 *et seq.,* and 39 CFR 3035.105; *Public Representative:* Christopher C. Mohr; *Comments Due:* May 18, 2020.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2020–10361 Filed 5–13–20; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88840; File No. SR–NYSEAMER–2020–37]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change Modifying the NYSE American Options Fee Schedule

May 8, 2020.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the ''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on May 6, 2020, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

Items I, II, and III below, which Items have been prepared by the self-regulatory organization. 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 modify the NYSE American Options Fee Schedule (''Fee Schedule'') to extend through May 2020 certain fee changes implemented for April 2020. The Exchange proposes to implement the fee change effective May 6, 2020.[4] The proposed change is available on the Exchange's website at *www.nyse.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 self-regulatory organization 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 those 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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to modify the Fee Schedule to extend through May 2020 certain fee changes implemented for April 2020, as described below. The Exchange proposes to implement the fee change effective May 6, 2020.

On March 18, 2020, the Exchange announced that it would temporarily close the Trading Floor, effective Monday, March 23, 2020, as a precautionary measure to prevent the potential spread of COVID–19. Following the temporary closure of the Trading Floor, the Exchange temporarily modified certain fees for April 2020.[5] Because the Trading Floor remains closed and has been closed for a longer period than expected—including seven business days in March, the Exchange proposes to extend the April 2020 fee changes through May 2020.

Waiver of Floor-Based Fixed Fees

First, the Exchange proposes to extend through May 2020 the waiver of the following Floor-based fix fees, which relate directly to Floor operations, are charged only to Floor participants and do not apply to participants that conduct business off-Floor:

- Floor Access Fee;
- Floor Broker Handheld
- Transport Charges
- Floor Market Maker Podia;
- Booth Premises; and
- Wire Services.[6]

This proposed extension of the fee waiver would reduce monthly costs for Floor participants whose operations have been disrupted by the unanticipated Floor closure. In reducing this monthly financial burden while the Floor remains temporarily closed, the proposed change would allow affected participants to reallocate funds to assist with the cost of shifting and maintaining their previously on-Floor operations to off-Floor and recoup losses as a result of the unanticipated Floor closure. Absent this change, such participants may experience an unexpected increase in the cost of doing business on the Exchange.[7] The Exchange believes that all ATP Holders that conduct business on the Trading Floor would benefit from this proposed fee change.

Floor Broker QCC Cap

Second, the Exchange proposes to extend through May 2020 the increase in the maximum allowable Floor Broker credit, which is typically $425,000 up to $625,000 per month per Floor Broker (the ''FB QCC Cap'').[8] Following the temporary closure of the Trading Floor, the Exchange experienced an unanticipated surge in QCC trades. The Exchange therefore believes that extending this fee change during the period while the Trading Floor remains temporarily closed would allow incentives to operate as intended—to encourage Floor Brokers to execute volume on the Exchange and to continue to execute all QCC transactions on the Exchange and, for the month of May, to continue to increase the number of such QCC transactions.

Absent the proposed change, participating Floor Brokers—whose operations have been disrupted by the unanticipated Floor closure for more than a month—could experience an unintended increase in the cost of trading on the Exchange, a result that is unintended and undesirable to the Exchange and its Floor Brokers trading QCCs. The Exchange believes that extending the increase in the FB QCC Cap through May would provide Floor Brokers with greater certainty as to their monthly costs and diminish the likelihood of an effective increase in the cost of trading.

The Exchange cannot predict with certainty whether any Floor Brokers would benefit from this proposed fee change. However, without this proposed change during a time when Floor Brokers have increasingly turned to QCCs because the temporary Trading Floor closure prevents open outcry trading, the Exchange believes the proposed change is necessary to prevent Floor Brokers from diverting QCC order flow from the Exchange if and when they hit the Cap.

Strategy Fee Execution Cap

Finally, the Exchange proposes to extend through May 2020 the inclusion of reversals and conversions executed as QCCs (''RevCon QCCs'') in the $1,000 daily Strategy Execution Cap (the ''Strategy Cap'').[9] Absent this change, RevCon QCCs are not eligible for the Strategy Cap (but instead are subject to QCC Fees & Credits).[10] With the temporary closure of the Trading Floor, which has continued longer than anticipated, Floor Brokers are unable to execute RevCons in open outcry. Floor

[4] The Exchange originally filed to amend the Fee Schedule on May 1, 2020 (SR–NYSEAMER–2020–36) and withdrew such filing on May 6, 2020.

[5] *See* Securities Exchange Act Release Nos. 88595 (April 8, 2020), 85 FR 20737 (April 14, 2020) (SR–NYSEAMER–2020–25) (waiving Floor-based fixed fees); 88682 (April 8, 2020), 85 FR 20799 (April 14, 2020) (SR–NYSEAMER–2020–26) (raising Floor Broker QCC Rebate Cap); 88682 (April 17, 2020), 85 FR 22772 (April 23, 2020) (SR–NYSEAMER–2020–31) (including reversals and conversions in Strategy Execution Fee Cap).

[6] *See* proposed Fee Schedule, Section III.B, Monthly Trading Permit, Rights, Floor Access and Premium Product Fees, and IV. Monthly Floor Communication, Connectivity, Equipment and Booth or Podia Fees.

[7] The Exchange will refund participants of the Floor Broker Prepayment Program for any prepaid May 2020 fees that are waived. *See* proposed Fee Schedule, Section III.E (providing that ''the Exchange will refund certain of the prepaid Eligible Fixed costs that were waived for April and May 2020, per Sections III.B and IV'').

[8] *See* proposed Fee Schedule, Section I.F., QCC Fees & Credits, n. 1 (setting forth available credits to Floor Brokers and providing that ''[t]he maximum Floor Broker credit paid shall not exceed $425,000 per month per Floor Broker firm (the ''Cap''), except that for the months of April and May 2020, the Cap would be $625,000 per Floor Broker firm'').

[9] *See* proposed Fee Schedule, Sections I.J., Strategy Execution Fee Cap (including RevCon QCCs in the Strategy Cap during May 2020) and Section I.F., QCC Fees & Credits, n. 1 (providing that ''[t]he Floor Broker credit will not apply to any QCC trades that qualify for the Strategy Cap during the months of April and May 2020 (per Section I.J.)'').

[10] *See* Fee Schedule, Section I.F., QCC Fees & Credits.

Brokers, however, are able to execute RevCon QCCs electronically via the Exchange systems. The Exchange believes the proposed inclusion of RevCon QCCs in the Strategy Cap, which is available to all ATP Holders, would encourage ATP Holders (including those acting as Floor Brokers) to execute their RevCon QCC volume on the Exchange, particularly during the period when open outcry is unavailable and to continue to increase the number of such RevCon QCC transactions during the month of May.

The Exchange cannot predict with certainty whether any ATP Holders would benefit from this proposed fee change. At present, whether or when an ATP Holder qualifies for the Strategy Cap varies day-to-day, month-to-month. That said, the Exchange believes that ATP Holders would be encouraged to take advantage of the modified Cap. In addition, the Exchange believes the proposed change is necessary to prevent ATP Holders from diverting RevCon QCC order flow from the Exchange to a more economical venue.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[11] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[12] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. 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.''[13]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[14] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in January 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.[15]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, changes to exchange transaction fees and credits can have a direct effect on the ability of an exchange to compete for order flow. The proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange's fees are constrained by intermarket competition, as ATP Holders—whose operations may have been (unintentionally) disrupted by the unanticipated temporary closure of the Floor—may direct their order flow to any of the 16 options exchanges.

Waiver of Floor-Based Fixed Fees

This proposed extension of the fee waiver is reasonable, equitable, and not unfairly discriminatory because it would reduce monthly costs for Floor participants whose operations have been disrupted by the unanticipated Floor closure for more than a month. In reducing this monthly financial burden, the proposed change would allow affected participants to reallocate funds to assist with the cost of shifting and maintaining their previously on-Floor operations to off-Floor and recoup losses as a result of the unanticipated Floor closure. Absent this change, such participants may experience an unexpected increase in the cost of doing business on the Exchange.

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits as it merely continues the fee waiver granted in April 2020, which impacts fees charged only to Floor participants and do not apply to participants that conduct business off-Floor.

The Exchange believes that the proposal is not unfairly discriminatory because the proposed continuation of the fee waiver would affect all similarly-situated market participants on an equal and non-discriminatory basis.

The Exchange believes that all ATP Holders that conduct business on the Trading Floor would benefit from this proposed fee change.

FB QCC Cap

This proposed extension of the increase to the FB QCC Cap through May is reasonable, equitable, and not unfairly discriminatory because it would allow Exchange incentives to operate as intended and continue encourage QCC volume, which has seen an uptick in volume on the Exchange following the temporary closure of the Trading Floor. The proposed change would also facilitate fair and orderly markets by attempting to avoid an unintended increase in the cost of Floor Brokers' QCC trading on the Exchange. Absent the proposed change, participating Floor Brokers could experience an unintended increase in the cost of trading on the Exchange, a result that is unintended and undesirable to the Exchange and its Floor Brokers trading QCCs. The Exchange believes that the proposed increase to the Cap for May when the Trading Floor continues to be unavailable would provide Floor Brokers with greater certainty as to their monthly costs and diminish the likelihood of an effective increase in the cost of trading. To the extent that the proposed change attracts more QCC trades to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system.

The Exchange cannot predict with certainty whether any Floor Brokers would benefit from this proposed fee change. However, without this proposed change during a time when Floor Brokers have increasingly turned to QCCs because the ongoing temporary Trading Floor closure prevents open outcry trading, the Exchange believes the proposed change is necessary to prevent Floor Brokers from diverting QCC order flow from the Exchange if and when they hit the FB QCC Cap.

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits and not unfairly

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(4) and (5).

[13] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[14] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, *available here: https://www.theocc.com/market-data/volume/default.jsp.*

[15] Based on OCC data, *see id.,* the Exchange's market share in equity-based options declined from 9.82% for the month of January 2019 to 8.08% for the month of January 2020.

discriminatory because it is based on the amount and type of business transacted on the Exchange during May and Floor Brokers can opt to avail themselves of the modified Cap (*i.e.,* by executing more QCC transactions) or not. The proposed change would incent Floor Brokers to attract increased QCC order flow to the Exchange that might otherwise go to other options exchanges.

The Exchange believes it is not unfairly discriminatory to modify the maximum allowable credit on QCC transactions to Floor Brokers because the proposed modification would be available to all similarly-situated market participants (*i.e.,* Floor Brokers) on an equal and non-discriminatory basis.

Strategy Cap

This proposed extension of the inclusion of RevCon QCCs in the $1,000 daily Strategy Cap for May 2020 is reasonable, equitable, and not unfairly discriminatory because it would encourage ATP Holders to execute their RevCon QCC volume on the Exchange, particularly during the period when open outcry is unavailable due to the ongoing temporary closure of the Trading Floor and to increase the number of such RevCon QCC transactions during the month of May. Further, the proposal is designed to encourage ATP Holders to aggregate all Strategy Executions—including RevCon QCCs—at the Exchange as a primary execution venue. To the extent that the proposed change attracts more Strategy Executions to the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits and not unfairly discriminatory because it is based on the amount and type of business transacted on the Exchange and ATP Holders can opt to avail themselves of the modified Strategy Cap (*i.e.,* by executing more RevCon QCC transactions) or not.

The Exchange believes it is not unfairly discriminatory to extend the modification of the Strategy Cap through May because the proposed change would be available to all similarly-situated market participants on an equal and non-discriminatory basis.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed changes would encourage the continued participation of affected ATP Holders, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [16]

Intramarket Competition. The proposed continuation of the April 2020 fee changes through May 2020 are designed to reduce monthly costs for Floor participants whose operations have been disrupted by the unanticipated Floor closure as well as to avoid an unintended increase in trading costs given the unavailability of open outcry trading on the Exchange. In addition, the continuation of the April 2020 fee changes is designed to attract additional order flow (particularly QCC trades and RevCon QCCs) to the Exchange

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange currently has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[17] Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity & ETF options order flow. More specifically, in January 2020, the Exchange had less than 10% market share of executed volume of multiply-listed equity & ETF options trades.[18]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to reduce monthly costs for Floor participants whose operations have been disrupted by the unanticipated Floor closure and to encourage ATP Holders to direct trading interest (particularly QCCs and RevCon QCCs) to the Exchange, to provide liquidity and to attract order flow. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [19] of the Act and subparagraph (f)(2) of Rule 19b–4 [20] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such 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 under Section 19(b)(2)(B) [21] of the Act 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.

[16] *See* Reg NMS Adopting Release, *supra* note 13, at 37499.

[17] *See supra* note 14.

[18] Based on OCC data, *supra* note 15, the Exchange's market share in equity-based options was 9.57% for the month of January 2019 and 9.59% for the month of January, 2020.

[19] 15 U.S.C. 78s(b)(3)(A).

[20] 17 CFR 240.19b–4(f)(2).

[21] 15 U.S.C. 78s(b)(2)(B).

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–NYSEAMER–2020–37 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–NYSEAMER–2020–37. 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–NYSEAMER–2020–37, and should be submitted on or before June 4, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–10286 Filed 5–13–20; 8:45 am]

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[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88843; File No. SR–CboeEDGX–2020–021]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Adopting Rule 14.12 Governing the Trading, Pursuant to Unlisted Trading Privileges, of Exchange-Traded Fund Shares

May 8, 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 May 7, 2020, Cboe EDGX Exchange, Inc. (''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to adopt Rule 14.12 to permit the trading, pursuant to unlisted trading privileges, of Exchange-Traded Fund Shares. Additionally, the Exchange proposes to make corresponding changes to Rule 14.1(a). 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/options/regulation/rule_filings/edgx/*), 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 adopt Rule 14.12 to permit the trading, pursuant to unlisted trading privileges (''UTP''), of Exchange-Traded Fund (also referred to as ''ETF'') Shares,[5] which substantially conforms to Cboe BZX Exchange, Inc. (''BZX'') Rule 14.11(l).[6] Additionally, the Exchange proposes to make corresponding changes to Rule 14.1(a) to reference Exchange-Traded Fund Shares and proposed Rule 14.12, where applicable.

The Exchange does not currently list any securities as a primary listing market. Consistent with this fact, Exchange Rule 14.1(a) currently states that all securities traded on the Exchange are traded pursuant to UTP and that the Exchange will not list any securities before first filing and obtaining Commission approval of rules that incorporate qualitative listing criteria and comply with Rules 10A–3[7] (''Rule 10A–3'') and 10C–1[8] (''Rule 10C–1'') under the Act. Therefore, the provisions of existing Rules 14.2 through 14.9, 14.11, and proposed Rule 14.12 that permit the listing of certain Equity Securities[9] will not be effective

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] ETF Shares means shares of stock issued by an Exchange-Traded Fund. *See* proposed Rule 14.12(c)(1).

[6] *See* Securities and Exchange Act Release No. 88566 (April 6, 2020) 85 FR 20312 (April 10, 2020) (SR–CboeBZX–2019–097) (the ''BZX Approval Order'').

[7] Rule 10A–3 obligates the Exchange to prohibit the initial or continued listing of any security of an issuer that is not in compliance with certain required standards. *See* 17 CFR 240.10A–3.

[8] Rule 10C–1 obligates the Exchange to establish listing standards that require each member of a listed issuer's compensation committee to be a member of the issuer's board and to be independent, as well as establish certain factors that an issuer must consider when evaluating the independence of a director. *See* 17 CFR 240.10C–1.

[9] As provided in Rule 14.1(a), the term ''Equity Security'' means, but is not limited to, common stock, secondary classes of common stock, preferred stock and similar issues, shares or certificates of beneficial interest of trusts, notes, limited partnership interests, warrants, certificates of deposit for common stock, convertible debt securities, ADRs, CVRs, Investment Company Units, Trust Issued Receipts (including those based on Investment Shares), Commodity-Based Trust Shares, Currency Trust Shares, Partnership Units,

until the Exchange files a proposed rule change under Section 19(b)(2) under the Exchange Act to amend its rules to comply with Rule 10A–3 and 10C–1 under the Exchange Act and to incorporate qualitative listing criteria, and such proposed rule change is approved by the Commission. Considering the foregoing, the Exchange proposes to adopt Rule 14.12 as set forth below.

Proposed Listing Rules

Proposed Rule 14.12(a) provides that the Exchange will consider for trading, whether by listing or pursuant to UTP, ETF Shares that meet the criteria of Rule 14.12.

Proposed Rule 14.12(b) provides that Rule 14.12 is applicable only to ETF Shares and that, except to the extent inconsistent with Rule 14.12, or unless the context otherwise requires, the rules and procedures of the Exchange's Board of Directors shall be applicable to the trading on the Exchange of such securities. Proposed Rule 14.12(b) provides further that ETF Shares are included within the definition of ''security'' or ''securities'' as such terms are used in the Rules of the Exchange.

Proposed Rule 14.12(b)(1) provides that transactions in ETF Shares will occur throughout the Exchange's trading hours.

Proposed Rule 14.12(b)(2) provides that the minimum price variation for quoting and entry of orders in ETF Shares will be $0.01.

Proposed Rule 14.12(b)(3) provides that the Exchange will implement and maintain written surveillance procedures for ETF Shares.

Proposed Rule 14.12(c)(1) defines the term ''ETF Shares'' as shares of stock issued by an Exchange-Traded Fund.[10]

Proposed Rule 14.12(c)(2) defines the term ''Exchange-Traded Fund'' as having the same meaning as the term ''exchange-traded fund'' as defined in Rule 6c–11 under the Investment Company Act of 1940.[11]

Proposed Rule 14.12(c)(3) defines the term ''Reporting Authority'' in respect of a particular series of ETF Shares means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists a particular series of ETF Shares (if the Exchange is trading such series pursuant to UTP) as the official source for calculating and reporting information relating to such series, including, but not limited to, the amount of any dividend equivalent payment or cash distribution to holders of ETF Shares, the net asset value (the ''NAV''), index or portfolio value, the current value of the portfolio of securities required to be deposited in connection with issuance of ETF Shares, or other information relating to the issuance, redemption or trading of ETF Shares. A series of ETF Shares may have more than one Reporting Authority, each having different functions.

Proposed Rule 14.12(d) provides for the initial and continued listing and/or trading of ETF Shares, including trading pursuant to UTP, pursuant to Rule 19b–4(e) under the Act. Proposed Rule 14.12(d)(1) sets forth initial listing criteria applicable to ETF Shares. Specifically, proposed Rule 14.12(d)(1) provides that the requirements of Rule 6c–11 must be satisfied by a series of ETF Shares on an initial and continued listing basis. Such securities must also satisfy the criteria on an initial and, with the exception of proposed subparagraph (d)(1)(A), a continued listing basis. Proposed Rule 14.12(d)(1)(A) provides that for each series, the Exchange will establish a minimum number of ETF Shares required to be outstanding at the time of commencement of trading on the Exchange. However, as noted above, such criteria is not applicable on a continued listing basis. Proposed rule 14.12(d)(1)(B) provides that if an index underlying a series of ETF Shares is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a ''fire wall'' around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to the investment company issuing an actively managed series of ETF Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Exchange-Traded Fund's portfolio. Additionally proposed rule 14.12(d)(1)(C) provides that any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a series of ETF Shares, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. For actively managed Exchange-Traded Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable portfolio.

Proposed Rule 14.12(d)(2) provides that each series of ETF Shares will be listed and traded subject to application of the following continued listing criteria. Proposed Rule 14.12(d)(2)(A) provides that the Exchange will consider the suspension of trading in or removal from listing of or termination of unlisted trading privileges for a series of ETF Shares under any of the following circumstances: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.12(d)(2)(B) provides that upon termination of an investment company, the Exchange will require that ETF Shares issued in connection with such entity be removed from Exchange listing.

Proposed Rule 14.12(e), which relates to limitation of Exchange liability, provides that neither the Exchange, the Reporting Authority, nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the open-end management investment company in connection with issuance of ETF Shares; the amount of any dividend

Equity-Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Portfolio Depositary Receipts, Equity-Linked Debt Securities, and Managed Portfolio Shares. Further, the Exchange now proposes to include the term ''Exchange-Traded Fund Shares'' to the definition of Equity Security.

[10] For purposes of this filing, references to a series of Exchange-Traded Fund Shares are referred to interchangeably as a series of Exchange-Traded Fund Shares or as a ''Fund'' and shares of a series of Exchange-Traded Fund Shares are generally referred to as the ''Shares''.

[11] Per Rule 6c–11, an exchange-traded fund means a registered open-end management company: (A) That issues (and redeems) creation units to (and from) authorized participants in exchange for a basket and a cash balancing amount if any; and (B) Whose shares are listed on a national securities exchange and traded at market-determined prices.

equivalent payment or cash distribution to holders of ETF Shares; net asset value; or other information relating to the purchase, redemption, or trading of ETF Shares, resulting from any negligent act or omission by the Exchange, the Reporting Authority, or any agent of the Exchange, or any act, condition, or cause beyond the reasonable control of the Exchange, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

The Exchange does not propose to adopt BZX Rule 14.11(l)(6) because it is not applicable as the Exchange does not currently have any listed products.

Quantitative Standards

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices because the Exchange will perform ongoing surveillance of ETF Shares listed on the Exchange in order to ensure compliance with Rule 6c–11 and the 1940 Act on an ongoing basis. While proposed Rule 14.12 does not include the quantitative requirements applicable to an ETF or an ETF's holdings or underlying index that are included in Rule 14.2, the Exchange believes that the manipulation concerns that such standards are intended to address are otherwise mitigated by a combination of the Exchange's surveillance procedures and the Exchange's ability to suspend trading or terminate unlisted trading privileges under the proposed Rule 14.12(d)(2)(A). The Exchange will also halt trading in ETF Shares under the conditions specified in Rule 11.16, ''Trading Halts Due to Extraordinary Market Volatility.'' The Exchange believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that will come from Rule 6c–11, specifically the additional flexibility provided to issuers of ETF Shares through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c–11.[12] The Exchange believes that the combination of these factors will act to keep ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of ETF Shares on the Exchange without the inclusion of quantitative standards.[13]

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of ETF Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of ETF Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products. The Exchange will require the issuer of each series of ETF Shares listed on the Exchange to represent to the Exchange that it will advise the Exchange of any failure by a Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements.

Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, among other product types, to monitor trading in ETF Shares. The Exchange or the Financial Industry Regulatory Authority, Inc. (''FINRA''), on behalf of the Exchange, will communicate as needed regarding trading in ETF Shares and certain of their applicable underlying components with other markets that are members of the Intermarket Surveillance Group (''ISG'') or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a series of ETF Shares reported to FINRA's Trade Reporting and Compliance Engine (''TRACE''). FINRA also can access data obtained from the Municipal Securities Rulemaking Board's (''MSRB'') Electronic Municipal Market Access (''EMMA'') system relating to municipal bond trading activity for surveillance purposes in connection with trading in a series of ETF Shares, to the extent that a series of ETF Shares holds municipal securities.

Trading Halts

As proposed above, the Exchange may consider all relevant factors in exercising its discretion to halt trading in a series of Managed Portfolio Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the series of ETF Shares inadvisable. These may include: (i) The extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (ii) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Additionally, the Exchange would halt trading as soon as practicable where the Exchange becomes aware that: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

Trading Rules

The Exchange deems ETF Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. ETF Shares will trade on the Exchange throughout the Exchange's trading hours. As provided in proposed Rule 14.12(b)(2), the minimum price variation for quoting and entry of orders in ETF Shares traded on the Exchange is $0.01.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act[14] in general and Section

[12] The Exchange notes that the Commission came to a similar conclusion in several places in the Rule 6c–11 Release. *See* Release Nos. 33–10695; IC–33646; File No. S7–15–18 (Exchange-Traded Funds) (September 25, 2019), 84 FR 57162 (October 24, 2019) (the ''Rule 6c–11 Release'') at 15–18; 60–61; 69–70; 78–79; 82–84; and 95–96.

[13] The Exchange believes that this applies to all quantitative standards, whether applicable to the portfolio holdings of a series of ETF Shares or the distribution of the ETF Shares.

[14] 15 U.S.C. 78f.

6(b)(5) of the Act[15] in particular in that it is 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.

The Exchange believes that proposed Rule 14.12 will remove impediments to and perfect the mechanism of a free and open market and national market system. Specifically, the proposed amendment raises no substantive issues that have not otherwise been considered by the Commission in either the BZX Approval Order or in the context of other similar Exchange Rules. This proposal is substantively similar to the BZX Approval Order, with the exception that the Exchange is only proposing to trade series of ETF Shares pursuant to unlisted trading privileges, while BZX will both list and trade series of ETF Shares. Further, while proposed Rule 14.12(d)(2)(A) provides that the Exchange may terminate unlisted trading privileges and BZX Rule 14.11(l) does not, the proposed rule text is substantially similar to existing Exchange Rules 14.3(g)(2) and 14.11(d)(2)(B) and therefore raises no novel issues.

The Exchange believes that proposed Rule 14.12 is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading ETF Shares on the Exchange provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 14.12(d) sets forth initial and continued listing criteria applicable to ETF Shares, specifically providing that the Exchange may approve a series of ETF Shares for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b–4(e) under the Act, provided such series of ETF Shares is eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940 and must satisfy the requirements of this Rule 14.12 on an initial and continued listing basis.

Proposed Rule 14.12(d)(1) provides that initial listing criteria which includes (A) for each series, the Exchange will establish a minimum number of ETF Shares required to be outstanding at the time of commencement of trading on the Exchange; (B) if an index underlying a series of ETF Shares is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a ''fire wall'' around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to the investment company issuing an actively managed series of ETF Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Exchange-Traded Fund's portfolio; and (C) any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a series of ETF Shares, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. For actively managed Exchange-Traded Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable portfolio.

Proposed Rule 14.12(d)(2) provides that each series of ETF Shares will be listed and traded on the Exchange subject to application of Proposed Rule 14.12(d)(2)(A) and (B). Proposed Rule 14.12(d)(2)(A) provides that the Exchange will consider the suspension of trading in or removal from listing of or termination of UTP for a series of ETF Shares under any of the following circumstances: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.12(d)(2)(B) provides that upon termination of an investment company, the Exchange requires that ETF Shares issued in connection with such entity be removed from Exchange listing.

The Exchange further believes that proposed Rule 14.12 is designed to prevent fraudulent and manipulative acts and practices because of the robust surveillances in place on the Exchange as required under proposed Rule 14.12(b)(3) along with the similarities of proposed Rule 14.12 to the rules related to other securities that are already traded on the Exchange pursuant to UTP and which would qualify as ETF Shares. Proposed Rule 14.12 is based in large part on Rule 14.2 related to the listing and trading of Investment Company Units on the Exchange, which are issued under the 1940 Act and would qualify as ETF Shares after Rule 6c–11 is effective. As such, the Exchange believes that using Rule 14.2 (the ''Current ETF Standards'') as the basis for proposed Rule 14.12 is appropriate because they are generally designed to address the issues associated with ETF Shares. The only substantial differences between proposed Rule 14.12 and the Current ETF Standards that are not otherwise required under Rule 6c–11 are as follows: (i) Proposed Rule 14.12 does not include the quantitative standards applicable to a fund or an index that are included in the Current ETF Standards; and (ii) Proposed Rule 14.12 does not include any requirements related to the dissemination of a fund's intraday indicative value.[16]

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the ETF Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, among other product types, to monitor trading in ETF Shares. The Exchange or the FINRA, on behalf of the Exchange, will communicate as needed regarding trading in ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in ETF Shares and certain of their applicable underlying components from markets

[15] 15 U.S.C. 78f(b)(5).

[16] For purposes of this filing, the term ''intraday indicative value'' or ''IIV'' shall mean an intraday estimate of the value of a share of each series Investment Company Units.

and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a series of ETF Shares reported to FINRA's TRACE. FINRA also can access data obtained from the MSRB EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in a series of ETF Shares, to the extent that a series of ETF Shares holds municipal securities.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

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 that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the trading, pursuant to UTP, of ETF Shares that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

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

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) of the Act [17] and Rule 19b–4(f)(6) thereunder.[18]

A proposed rule change filed under Rule 19b–4(f)(6) [19] normally does not become operative for 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[20] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to immediately allow ETF Shares to be traded on another venue. The Commission believes that waiver of the 30-day operative delay for this purpose is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[21]

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–CboeEDGX–2020–021 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–CboeEDGX–2020–021. 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–CboeEDGX–2020–021 and should be submitted on or before June 4, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–10287 Filed 5–13–20; 8:45 am]

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[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of 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.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88844; File No. SR-CboeEDGA–2020–013]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Adopting Rule 14.12 Governing the Trading, Pursuant to Unlisted Trading Privileges, of Exchange-Traded Fund Shares

May 8, 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 May 7, 2020, Cboe EDGA Exchange, Inc. (''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act [3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to adopt Rule 14.12 to permit the trading, pursuant to unlisted trading privileges, of Exchange-Traded Fund Shares. Additionally, the Exchange proposes to make corresponding changes to Rule 14.1(a). 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/options/regulation/rule_filings/edga/*), 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 adopt Rule 14.12 to permit the trading, pursuant to unlisted trading privileges (''UTP''), of Exchange-Traded Fund (also referred to as ''ETF'') Shares,[5] which substantially conforms to Cboe BZX Exchange, Inc. (''BZX'') Rule 14.11(l).[6] Additionally, the Exchange proposes to make corresponding changes to Rule 14.1(a) to reference Exchange-Traded Fund Shares and proposed Rule 14.12, where applicable.

The Exchange does not currently list any securities as a primary listing market. Consistent with this fact, Exchange Rule 14.1(a) currently states that all securities traded on the Exchange are traded pursuant to UTP and that the Exchange will not list any securities before first filing and obtaining Commission approval of rules that incorporate qualitative listing criteria and comply with Rules 10A–3 [7] (''Rule 10A–3'') and 10C–1 [8] (''Rule 10C–1'') under the Act. Therefore, the provisions of existing Rules 14.2 through 14.9, 14.11, and proposed Rule 14.12 that permit the listing of certain Equity Securities [9] will not be effective until the Exchange files a proposed rule change under Section 19(b)(2) under the Exchange Act to amend its rules to comply with Rule 10A–3 and 10C–1 under the Exchange Act and to incorporate qualitative listing criteria, and such proposed rule change is approved by the Commission. Considering the foregoing, the Exchange proposes to adopt Rule 14.12 as set forth below.

Proposed Listing Rules

Proposed Rule 14.12(a) provides that the Exchange will consider for trading, whether by listing or pursuant to UTP, ETF Shares that meet the criteria of Rule 14.12.

Proposed Rule 14.12(b) provides that Rule 14.12 is applicable only to ETF Shares and that, except to the extent inconsistent with Rule 14.12, or unless the context otherwise requires, the rules and procedures of the Exchange's Board of Directors shall be applicable to the trading on the Exchange of such securities. Proposed Rule 14.12(b) provides further that ETF Shares are included within the definition of ''security'' or ''securities'' as such terms are used in the Rules of the Exchange.

Proposed Rule 14.12(b)(1) provides that transactions in ETF Shares will occur throughout the Exchange's trading hours.

Proposed Rule 14.12(b)(2) provides that the minimum price variation for quoting and entry of orders in ETF Shares will be $0.01.

Proposed Rule 14.12(b)(3) provides that the Exchange will implement and maintain written surveillance procedures for ETF Shares.

Proposed Rule 14.12(c)(1) defines the term ''ETF Shares'' as shares of stock issued by an Exchange-Traded Fund.[10]

Proposed Rule 14.12(c)(2) defines the term ''Exchange-Traded Fund'' as having the same meaning as the term ''exchange-traded fund'' as defined in Rule 6c–11 under the Investment Company Act of 1940.[11]

Proposed Rule 14.12(c)(3) defines the term ''Reporting Authority'' in respect of a particular series of ETF Shares means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists a particular series of ETF Shares (if the Exchange is trading such series pursuant to UTP) as the official source for calculating and reporting information relating to such series, including, but not limited to, the amount of any dividend equivalent payment or cash distribution to holders of ETF Shares, the net asset value (the ''NAV''), index or portfolio value, the current value of the portfolio of securities required to be deposited in connection with issuance of ETF Shares, or other information relating to the issuance, redemption or trading of ETF

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] ETF Shares means shares of stock issued by an Exchange-Traded Fund. *See* proposed Rule 14.12(c)(1).

[6] *See* Securities and Exchange Act Release No. 88566 (April 6, 2020) 85 FR 20312 (April 10, 2020) (SR-CboeBZX–2019–097) (the ''BZX Approval Order'').

[7] Rule 10A–3 obligates the Exchange to prohibit the initial or continued listing of any security of an issuer that is not in compliance with certain required standards. *See* 17 CFR 240.10A–3.

[8] Rule 10C–1 obligates the Exchange to establish listing standards that require each member of a listed issuer's compensation committee to be a member of the issuer's board and to be independent, as well as establish certain factors that an issuer must consider when evaluating the independence of a director. *See* 17 CFR 240.10C–1.

[9] As provided in Rule 14.1(a), the term ''Equity Security'' means, but is not limited to, common stock, secondary classes of common stock, preferred stock and similar issues, shares or certificates of beneficial interest of trusts, notes, limited partnership interests, warrants, certificates of deposit for common stock, convertible debt securities, ADRs, CVRs, Investment Company Units, Trust Issued Receipts (including those based on Investment Shares), Commodity-Based Trust Shares, Currency Trust Shares, Partnership Units, Equity-Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Portfolio Depositary Receipts, Equity-Linked Debt Securities, and Managed Portfolio Shares. Further, the Exchange now proposes to include the term ''Exchange-Traded Fund Shares'' to the definition of Equity Security.

[10] For purposes of this filing, references to a series of Exchange-Traded Fund Shares are referred to interchangeably as a series of Exchange-Traded Fund Shares or as a ''Fund'' and shares of a series of Exchange-Traded Fund Shares are generally referred to as the ''Shares''.

[11] Per Rule 6c-11, an exchange-traded fund means a registered open-end management company: (A) That issues (and redeems) creation units to (and from) authorized participants in exchange for a basket and a cash balancing amount if any; and (B) Whose shares are listed on a national securities exchange and traded at market-determined prices.

Shares. A series of ETF Shares may have more than one Reporting Authority, each having different functions.

Proposed Rule 14.12(d) provides for the initial and continued listing and/or trading of ETF Shares, including trading pursuant to UTP, pursuant to Rule 19b4–(e) under the Act. Proposed Rule 14.12(d)(1) sets forth initial listing criteria applicable to ETF Shares. Specifically, proposed Rule 14.12(d)(1) provides that the requirements of Rule 6c-11 must be satisfied by a series of ETF Shares on an initial and continued listing basis. Such securities must also satisfy the criteria on an initial and, with the exception of proposed subparagraph (d)(1)(A), a continued listing basis. Proposed Rule 14.12(d)(1)(A) provides that for each series, the Exchange will establish a minimum number of ETF Shares required to be outstanding at the time of commencement of trading on the Exchange. However, as noted above, such criteria is not applicable on a continued listing basis. Proposed rule 14.12(d)(1)(B) provides that if an index underlying a series of ETF Shares is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a ''fire wall'' around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to the investment company issuing an actively managed series of ETF Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Exchange-Traded Fund's portfolio. Additionally proposed rule 14.12(d)(1)(C) provides that any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a series of ETF Shares, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. For actively managed Exchange-Traded Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable portfolio.

Proposed Rule 14.12(d)(2) provides that each series of ETF Shares will be listed and traded subject to application of the following continued listing criteria. Proposed Rule 14.12(d)(2)(A) provides that the Exchange will consider the suspension of trading in or removal from listing of or termination of unlisted trading privileges for a series of ETF Shares under any of the following circumstances: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.12(d)(2)(B) provides that upon termination of an investment company, the Exchange will require that ETF Shares issued in connection with such entity be removed from Exchange listing.

Proposed Rule 14.12(e), which relates to limitation of Exchange liability, provides that neither the Exchange, the Reporting Authority, nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the open-end management investment company in connection with issuance of ETF Shares; the amount of any dividend equivalent payment or cash distribution to holders of ETF Shares; net asset value; or other information relating to the purchase, redemption, or trading of ETF Shares, resulting from any negligent act or omission by the Exchange, the Reporting Authority, or any agent of the Exchange, or any act, condition, or cause beyond the reasonable control of the Exchange, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

The Exchange does not propose to adopt BZX Rule 14.11(l)(6) because it is not applicable as the Exchange does not currently have any listed products.

Quantitative Standards

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices because the Exchange will perform ongoing surveillance of ETF Shares listed on the Exchange in order to ensure compliance with Rule 6c-11 and the 1940 Act on an ongoing basis. While proposed Rule 14.12 does not include the quantitative requirements applicable to an ETF or an ETF's holdings or underlying index that are included in Rule 14.2, the Exchange believes that the manipulation concerns that such standards are intended to address are otherwise mitigated by a combination of the Exchange's surveillance procedures and the Exchange's ability to suspend trading or terminate unlisted trading privileges under the proposed Rule 14.12(d)(2)(A). The Exchange will also halt trading in ETF Shares under the conditions specified in Rule 11.16, ''Trading Halts Due to Extraordinary Market Volatility.'' The Exchange believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that will come from Rule 6c–11, specifically the additional flexibility provided to issuers of ETF Shares through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c–11.[12] The Exchange believes that the combination of these factors will act to keep ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of ETF Shares on the Exchange without the inclusion of quantitative standards.[13]

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of ETF Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of ETF Shares through the

[12] The Exchange notes that the Commission came to a similar conclusion in several places in the Rule 6c-11 Release. *See* Release Nos. 33–10695; IC–33646; File No. S7–15–18 (Exchange-Traded Funds) (September 25, 2019), 84 FR 57162 (October 24, 2019) (the ''Rule 6c–11 Release'') at 15–18; 60–61; 69–70; 78–79; 82–84; and 95–96.

[13] The Exchange believes that this applies to all quantitative standards, whether applicable to the portfolio holdings of a series of ETF Shares or the distribution of the ETF Shares.

Exchange will be subject to the Exchange's surveillance procedures for derivative products. The Exchange will require the issuer of each series of ETF Shares listed on the Exchange to represent to the Exchange that it will advise the Exchange of any failure by a Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements.

Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, among other product types, to monitor trading in ETF Shares. The Exchange or the Financial Industry Regulatory Authority, Inc. (''FINRA''), on behalf of the Exchange, will communicate as needed regarding trading in ETF Shares and certain of their applicable underlying components with other markets that are members of the Intermarket Surveillance Group (''ISG'') or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a series of ETF Shares reported to FINRA's Trade Reporting and Compliance Engine (''TRACE''). FINRA also can access data obtained from the Municipal Securities Rulemaking Board's (''MSRB'') Electronic Municipal Market Access (''EMMA'') system relating to municipal bond trading activity for surveillance purposes in connection with trading in a series of ETF Shares, to the extent that a series of ETF Shares holds municipal securities.

Trading Halts

As proposed above, the Exchange may consider all relevant factors in exercising its discretion to halt trading in a series of Managed Portfolio Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the series of ETF Shares inadvisable. These may include: (i) The extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (ii) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Additionally, the Exchange would halt trading as soon as practicable where the Exchange becomes aware that: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

Trading Rules

The Exchange deems ETF Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. ETF Shares will trade on the Exchange throughout the Exchange's trading hours. As provided in proposed Rule 14.12(b)(2), the minimum price variation for quoting and entry of orders in ETF Shares traded on the Exchange is $0.01.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b) of the Act [14] in general and Section 6(b)(5) of the Act [15] in particular in that it is 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.

The Exchange believes that proposed Rule 14.12 will remove impediments to and perfect the mechanism of a free and open market and national market system. Specifically, the proposed amendment raises no substantive issues that have not otherwise been considered by the Commission in either the BZX Approval Order or in the context of other similar Exchange Rules. This proposal is substantively similar to the BZX Approval Order, with the exception that the Exchange is only proposing to trade series of ETF Shares pursuant to unlisted trading privileges, while BZX will both list and trade series of ETF Shares. Further, while proposed Rule 14.12(d)(2)(A) provides that the Exchange may terminate unlisted trading privileges and BZX Rule 14.11(l) does not, the proposed rule text is substantially similar to existing Exchange Rules 14.3(g)(2) and 14.11(d)(2)(B) and therefore raises no novel issues.

The Exchange believes that proposed Rule 14.12 is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading ETF Shares on the Exchange provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 14.12(d) sets forth initial and continued listing criteria applicable to ETF Shares, specifically providing that the Exchange may approve a series of ETF Shares for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b–4(e) under the Act, provided such series of ETF Shares is eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940 and must satisfy the requirements of this Rule 14.12 on an initial and continued listing basis.

Proposed Rule 14.12(d)(1) provides that initial listing criteria which includes (A) for each series, the Exchange will establish a minimum number of ETF Shares required to be outstanding at the time of commencement of trading on the Exchange; (B) if an index underlying a series of ETF Shares is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a ''fire wall'' around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to the investment company issuing an actively managed series of ETF Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Exchange-Traded Fund's portfolio; and (C) any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a series of ETF Shares, must implement and maintain, or be subject to, procedures designed to prevent the use

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(5).

and dissemination of material non-public information regarding the applicable index. For actively managed Exchange-Traded Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable portfolio.

Proposed Rule 14.12(d)(2) provides that each series of ETF Shares will be listed and traded on the Exchange subject to application of Proposed Rule 14.12(d)(2)(A) and (B). Proposed Rule 14.12(d)(2)(A) provides that the Exchange will consider the suspension of trading in or removal from listing of or termination of UTP for a series of ETF Shares under any of the following circumstances: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.12(d)(2)(B) provides that upon termination of an investment company, the Exchange requires that ETF Shares issued in connection with such entity be removed from Exchange listing.

The Exchange further believes that proposed Rule 14.12 is designed to prevent fraudulent and manipulative acts and practices because of the robust surveillances in place on the Exchange as required under proposed Rule 14.12(b)(3) along with the similarities of proposed Rule 14.12 to the rules related to other securities that are already traded on the Exchange pursuant to UTP and which would qualify as ETF Shares. Proposed Rule 14.12 is based in large part on Rule 14.2 related to the listing and trading of Investment Company Units on the Exchange, which are issued under the 1940 Act and would qualify as ETF Shares after Rule 6c–11 is effective. As such, the Exchange believes that using Rule 14.2 (the ''Current ETF Standards'') as the basis for proposed Rule 14.12 is appropriate because they are generally designed to address the issues associated with ETF Shares. The only substantial differences between proposed Rule 14.12 and the Current ETF Standards that are not otherwise required under Rule 6c–11 are as follows: (i) proposed Rule 14.12 does not include the quantitative standards applicable to a fund or an index that are included in the Current ETF Standards; and (ii) proposed Rule 14.12 does not include any requirements related to the dissemination of a fund's intraday indicative value.[16]

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the ETF Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, among other product types, to monitor trading in ETF Shares. The Exchange or the FINRA, on behalf of the Exchange, will communicate as needed regarding trading in ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a series of ETF Shares reported to FINRA's TRACE. FINRA also can access data obtained from the MSRB EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in a series of ETF Shares, to the extent that a series of ETF Shares holds municipal securities.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

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 that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the trading, pursuant to UTP, of ETF Shares that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

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

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) of the Act[17] and Rule 19b–4(f)(6) thereunder.[18]

A proposed rule change filed under Rule 19b–4(f)(6)[19] normally does not become operative for 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[20] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to immediately allow ETF Shares to be traded on another venue. The Commission believes that waiver of the 30-day operative delay for this purpose is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[21]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if

[16] For purposes of this filing, the term ''intraday indicative value'' or ''IIV'' shall mean an intraday estimate of the value of a share of each series Investment Company Units.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of 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.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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–CboeEDGA–2020–013 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–CboeEDGA–2020–013. 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–CboeEDGA–2020–013 and should be submitted on or before June 4, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–10288 Filed 5–13–20; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88839; File No. SR–FINRA–2020–014]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rule 9231 To Provide for the Compensation of All Panelists That Serve in Connection With a FINRA Disciplinary Hearing

May 8, 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 May 5, 2020, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. 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

FINRA is proposing to amend FINRA Rule 9231 to provide for the compensation of all panelists that serve in connection with a FINRA disciplinary hearing, regardless of whether it is an Extended or non-Extended Hearing.[4]

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org,* at the principal office of FINRA 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, FINRA 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. FINRA 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

FINRA Rule 9231 governs the appointment by FINRA's Chief Hearing Officer of Hearing Panels, both Extended and non-Extended, and replacement Hearing Officers.

A Hearing Panel consists of a Hearing Officer and two Panelists.[5] Each Panelist must be associated with a FINRA member or retired therefrom.[6] Service as a Panelist is voluntary.

Rule 9231 authorizes the Chief Hearing Officer to exercise his or her discretion to compensate Panelists who serve on Extended Hearing Panels only. The proposed rule change would amend Rule 9231 to provide for the compensation of all Panelists, irrespective of whether they serve on Extended or non-Extended Hearing Panels, and without the exercise of discretion by the Chief Hearing Officer. FINRA believes the proposed rule change will encourage a greater and more diverse pool of eligible individuals

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[22] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6). 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. FINRA has satisfied this requirement.

[4] FINRA Rule 9231(c) sets forth the circumstances in which a hearing may be designated an Extended Hearing. Matters that require an Extended Hearing are assigned an Extended Hearing Panel. For the purposes of this proposal only, the term ''Hearing Panel'' collectively refers to both Extended and non-Extended Hearing Panels.

[5] *See* FINRA Rule 9231(b) and (c). If, after appointment, a Panelist withdraws, is unable to serve, or is disqualified, the Chief Hearing Officer may, in his or her discretion, determine whether to appoint a replacement Panelist. If two Panelists withdraw, are unable to serve, or are disqualified, the Chief Hearing Officer must appoint two replacement Panelists. *See* FINRA Rule 9234.

[6] *See* FINRA Rule 9231(b) and (c).

to agree to serve on Hearing Panels. A larger and more diverse pool of eligible individuals willing to serve as Panelists will facilitate the Chief Hearing Officer's ability readily to appoint Hearing Panels with appropriate experience and expertise as needed.

Background

FINRA's disciplinary process begins with the Department of Enforcement filing a complaint with the Office of Hearing Officers (''OHO'') alleging that a Respondent [7] is violating or has violated a rule, regulation, or statutory provision, including the federal securities laws and related regulations, that FINRA has jurisdiction to enforce.[8] Following the filing of a complaint, the Chief Hearing Officer assigns a Hearing Officer to preside over the disciplinary proceeding [9] and appoints Panelists to an Extended or non-Extended Hearing Panel to conduct the disciplinary proceeding. Disciplinary matters are assigned to an Extended Hearing Panel if, upon consideration of the complexity of the issues involved, the probable length of the hearing, or other factors that the Chief Hearing Officer deems material, the Chief Hearing Officer determines that a matter shall be an Extended Hearing.[10]

Responsibilities of Hearing Panelists; Criteria for Appointment

Panelists are essential to FINRA's disciplinary process. The Hearing Panel listens to the presentation of evidence and issues a written decision setting forth findings as to whether a Respondent engaged in violative conduct and describing the sanctions, if any, imposed.[11] In addition to traveling to hearing locations and attending hearings, Panelists are expected to review materials in preparation for the hearing, participate in conference calls with the Hearing Officer, review post-hearing briefs, participate in deliberations (which may require a full day or several days of shorter sessions), and review and comment on a draft Hearing Panel decision. Hearing Panel decisions generally may be appealed to, and are subject to discretionary review by, the National Adjudicatory Council (''NAC'').[12] Hearing Panel decisions are also subject to discretionary review by FINRA's Board of Governors, and final disciplinary action by FINRA may be appealed to the Commission.[13]

The appointment of Panelists is subject to specific criteria under Rules 9231 and 9232. These criteria help ensure that Panelists possess the requisite experience and expertise to fulfill their responsibilities in a manner that results in fair, deliberative disciplinary proceedings. The Chief Hearing Officer appoints Panelists from a pool that generally includes persons who: (1) Previously served on a District Committee; [14] (2) currently serve or previously served on a Regional Committee; (3) previously served on the NAC; (4) previously served on a disciplinary subcommittee of the NAC or the National Business Conduct Committee; (5) previously served as a FINRA Governor or Director, but do not currently serve in either of these positions; [15] or (6) currently serve or previously served on a committee appointed or approved by the FINRA Board, but does not serve currently on the NAC or as a Director or a Governor of the FINRA Board.[16] If the complaint alleges at least one cause of action involving a violation of a statute or a rule described in Rule 9120(u), the Chief Hearing Officer may select one Panelist who currently serves or previously served on the Market Regulation Committee.[17]

The selection of Panelists from among those eligible under Rule 9231 is subject to criteria set forth in Rule 9232. The Chief Hearing Officer must determine which Regional Committee shall be the Primary Regional Committee from which he or she will first seek Panelists.[18] Once a Primary Regional Committee has been designated, the Chief Hearing Officer selects Panelists from (1) the current members of the Primary Regional Committee; (2) the categories of persons eligible to serve as Panelists under FINRA Rule 9231 who are located in the same geographic area as the Primary Regional Committee; and, if applicable, (3) current or former members of the Market Regulation Committee.[19] Selection is based on (1) expertise; (2) the absence of any conflict of interest or bias, and any appearance thereof; (3) availability; and (4) the frequency with which a person has served as a Panelist during the past two years, favoring the selection of a person as a Panelist who has never served or served infrequently as a Panelist during that period.[20]

Rule 9232 does not preclude the Chief Hearing Officer from appointing Panelists from other categories of those eligible under Rule 9231. The Chief Hearing Officer may make such an appointment if he or she determines that one or more persons from other categories of eligible Panelists more clearly meet the criteria of paragraph (d)(1) through (4) of Rule 9232 and the public interest or the administration of FINRA's regulatory and enforcement

[7] A Respondent is a FINRA member or associated person against whom a complaint is filed. *See* FINRA Rule 9120(aa).

[8] *See* FINRA Rule 9211.

[9] *See* FINRA Rule 9213. A Hearing Officer must be an attorney who is an employee of FINRA or former employee of FINRA who previously acted as a Hearing Officer. *See* FINRA Rule 9120(r). Among other things, a Hearing Officer administers pre-hearing matters, including most motions, resolves procedural and evidentiary matters, oversees the settlement and discovery process, regulates the course of the proceeding, and drafts a decision that represents the view of the majority of the Hearing Panel. *See* FINRA Rule 9235.

[10] *See* FINRA Rule 9231(c). Rule 9231 does not establish a minimum number of hearing days required to make a hearing an Extended Hearing. OHO's policy is to treat any hearing scheduled to last five or more days as an Extended Hearing.

[11] *See* FINRA Rule 9260 Series.

[12] *See* FINRA Rules 9311 and 9312. In addition, a member of FINRA's Board of Governors may call a disciplinary proceeding for review by the FINRA Board. *See* FINRA Rule 9351. A Respondent may appeal a final disciplinary action by FINRA to the SEC pursuant to Section 19(d)(2) of the Exchange Act and FINRA Rule 9370.

[13] *See* FINRA Rules 9351 and 9370.

[14] In 2018, FINRA reorganized its 11 District Committees into five Regional Committees.

[15] FINRA, Inc. (FINRA), a securities association registered under Section 15A of the Exchange Act, is the parent company of FINRA Regulation, Inc. (FINRA Regulation). ''Governor'' refers to a member of the Board of Governors of FINRA. ''Director'' refers to a member of the Board of Directors of FINRA Regulation.

[16] *See* FINRA Rule 9231(b)(1)(A) to (F).

[17] *See* FINRA Rule 9231(b)(2). A former Market Regulation Committee member must have served no earlier than four years before the date the complaint was served upon the Respondent who was the first Respondent served in the disciplinary proceeding. *See also* FINRA Rule 9232(b).

FINRA Rule 9120(u) refers to the federal securities laws and the rules and regulations adopted thereunder and various FINRA rules and policies relating to (i) the quotations of securities; (ii) the execution of transactions; (iii) the reporting of transactions; and (iv) trading practices, including rules prohibiting manipulation and insider trading, and trading-related rules such as FINRA Rule 4560 and FINRA Rule 5200, 6000, 7100, 7200, 7300 and 7400 Series.

[18] *See* FINRA Rule 9232(a). The Chief Hearing Officer designates a Regional Committee as the Primary Regional Committee based on the relevant facts and circumstances of the case, including but not limited to (1) the location of a Respondent's principal office if the Respondent is or was a member firm; (2) the location of a Respondent's office at the time of the alleged misconduct if the Respondent is or was an associated person; (3) the location of the office of a member or an associated person, or a former member or associated person, where the alleged misconduct occurred; (4) the location of witnesses at the time of the filing of the complaint, especially the location of witnesses who are or were customers of a Respondent; (5) the location, at the time of the alleged misconduct, of the main, branch, or other office in which supervisory personnel, who are or were responsible for the supervision of a Respondent, were employed; and (6) the location, at the time of the alleged misconduct, of the main, branch, or other office in which supervisory personnel, who are or were responsible for the supervision of the office, division, function, or segment of the member where the alleged misconduct occurred, were employed. *See* FINRA Rule 9232(c).

[19] *See* FINRA Rule 9232(d).

[20] *See supra* footnote 19.

program would be enhanced by the selection of such Panelists.[21]

Compensation of Panelists

The Chief Hearing Officer has discretion to compensate any or all Panelists of an Extended Hearing Panel at the rate then in effect for arbitrators appointed under the Rule 12000 Series.[22] In practice, the Chief Hearing Officer exercises his or her discretion to compensate all Panelists on all Extended Hearing Panels. The Chief Hearing Officer does not have the authority to compensate Panelists on non-Extended Hearing Panels. In practice, because only hearings that are scheduled to last five or more days are designated Extended Hearings, Panelists who serve on hearings that are scheduled to last four or fewer days are not compensated.[23]

OHO has encountered increasing difficulty in finding eligible individuals willing to serve on Hearing Panels. At the same time, the number, length and complexity of hearings are increasing. Some eligible individuals have indicated that they are only willing to serve on Extended Hearing Panels because they want to be compensated for their time. Others have indicated that they should be compensated for their time in the case of a hearing lasting more than one or two days.

FINRA places a high value on a fair, efficient, and expeditious adjudicatory process. OHO therefore must be able to quickly and efficiently assign adjudicated matters to Hearing Panels, both Extended and non-Extended, and schedule cases for hearing. FINRA believes OHO's ability to identify willing and eligible Panelists will be improved if all Hearing Panelists are compensated.

As is the case with Extended Hearing Panelists, the Chief Hearing Officer would compensate all non-Extended Hearing Panelists if granted discretion to do so. Rather than adding a grant of discretion to cover non-Extended Hearing Panels, FINRA instead proposes to amend Rule 9231 to provide that all Panelists—*i.e.,* both Extended and non-Extended Hearing Panelists—will be compensated at the rate then in effect for arbitrators set forth in FINRA Rule 12214(a)(1), (3) and (4). The proposed rule change does not establish or change a fee in connection with FINRA disciplinary proceedings. Extended Hearing Panelists are currently paid pursuant to the payment provisions set forth in Rule 12214(a)(1), (3) and (4). The proposed rule change merely extends those payment provisions to Panelists who serve in connection with non-Extended Hearings.

Payments to arbitrators is established in Rule 12214. The payments that non-Extended Hearing Panelists would be eligible to receive are set forth in Rule 12214(a)(1), (3) and (4). Rule 12214(a)(1) provides for a $300 payment to an arbitrator for each hearing session in which he or she participates. A typical hearing day may consist of two four-hour hearing sessions.[24] Rule 12214(a)(3) establishes a $50 payment to an arbitrator for travel to a hearing session that is postponed. Rule 12214(a)(4) provides for a $600 payment to an arbitrator if a hearing session other than a prehearing conference is postponed within ten days before the scheduled date.

Other honoraria provided for by Rule 12214 are inapplicable to Hearing Panelists. Rule 12214(a)(2) provides for an additional $125 per day to the chairperson for each hearing on the merits. An OHO Hearing Officer who is a FINRA employee serves as the chair of each Hearing Panel. Thus, the provision in Rule 12214(a)(2) has no effect in the case of Hearing Panelists.

Rule 12214(a)(5) provides for a $100 payment to each arbitrator for a prehearing conference that is cancelled by agreement of the parties, or is requested by one or more of the parties, within three business days of its scheduled date. Hearing Panelists, however, typically do not participate in prehearing conferences.[25] In most cases, the OHO Hearing Officer handles a prehearing conference alone. In the limited cases where Hearing Panelists participate in a prehearing conference, those conferences are set by the OHO Hearing Officer and are not scheduled at the request of a party. Therefore, the provision in Rule 12214(a)(5) is likewise inapplicable to Hearing Panelists.

In addition, the honoraria established in Rule 12214(b), (c) and (d) do not apply to Hearing Panelists. Rule 12214(b) authorizes a higher or additional honorarium in the case of a foreign hearing location; all FINRA disciplinary hearings, however, occur at U.S. locations. Rule 12214(c) provides for honorarium payments to arbitrators for deciding motions concerning discovery, contested subpoena requests, and contested orders for production or appearance without a hearing session. Subpoenas are not issued in FINRA disciplinary hearings, however, and discovery-related motions are decided by the OHO Hearing Officer alone.[26] Rule 12214(d) provides an additional honorarium for explained decisions written in support of arbitration awards. This provision does not apply to Hearing Panel decisions written in connection with FINRA disciplinary proceedings, which are governed by Rule 9268, and is therefore inapplicable to Hearing Panelists.

FINRA notes that, except in limited circumstances, Rule 12214 does not provide for payments for time spent on travel or preparation. Non-Extended Hearing Panelists, like Extended Hearing Panelists, therefore still may accrue not-insubstantial amounts of uncompensated time in connection with service on a Hearing Panel.

FINRA has filed the proposed rule change for immediate effectiveness. The proposed rule change will become operative 30 days after the date of filing.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(8) of the Act,[27] which requires, among other things, that FINRA rules provide a fair procedure for the disciplining of members and persons associated with members. FINRA believes that the proposed rule change, consistent with this purpose of the Act, will help assure that complaints filed with OHO continue to be heard and resolved in a timely manner by Panelists with the expertise, experience, and perspective necessary to render a fair and informed judgment and, where necessary, to impose appropriately remedial sanctions. By compensating all Panelists, the proposed rule change will encourage a greater number of eligible individuals to agree to devote their time and experience in service as Panelists. This will enable the Chief Hearing Officer to appoint Hearing Panels from a larger and potentially more diverse group of eligible individuals willing to serve and capable of responding to the complex issues and time demands presented by disciplinary hearings.

[21] *See* FINRA Rule 9232(e).

[22] *See* FINRA Rule 9231(c). The FINRA Rule 12000 Series is the Code of Arbitration Procedure for Customer Disputes.

[23] OHO conducts disciplinary hearings in all 50 states, thereby requiring most Panelists to travel to FINRA hearings. FINRA covers all travel-related expenses for Panelists regardless of the length of the hearing.

[24] A hearing session is a meeting of four hours or less. *See* FINRA Rule 12100(p). Occasionally, a Panelist may prepare for and travel to a hearing only to discover just prior to a hearing session that he or she cannot participate. This may occur, for example, if a Panelist discovers just prior to the commencement of a hearing session that she must recuse herself because of her connection to a witness. In such a case, the Panelist will be compensated for one hearing session.

[25] *See* FINRA Rule 9241.

[26] *See* FINRA Rules 9252 and 9253.

[27] 15 U.S.C. 78*o*–3(b)(8).

FINRA also believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[28] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that encouraging a greater number of eligible individuals to serve as Panelists by compensating them for their time and expertise will enhance FINRA's disciplinary processes, promote high business standards for FINRA members, and allow for the prompt adjudication of allegations of misconduct by FINRA members and their associated persons. It is in the public interest, and consistent with the Act's purpose, that FINRA disciplinary proceedings be timely resolved and that appropriate sanctions be imposed where necessary to redress customer harm and deter future misconduct.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change is intended solely to enhance the administration of FINRA's process for the disciplining of members and persons associated with members. FINRA believes the proposed rule change will allow the Chief Hearing Officer flexibility to appoint Panelists and thereby maintain the timely progress of cases to a hearing. FINRA does not believe that the proposed rule change will have any negative effect on members or impose any new costs.

Economic Impact Assessment

As described above, under current FINRA rules, the Chief Hearing Officer may pay honoraria only to individuals who serve as Panelists at Extended Hearings. The rules do not allow OHO to pay honoraria to Panelists at non-Extended Hearings. As a result, potential Panelists may lack sufficient incentive to serve on non-Extended Hearing Panels, which impairs OHO's ability to assemble Hearing Panels for non-Extended Hearings expediently. FINRA believes that paying honoraria to all Hearing Panelists, regardless of whether the hearing is designated as an Extended Hearing, will expand the number of qualified current or retired industry members willing to serve on Hearing Panels.

Economic Baseline

The baseline for the proposal is Rule 9231, which allows for payments to Panelists serving on Extended Hearing Panels only. Based on FINRA's experience, this inequity creates a preference among eligible individuals to serve on Extended Hearing Panels. This can limit the pool of Panelists available to serve for non-Extended Hearings.

Of the 59 hearings that occurred between 2017 and 2019, 51% were Extended Hearings, and thus generated payments to Panelists.[29] In the three-year sample period, OHO conducted hearings, on average, 82 days per year, of which 57 days were for Extended Hearings. FINRA spent, on average, $68,400 annually to pay Extended Hearing Panelists.[30]

Anticipated Benefits

The proposal provides a monetary benefit of $600 per day to Hearing Panelists serving on non-Extended Hearing Panels, among other potential payments. This proposed honorarium may potentially create a new incentive for industry members to serve (or continue to serve) on non-Extended Hearing Panels. The proposal may also benefit FINRA as it should increase the number of eligible individuals willing to serve as Panelists and make it easier for FINRA to assemble Hearing Panels with appropriate experience and expertise, which is the regulatory objective.

Both industry members and investors share an incentive to have enforcement actions timely brought before a suitably qualified panel. To the extent that the proposal expands the pool of willing Panelists, and thereby improves FINRA's ability to expeditiously organize expert Hearing Panels, both of these groups will benefit.

Anticipated Costs

The proposed rule change, which expands honoraria to non-Extended Hearing Panelists, would not impose any additional requirements or fees on firms or respondents in FINRA disciplinary hearings. Direct costs associated with this proposal will be incurred by FINRA only. FINRA estimates these costs at approximately $26,400 per year. Based on its experience with paying honoraria to Panelists in Extended Hearings, OHO does not anticipate that paying honoraria to Panelists serving on non-Extended Hearing Panels will adversely impact the hearing process.

Alternatives Considered

FINRA considered allowing the Chief Hearing Officer to use his or her discretion in determining whether to compensate Hearing Panelists. A primary objective of the amendment is to increase eligible Hearing Panelists' incentive to serve. Therefore, requiring compensation in the form of an honorarium at the rate set for arbitrators to all Hearing Panelists—rather than at the discretion of the Chief Hearing Officer—should only increase the likelihood that the amendment will yield the desired outcome.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor 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) of the Act[31] and Rule 19b–4(f)(6) thereunder.[32]

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

[28] 15 U.S.C. 78*o*–3(b)(6).

[29] In 2017, there were 25 hearings, 14 of which were Extended Hearings; in 2018, of 21 hearings, 10 were Extended Hearings; and in 2019, of 13 hearings, six were Extended Hearings.

[30] Figures based on a three-year period from January 2017 to December 2019.

[31] 15 U.S.C. 78s(b)(3)(A).

[32] 17 CFR 240.19b–4(f)(6).

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2020–014 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–FINRA–2020–014. 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 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. 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–FINRA–2020–014 and should be submitted on or before June 4, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–10285 Filed 5–13–20; 8:45 am]

BILLING CODE 8011–01–P

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88845; File No. SR-CboeBYX–2020–014]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Adopting Rule 14.12 Governing the Trading, Pursuant to Unlisted Trading Privileges, of Exchange-Traded Fund Shares

May 8, 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 May 7, 2020, Cboe BYX Exchange, Inc. (''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a ''non-controversial'' proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[3] and Rule 19b–4(f)(6) thereunder.[4] 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

Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to adopt Rule 14.12 to permit the trading, pursuant to unlisted trading privileges, of Exchange-Traded Fund Shares. Additionally, the Exchange proposes to make corresponding changes to Rule 14.1(a). 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/byx/*), 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 adopt Rule 14.12 to permit the trading, pursuant to unlisted trading privileges (''UTP''), of Exchange-Traded Fund (also referred to as ''ETF'') Shares,[5] which substantially conforms to Cboe BZX Exchange, Inc. (''BZX'') Rule 14.11(l).[6] Additionally, the Exchange proposes to make corresponding changes to Rule 14.1(a) to reference Exchange-Traded Fund Shares and proposed Rule 14.12, where applicable.

The Exchange does not currently list any securities as a primary listing market. Consistent with this fact, Exchange Rule 14.1(a) currently states that all securities traded on the Exchange are traded pursuant to UTP and that the Exchange will not list any securities before first filing and obtaining Commission approval of rules that incorporate qualitative listing criteria and comply with Rules 10A–3[7] (''Rule 10A–3'') and 10C–1[8] (''Rule 10C–1'') under the Act. Therefore, the provisions of existing Rules 14.2 through 14.9, 14.11, and proposed Rule 14.12 that permit the listing of certain Equity Securities[9] will not be effective

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b-4(f)(6).

[5] ETF Shares means shares of stock issued by an Exchange-Traded Fund. *See* proposed Rule 14.12(c)(1).

[6] *See* Securities and Exchange Act Release No. 88566 (April 6, 2020) 85 FR 20312 (April 10, 2020) (SR–CboeBZX–2019–097) (the ''BZX Approval Order'').

[7] Rule 10A–3 obligates the Exchange to prohibit the initial or continued listing of any security of an issuer that is not in compliance with certain required standards. *See* 17 CFR 240.10A–3.

[8] Rule 10C–1 obligates the Exchange to establish listing standards that require each member of a listed issuer's compensation committee to be a member of the issuer's board and to be independent, as well as establish certain factors that an issuer must consider when evaluating the independence of a director. *See* 17 CFR 240.10C–1.

[9] As provided in Rule 14.1(a), the term ''Equity Security'' means, but is not limited to, common stock, secondary classes of common stock, preferred stock and similar issues, shares or certificates of beneficial interest of trusts, notes, limited partnership interests, warrants, certificates of deposit for common stock, convertible debt securities, ADRs, CVRs, Investment Company Units, Trust Issued Receipts (including those based on Investment Shares), Commodity-Based Trust

Continued

until the Exchange files a proposed rule change under Section 19(b)(2) under the Exchange Act to amend its rules to comply with Rule 10A–3 and 10C–1 under the Exchange Act and to incorporate qualitative listing criteria, and such proposed rule change is approved by the Commission. Considering the foregoing, the Exchange proposes to adopt Rule 14.12 as set forth below.

Proposed Listing Rules

Proposed Rule 14.12(a) provides that the Exchange will consider for trading, whether by listing or pursuant to UTP, ETF Shares that meet the criteria of Rule 14.12.

Proposed Rule 14.12(b) provides that Rule 14.12 is applicable only to ETF Shares and that, except to the extent inconsistent with Rule 14.12, or unless the context otherwise requires, the rules and procedures of the Exchange's Board of Directors shall be applicable to the trading on the Exchange of such securities. Proposed Rule 14.12(b) provides further that ETF Shares are included within the definition of ''security'' or ''securities'' as such terms are used in the Rules of the Exchange.

Proposed Rule 14.12(b)(1) provides that transactions in ETF Shares will occur throughout the Exchange's trading hours.

Proposed Rule 14.12(b)(2) provides that the minimum price variation for quoting and entry of orders in ETF Shares will be $0.01.

Proposed Rule 14.12(b)(3) provides that the Exchange will implement and maintain written surveillance procedures for ETF Shares.

Proposed Rule 14.12(c)(1) defines the term ''ETF Shares'' as shares of stock issued by an Exchange-Traded Fund.[10]

Proposed Rule 14.12(c)(2) defines the term ''Exchange-Traded Fund'' as having the same meaning as the term ''exchange-traded fund'' as defined in Rule 6c–11 under the Investment Company Act of 1940.[11]

Proposed Rule 14.12(c)(3) defines the term ''Reporting Authority'' in respect of a particular series of ETF Shares means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists a particular series of ETF Shares (if the Exchange is trading such series pursuant to UTP) as the official source for calculating and reporting information relating to such series, including, but not limited to, the amount of any dividend equivalent payment or cash distribution to holders of ETF Shares, the net asset value (the ''NAV''), index or portfolio value, the current value of the portfolio of securities required to be deposited in connection with issuance of ETF Shares, or other information relating to the issuance, redemption or trading of ETF Shares. A series of ETF Shares may have more than one Reporting Authority, each having different functions.

Proposed Rule 14.12(d) provides for the initial and continued listing and/or trading of ETF Shares, including trading pursuant to UTP, pursuant to Rule 19b4–(e) under the Act. Proposed Rule 14.12(d)(1) sets forth initial listing criteria applicable to ETF Shares. Specifically, proposed Rule 14.12(d)(1) provides that the requirements of Rule 6c–11 must be satisfied by a series of ETF Shares on an initial and continued listing basis. Such securities must also satisfy the criteria on an initial and, with the exception of proposed subparagraph (d)(1)(A), a continued listing basis. Proposed Rule 14.12(d)(1)(A) provides that for each series, the Exchange will establish a minimum number of ETF Shares required to be outstanding at the time of commencement of trading on the Exchange. However, as noted above, such criteria is not applicable on a continued listing basis. Proposed rule 14.12(d)(1)(B) provides that if an index underlying a series of ETF Shares is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a ''fire wall'' around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to the investment company issuing an actively managed series of ETF Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Exchange-Traded Fund's portfolio. Additionally proposed rule 14.12(d)(1)(C) provides that any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a series of ETF Shares, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. For actively managed Exchange-Traded Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable portfolio.

Proposed Rule 14.12(d)(2) provides that each series of ETF Shares will be listed and traded subject to application of the following continued listing criteria. Proposed Rule 14.12(d)(2)(A) provides that the Exchange will consider the suspension of trading in or removal from listing of or termination of unlisted trading privileges for a series of ETF Shares under any of the following circumstances: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.12(d)(2)(B) provides that upon termination of an investment company, the Exchange will require that ETF Shares issued in connection with such entity be removed from Exchange listing.

Proposed Rule 14.12(e), which relates to limitation of Exchange liability, provides that neither the Exchange, the Reporting Authority, nor any agent of the Exchange shall have any liability for damages, claims, losses or expenses caused by any errors, omissions, or delays in calculating or disseminating any current index or portfolio value; the current value of the portfolio of securities required to be deposited to the open-end management investment

Shares, Currency Trust Shares, Partnership Units, Equity-Linked Securities, Commodity-Linked Securities, Currency-Linked Securities, Portfolio Depositary Receipts, Equity-Linked Debt Securities, and Managed Portfolio Shares. Further, the Exchange now proposes to include the term ''Exchange-Traded Fund Shares'' to the definition of Equity Security.

[10] For purposes of this filing, references to a series of Exchange-Traded Fund Shares are referred to interchangeably as a series of Exchange-Traded Fund Shares or as a ''Fund'' and shares of a series of Exchange-Traded Fund Shares are generally referred to as the ''Shares''.

[11] Per Rule 6c–11, an exchange-traded fund means a registered open-end management company: (A) That issues (and redeems) creation units to (and from) authorized participants in exchange for a basket and a cash balancing amount if any; and (B) Whose shares are listed on a national securities exchange and traded at market-determined prices.

company in connection with issuance of ETF Shares; the amount of any dividend equivalent payment or cash distribution to holders of ETF Shares; net asset value; or other information relating to the purchase, redemption, or trading of ETF Shares, resulting from any negligent act or omission by the Exchange, the Reporting Authority, or any agent of the Exchange, or any act, condition, or cause beyond the reasonable control of the Exchange, its agent, or the Reporting Authority, including, but not limited to, an act of God; fire; flood; extraordinary weather conditions; war; insurrection; riot; strike; accident; action of government; communications or power failure; equipment or software malfunction; or any error, omission, or delay in the reports of transactions in one or more underlying securities.

The Exchange does not propose to adopt BZX Rule 14.11(l)(6) because it is not applicable as the Exchange does not currently have any listed products.

Quantitative Standards

The Exchange believes that the proposal is designed to prevent fraudulent and manipulative acts and practices because the Exchange will perform ongoing surveillance of ETF Shares listed on the Exchange in order to ensure compliance with Rule 6c-11 and the 1940 Act on an ongoing basis. While proposed Rule 14.12 does not include the quantitative requirements applicable to an ETF or an ETF's holdings or underlying index that are included in Rule 14.2, the Exchange believes that the manipulation concerns that such standards are intended to address are otherwise mitigated by a combination of the Exchange's surveillance procedures and the Exchange's ability to suspend trading or terminate unlisted trading privileges under the proposed Rule 14.12(d)(2)(A). The Exchange will also halt trading in ETF Shares under the conditions specified in Rule 11.18, ''Trading Halts Due to Extraordinary Market Volatility.'' The Exchange believes that such concerns are further mitigated by enhancements to the arbitrage mechanism that will come from Rule 6c–11, specifically the additional flexibility provided to issuers of ETF Shares through the use of custom baskets for creations and redemptions and the additional information made available to the public through the additional daily website disclosure obligations applicable under Rule 6c–11.[12] The Exchange believes that the combination of these factors will act to keep ETF Shares trading near the value of their underlying holdings and further mitigate concerns around manipulation of ETF Shares on the Exchange without the inclusion of quantitative standards.[13]

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of ETF Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of ETF Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products. The Exchange will require the issuer of each series of ETF Shares listed on the Exchange to represent to the Exchange that it will advise the Exchange of any failure by a Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements.

Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, among other product types, to monitor trading in ETF Shares. The Exchange or the Financial Industry Regulatory Authority, Inc. (''FINRA''), on behalf of the Exchange, will communicate as needed regarding trading in ETF Shares and certain of their applicable underlying components with other markets that are members of the Intermarket Surveillance Group (''ISG'') or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in ETF Shares and certain of their applicable underlying components from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a series of ETF Shares reported to FINRA's Trade Reporting and Compliance Engine (''TRACE''). FINRA also can access data obtained from the Municipal Securities Rulemaking Board's (''MSRB'') Electronic Municipal Market Access (''EMMA'') system relating to municipal bond trading activity for surveillance purposes in connection with trading in a series of ETF Shares, to the extent that a series of ETF Shares holds municipal securities.

Trading Halts

As proposed above, the Exchange may consider all relevant factors in exercising its discretion to halt trading in a series of Managed Portfolio Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the series of ETF Shares inadvisable. These may include: (i) The extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (ii) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Additionally, the Exchange would halt trading as soon as practicable where the Exchange becomes aware that: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

Trading Rules

The Exchange deems ETF Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. ETF Shares will trade on the Exchange throughout the Exchange's trading hours. As provided in proposed Rule 14.12(b)(2), the minimum price variation for quoting and entry of orders in ETF Shares traded on the Exchange is $0.01.

2. Statutory Basis

The Exchange believes that the proposal is consistent with Section 6(b)

[12] The Exchange notes that the Commission came to a similar conclusion in several places in the Rule 6c-11 Release. *See* Release Nos. 33–10695; IC–33646; File No. S7–15–18 (Exchange-Traded Funds) (September 25, 2019), 84 FR 57162 (October 24, 2019) (the ''Rule 6c–11 Release'') at 15–18; 60–61; 69–70; 78–79; 82–84; and 95–96.

[13] The Exchange believes that this applies to all quantitative standards, whether applicable to the portfolio holdings of a series of ETF Shares or the distribution of the ETF Shares.

of the Act [14] in general and Section 6(b)(5) of the Act [15] in particular in that it is 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.

The Exchange believes that proposed Rule 14.12 will remove impediments to and perfect the mechanism of a free and open market and national market system. Specifically, the proposed amendment raises no substantive issues that have not otherwise been considered by the Commission in either the BZX Approval Order or in the context of other similar Exchange Rules. This proposal is substantively similar to the BZX Approval order, with the exception that the Exchange is only proposing to trade series of ETF Shares pursuant to unlisted trading privileges, while BZX will both list and trade series of ETF Shares. Further, while proposed Rule 14.12(d)(2)(A) provides that the Exchange may terminate unlisted trading privileges and BZX Rule 14.11(l) does not, the proposed rule text is substantially similar to existing Exchange Rules 14.3(g)(2) and 14.11(d)(2)(B) and therefore raises no novel issues.

The Exchange believes that proposed Rule 14.12 is designed to prevent fraudulent and manipulative acts and practices in that the proposed rules relating to listing and trading ETF Shares on the Exchange provide specific initial and continued listing criteria required to be met by such securities. Proposed Rule 14.12(d) sets forth initial and continued listing criteria applicable to ETF Shares, specifically providing that the Exchange may approve a series of ETF Shares for listing and/or trading (including pursuant to unlisted trading privileges) on the Exchange pursuant to Rule 19b–4(e) under the Act, provided such series of ETF Shares is eligible to operate in reliance on Rule 6c-11 under the Investment Company Act of 1940 and must satisfy the requirements of this Rule 14.12 on an initial and continued listing basis.

Proposed Rule 14.12(d)(1) provides that initial listing criteria which includes (A) for each series, the Exchange will establish a minimum number of ETF Shares required to be outstanding at the time of commencement of trading on the Exchange; (B) if an index underlying a series of ETF Shares is maintained by a broker-dealer or fund adviser, the broker-dealer or fund adviser shall erect and maintain a ''fire wall'' around the personnel who have access to information concerning changes and adjustments to the index and the index shall be calculated by a third party who is not a broker-dealer or fund adviser. If the investment adviser to the investment company issuing an actively managed series of ETF Shares is affiliated with a broker-dealer, such investment adviser shall erect and maintain a ''fire wall'' between the investment adviser and the broker-dealer with respect to access to information concerning the composition and/or changes to such Exchange-Traded Fund's portfolio; and (C) any advisory committee, supervisory board, or similar entity that advises a Reporting Authority or that makes decisions on the composition, methodology, and related matters of an index underlying a series of ETF Shares, must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material non-public information regarding the applicable index. For actively managed Exchange-Traded Funds, personnel who make decisions on the portfolio composition must be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the applicable portfolio.

Proposed Rule 14.12(d)(2) provides that each series of ETF Shares will be listed and traded on the Exchange subject to application of Proposed Rule 14.12(d)(2)(A) and (B). Proposed Rule 14.12(d)(2)(A) provides that the Exchange will consider the suspension of trading in or removal from listing of or termination of UTP for a series of ETF Shares under any of the following circumstances: (i) If the Exchange becomes aware that the issuer of the ETF Shares is no longer eligible to operate in reliance on Rule 6c–11 under the Investment Company Act of 1940; (ii) if any of the other listing requirements set forth in this Rule 14.12 are not continuously maintained; (iii) if, following the initial twelve month period after commencement of trading on the Exchange of a series of ETF Shares, there are fewer than 50 beneficial holders of the series of ETF Shares for 30 or more consecutive trading days; or (iv) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable. Proposed Rule 14.12(d)(2)(B) provides that upon termination of an investment company, the Exchange requires that ETF Shares issued in connection with such entity be removed from Exchange listing.

The Exchange further believes that proposed Rule 14.12 is designed to prevent fraudulent and manipulative acts and practices because of the robust surveillances in place on the Exchange as required under proposed Rule 14.12(b)(3) along with the similarities of proposed Rule 14.12 to the rules related to other securities that are already traded on the Exchange pursuant to UTP and which would qualify as ETF Shares. Proposed Rule 14.12 is based in large part on Rule 14.2 related to the listing and trading of Investment Company Units on the Exchange, which are issued under the 1940 Act and would qualify as ETF Shares after Rule 6c–11 is effective. As such, the Exchange believes that using Rule 14.2 (the ''Current ETF Standards'') as the basis for proposed Rule 14.12 is appropriate because they are generally designed to address the issues associated with ETF Shares. The only substantial differences between proposed Rule 14.12 and the Current ETF Standards that are not otherwise required under Rule 6c-11 are as follows: (i) Proposed Rule 14.12 does not include the quantitative standards applicable to a fund or an index that are included in the Current ETF Standards; and (ii) proposed Rule 14.12 does not include any requirements related to the dissemination of a fund's intraday indicative value.[16]

Further, the Exchange also represents that its surveillance procedures are adequate to properly monitor the trading of the ETF Shares in all trading sessions and to deter and detect violations of Exchange rules and applicable federal securities laws. Specifically, the Exchange intends to utilize its existing surveillance procedures applicable to derivative products, which are currently applicable to Investment Company Units, among other product types, to monitor trading in ETF Shares. The Exchange or the FINRA, on behalf of the Exchange, will communicate as needed regarding trading in ETF Shares and certain of their applicable underlying components with other markets that are members of the ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. In addition, the Exchange may obtain information regarding trading in ETF Shares and certain of their applicable underlying components from markets

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(5).

[16] For purposes of this filing, the term ''intraday indicative value'' or ''IIV'' shall mean an intraday estimate of the value of a share of each series Investment Company Units.

and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. Additionally, FINRA, on behalf of the Exchange, is able to access, as needed, trade information for certain fixed income securities that may be held by a series of ETF Shares reported to FINRA's TRACE. FINRA also can access data obtained from the MSRB EMMA system relating to municipal bond trading activity for surveillance purposes in connection with trading in a series of ETF Shares, to the extent that a series of ETF Shares holds municipal securities.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

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 that is not necessary or appropriate in furtherance of the purpose of the Act. The Exchange notes that the proposed rule change, rather will facilitate the trading, pursuant to UTP, of ETF Shares that will enhance competition among both market participants and listing venues, to the benefit of investors and the marketplace.

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

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) of the Act [17] and Rule 19b–4(f)(6) thereunder.[18]

A proposed rule change filed under Rule 19b–4(f)(6) [19] normally does not become operative for 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[20] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay to immediately allow ETF Shares to be traded on another venue. The Commission believes that waiver of the 30-day operative delay for this purpose is consistent with the protection of investors and the public interest and hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[21]

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–CboeBYX–2020–014 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–CboeBYX–2020–014. 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–CboeBYX–2020–014 and should be submitted on or before June 4, 2020.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–10289 Filed 5–13–20; 8:45 am]

BILLING CODE 8011–01–P

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of 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.

[19] 17 CFR 240.19b–4(f)(6).

[20] 17 CFR 240.19b–4(f)(6)(iii).

[21] For purposes only of waiving the operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[22] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–88838; File No. SR–NASDAQ–2020–018]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Eliminate a Transitional Rule That Has Expired Related to Nasdaq Global and Global Select Markets Entry Fees

May 8, 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 May 5, 2020, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 delete [sic] Rule 5910(a)(1) to remove a transitional rule that is no longer applicable to any companies.

The text of the proposed rule change is available on the Exchange's website at *http://nasdaq.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

Nasdaq proposes to modify Rule 5910(a)(1) to remove a transitional rule that is no longer applicable to any companies. This transitional rule was adopted in connection with changes to the entry fees for the Nasdaq Global and Global Select Markets.[3] These changes to the entry fees were fully phased in on July 1, 2019 and the transitional rule no longer applies to any companies.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[4] in general, and furthers the objectives of Section 6(b)(5) of the Act,[5] in particular, in that it is designed 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. Nasdaq believes that it is in the public interest to eliminate the obsolete Nasdaq Global and Global Select Markets entry fee rule. Eliminating this provision, which was fully phased out on July 1, 2019, will improve the readability of Nasdaq's rules.

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. Nasdaq does not believe the proposed rule change, which merely eliminates obsolete provisions and does not make any substantive change to Nasdaq's rules, will impose any burden, nor have any impact, on competition.

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[6] and subparagraph (f)(6) of Rule 19b–4 thereunder.[7]

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–NASDAQ–2020–018 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–NASDAQ–2020–018. 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–NASDAQ–2020–018 and should be submitted on or before June 4, 2020.

[3] Securities Exchange Act Release No. 84930 (December 21, 2018), 83 FR 67752 (December 31, 2018) (SR–NASDAQ–2018–105)

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 15 U.S.C. 78s(b)(3)(A)(iii).

[7] 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.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[8]

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2020–10284 Filed 5–13–20; 8:45 am]

BILLING CODE 8011–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36401]

Indiana & Ohio Railway Company—Operation Exemption—Fulton Railroad Co. Ltd.

Indiana & Ohio Railway Company (IORY), a Class III railroad, has filed a verified notice of exemption pursuant to 49 CFR 1150.41 to continue to operate a Fulton Railroad Co. Ltd. (Fulton Railroad) rail line, from its connection at IORY milepost 0.0 and continuing to the end of Fulton Railroad's tracks in the City of Cincinnati, Millcreek Township, Hamilton County, Ohio, a total distance of approximately 4,800 feet (the Line). IORY states that it has entered into an amended and restated operating rights agreement (Amended Agreement) with Fulton Railroad to amend the existing operating agreement (Current Agreement).[1]

IORY states that it is the present operator of the Line under the Current Agreement. IORY states that the Amended Agreement extends the term and revises other commercial provisions which will allow IORY to continue operating the Line until either party decides to terminate.

IORY certifies that the Amended Agreement does not include an interchange commitment.

IORY certifies that its projected revenues as a result of this transaction will not exceed those that would qualify it as a Class III carrier. IORY also certifies that its revenues currently exceed $5 million. Pursuant to 49 CFR 1150.42(e), if a carrier's projected annual revenues will exceed $5 million, it must, at least 60 days before the exemption becomes effective, post a notice of its intent to undertake the proposed transaction at the workplace of the employees on the affected lines, serve a copy of the notice on the national offices of the labor unions with employees on the affected lines, and certify to the Board that it has done so. However, IORY's verified notice includes a request for waiver of the 60-day advance labor notice requirements. IORY's waiver 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 May 21, 2020.

All pleadings, referring to Docket No. FD 36401, 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 IORY's representative, Eric M. Hocky, Esq., Clark Hill PLC, Two Commerce Square, 2001 Market St., Suite 2620, Philadelphia, PA 19103.

According to IORY, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: May 11, 2020.

By the Board, Allison C. Davis, Director, Office of Proceedings.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2020–10320 Filed 5–13–20; 8:45 am]

BILLING CODE 4915–01–P

[8] 17 CFR 200.30–3(a)(12).

[1] *See Ind. & Ohio Ry.—Trackage Rights Exemption—Fulton Ry.*, FD 34800 (STB served Dec. 23, 2005). IORY states that it filed its verified notice for the Current Agreement under the trackage rights class exemption at 49 CFR 1180.2(d)(7) but is filing this verified notice under 49 CFR 1150.41 because the Amended Agreement contains characteristics more closely aligned with a lease than a trackage rights agreement.

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

[Docket Number USTR–2020–0019]

List of Countries Denying Fair Market Opportunities for Government-Funded Airport Construction Projects

AGENCY: Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The U.S. Trade Representative has determined not to list any countries as denying fair market opportunities for U.S. products, suppliers, or bidders in foreign government-funded airport construction projects.

FOR FURTHER INFORMATION CONTACT: Kate Psillos, International Procurement Negotiator, *Kathryn.W.Psillos@ustr.eop.gov* or 202–395–9581, or J. Daniel Stirk, Senior Associate General Counsel, *John_Stirk@ustr.eop.gov* or 202–395–3150.

SUPPLEMENTARY INFORMATION: Section 533 of the Airport and Airway Improvement Act of 1982, as amended by section 115 of the Airport and Airway Safety and Capacity Expansion Act of 1987 (Pub. L. 100–223, *codified at* 49 U.S.C. 50104), requires the U.S. Trade Representative to decide whether any foreign country has denied fair market opportunities to U.S. products, suppliers, or bidders in connection with airport construction projects of $500,000 or more that are funded in whole or in part by the government of such country. The Office of the United States Trade Representative has not received any complaints or other information that indicates that U.S. products, suppliers, or bidders are being denied fair market opportunities in such airport construction projects. Therefore, the U.S. Trade Representative has decided not to list any countries as denying fair market opportunities for U.S. products, suppliers, or bidders in foreign government-funded airport construction projects.

Joseph Barloon,

General Counsel, Office of the United States Trade Representative.

[FR Doc. 2020–10300 Filed 5–13–20; 8:45 am]

BILLING CODE 3290–F0–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in California

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by the California Department of Transportation (Caltrans).

SUMMARY: The FHWA, on behalf of Caltrans, is issuing this notice to announce actions taken by Caltrans that are final. The actions relate to the proposed highway project, Merced Seismic Retrofit Project, which is a seismic retrofit project of seven bridges on State Route 59, 140 and 152 in the County of Merced, California. Those actions grant licenses, permits, and approvals for the project.

DATES: By this notice, the FHWA, on behalf of Caltrans, is advising the public of final agency actions subject to 23

U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before October 13, 2020. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For Caltrans: Jennifer Lugo, Branch Chief, Central Sierra Environmental Analysis Branch, 855 M Street, Suite 200, Fresno, CA 93721, weekdays from 7:30 a.m. to 4:15 p.m., *jennifer.lugo@dot.ca.gov,* telephone 559–445–6172. For FHWA, contact David Tedrick at (916) 498–5024 or email *david.tedrick@dot.gov.*

SUPPLEMENTARY INFORMATION: Effective July 1, 2007, the FHWA assigned, and the Caltrans assumed, environmental responsibilities for this project pursuant to 23 U.S.C. 327. Notice is hereby given that the Caltrans has taken final agency actions subject to 23 U.S.C. 139(*l*)(1) by issuing licenses, permits, and approvals for the following highway project in the State of California: Merced Seismic Retrofit Project on State Routes 59, 140, and 152 in Merced County. The project would seismically retrofit seven bridges to bring them to current standard. A Draft Initial Study/Environmental Assessment was circulated, which proposed to bring the Bear Creek Bridge on State Route 59, the Los Banos Creek Bridge and the San Joaquin Bridge on State Route 140, and the San Joaquin (Santa Rita) Bridge and the Eastside Bypass Bypass Channel on State Route 152 to current seismic standards. The actions by the Federal agencies, and the laws under which such actions were taken, are described in the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for the project, approved on March 2, 2020, and in other documents in the FHWA project records. The EA, FONSI, and other project records are available by contacting Caltrans at the addresses provided above. The Caltrans EA and FONSI can be viewed and downloaded from the project website at *https://dot.ca.gov/caltrans-near-me/district-10,* or due to the current COVID 19 pandemic, please contact David Farris at *david.farris@dot.ca.gov* for a printed version of this document.

This notice applies to all Federal agency decisions as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. National Environmental Policy Act (NEPA)
2. Fixing America's Surface Transportation Act (Fast Act)
3. Clean Air Act
4. Federal-Aid Highway Act
5. Clean Water Act
6. Historic Sites Act
7. Section 106 of the National Historic Preservation Act
8. Archeological Resources Protection Act
9. Archeological and Historic Preservation Act
10. Antiquities Act
11. Endangered Species Act
12. Migratory Bird Treaty Act
13. Fish and Wildlife Coordination Act
14. Magnuson-Stevens Fishery Conservation and Management Act
15. Section 4(f) of the Department of Transportation Act
16. Civil Rights Act, Title VI
17. Farmland Protection Policy Act
18. Uniform Relocation Assistance and Real Property Acquisition Policies Act
19. Rehabilitation Act
20. Americans with Disabilities Act
21. Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
22. Resource Conservation and Recovery Act (RCRA)
23. Safe Drinking Water Act
24. Occupational Safety and Health Act
25. Atomic Energy Act
26. Toxic Substances Control Act
27. Federal Insecticide, Fungicide and Rodenticide Act
28. E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management
29. E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations
30. E.O. 12088, Federal Compliance with Pollution Control Standards

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1)

Rodney Whitfield,

Director, Financial Services, Federal Highway Administration, California Division.

[FR Doc. 2020–10371 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–1998–4334; FMCSA–2001–10578; FMCSA–2002–12844; FMCSA–2003–16564; FMCSA–2005–21711; FMCSA–2005–22194; FMCSA–2007–0017; FMCSA–2007–27897; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2011–0140; FMCSA–2011–0298; FMCSA–2011–0325; FMCSA–2011–0365; FMCSA–2011–0366; FMCSA–2013–0168; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2013–0174; FMCSA–2015–0048; FMCSA–2015–0053; FMCSA–2015–0056; FMCSA–2015–0072; FMCSA–2015–0344; FMCSA–2015–0345; FMCSA–2015–0347; FMCSA–2015–0348; FMCSA–2017–0018; FMCSA–2017–0020; FMCSA–2017–0024; FMCSA–2017–0026; FMCSA–2017–0027; FMCSA–2017–0028; FMCSA–2018–0006]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 84 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these individuals to continue to operate CMVs in interstate commerce without meeting the vision requirement in one eye.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., ET, Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Docket Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Documents and Comments

To view comments, as well as any documents mentioned in this notice as being available in the docket, go to *http://www.regulations.gov.* Insert the docket number, FMCSA–1998–4334; FMCSA–2001–10578; FMCSA–2002–12844; FMCSA–2003–16564; FMCSA–

2005–21711; FMCSA–2005–22194; FMCSA–2007–0017; FMCSA–2007–27897; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2011–0140; FMCSA–2011–0298; FMCSA–2011–0325; FMCSA–2011–0365; FMCSA–2011–0366; FMCSA–2013–0168; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2013–0174; FMCSA–2015–0048; FMCSA–2015–0053; FMCSA–2015–0056; FMCSA–2015–0072; FMCSA–2015–0344; FMCSA–2015–0345; FMCSA–2015–0347; FMCSA–2015–0348; FMCSA–2017–0018; FMCSA–2017–0020; FMCSA–2017–0024; FMCSA–2017–0026; FMCSA–2017–0027; FMCSA–2017–0028; FMCSA–2018–0006, in the keyword box, and click ''Search.'' Next, click the ''Open Docket Folder'' button and choose the document to review. If you do not have access to the internet, you may view the docket online by visiting the Docket Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

B. 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, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

II. Background

On February 7, 2020, FMCSA published a notice announcing its decision to renew exemptions for 84 individuals from the vision requirement in 49 CFR 391.41(b)(10) to operate a CMV in interstate commerce and requested comments from the public (85 FR 6993). The public comment period ended on March 9, 2020, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would achieve a level of safety equivalent to, or greater than, the level that would be achieved by complying with the current regulation § 391.41(b)(10).

The physical qualification standard for drivers regarding vision found in § 391.41(b)(10) states that a person is physically qualified to drive a CMV if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based on its evaluation of the 84 renewal exemption applications and comments received, FMCSA confirms its decision to exempt the following drivers from the vision requirement in § 391.41(b)(10).

As of March 2, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 47 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (63 FR 66226; 64 FR 16517; 66 FR 41656; 66 FR 53826; 66 FR 66966; 68 FR 54775; 68 FR 69434; 70 FR 48797; 70 FR 48798; 70 FR 48799; 70 FR 48800; 70 FR 53412; 70 FR 57353; 70 FR 72689; 70 FR 74102; 72 FR 46261; 72 FR 54972; 72 FR 62896; 72 FR 67340; 73 FR 1395; 73 FR 5259; 74 FR 43221; 74 FR 53581; 74 FR 60021; 74 FR 60022; 74 FR 65842; 74 FR 65845; 75 FR 1451; 75 FR 4623; 75 FR 9482; 76 FR 37169; 76 FR 50318; 76 FR 53708; 76 FR 64171; 76 FR 70213; 76 FR 75942; 76 FR 78728; 77 FR 539; 77 FR 541; 77 FR 543; 77 FR 545; 77 FR 10604; 77 FR 10608; 78 FR 63302; 78 FR 64274; 78 FR 67452; 78 FR 67454; 78 FR 68137; 78 FR 74223; 78 FR 76704; 78 FR 76707; 78 FR 77778; 78 FR 77780; 78 FR 78475; 78 FR 78477; 79 FR 4531; 79 FR 4803; 79 FR 6993; 79 FR 10619; 80 FR 26139; 80 FR 40122; 80 FR 48409; 80 FR 59230; 80 FR 62163; 80 FR 67481; 80 FR 70060; 80 FR 76345; 80 FR 79414; 80 FR 80443; 81 FR 1284; 81 FR 1474; 81 FR 15401; 81 FR 16265; 81 FR 20433; 81 FR 44680; 81 FR 48493; 81 FR 60117; 82 FR 24430; 82 FR 33542; 82 FR 34564; 82 FR 35050; 82 FR 47296; 82 FR 58262; 83 FR 2292; 83 FR 2311; 83 FR 6919; 83 FR 6922; 83 FR 6925; 83 FR 15232; 83 FR 18648; 83 FR 24589):

Garry A. Baker (OH)
Steven A. Blinco (MT)
James E. Bragg (WV)
Lee S. Brown (ME)
Cris D. Bush (TN)
Johnnie E. Byler (PA)
Stewart K. Clayton (TX)
David N. Cleveland (ME)
James J. Coffield (NM)
Stephen W. Deminie (TX)
Bruce J. Dowd (CT)
David E. Evans (NC)
Mark A. Farnsley (IN)
Lee J. Gaffney (OH)
Jason L. Hoovan (UT)
Amos W. Hulsey (AL)
Darryl H. Johnson (WV)
Freddie H. Johnson (ID)
David B. Jones (FL)
Alfred Keehn (AZ)
Karen L. Kelly (DE)
Raymundo Maldonado (TX)
Stephen E. McLaren (TN)
Kevin D. Mendoza (WA)
Ralph S. Miller (WV)
Thomas B. Miller (VA)
John M. Moore (PA)
Kenneth R. Murphy (WA)
William E. Norris (NC)
Anthony D. Ovitt (VT)
Daniel F. Perez (CA)
Hubert O. Pollard (NC)
Ronald F. Prezzia (IL)
Steven S. Reinsvold (WI)
Miguel A. Sanchez (NM)
James A. Shepard (NY)
Robert L. Simpson (NC)
John R. Snyder (WA)
David B. Stone (OK)
Dustin W. Tharp (IA)
Kirk A. Thelen (MI)
John T. Thor (MN)
Larry J. Waldner (SD)
Eric C. Weidley (PA)
William H. Wrice (OH)
Reginald J. Wuethrich (IL)
Chadwick L. Wyatt (NC)

The drivers were included in docket numbers FMCSA–1998–4334; FMCSA–2001–10578; FMCSA–2005–21711; FMCSA–2005–22194; FMCSA–2007–0017; FMCSA–2007–27897; FMCSA–2009–0291; FMCSA–2009–0303; FMCSA–2011–0140; FMCSA–2011–0298; FMCSA–2011–0325; FMCSA–2013–0168; FMCSA–2013–0169; FMCSA–2013–0170; FMCSA–2015–0048; FMCSA–2015–0053; FMCSA–2015–0056; FMCSA–2015–0072; FMCSA–2015–0344; FMCSA–2015–0345; FMCSA–2015–0347; FMCSA–2017–0018; FMCSA–2017–0020; FMCSA–2017–0024; FMCSA–2017–0026; and FMCSA–2017–0027. Their exemptions are applicable as of March 2, 2020, and will expire on March 2, 2022.

As of March 5, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following four individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (68 FR 74699; 69 FR 10503; 70 FR 57353; 70 FR 72689; 71 FR 6829; 73 FR 8392; 75 FR 8184; 77 FR 7233; 79 FR 10602; 81 FR 20433; 83 FR 6919):

Barton C. Caldara (WI)
Allan Darley (UT)
Richard Hailey, Jr. (DC)
James T. Wortham, Jr. (GA)

The drivers were included in docket numbers FMCSA–2003–16564; and FMCSA–2005–22194. Their exemptions are applicable as of March 5, 2020, and will expire on March 5, 2022.

As of March 7, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (77 FR 3552; 77 FR 13691; 79 FR 12565; 81 FR 20433; 83 FR 6919):

Samuel V. Holder (IL)

The driver was included in docket number FMCSA–2011–0365. The exemption is applicable as of March 7, 2020, and will expire on March 7, 2022.

As of March 10, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (81 FR 6573; 81 FR 28136; 83 FR 6919):

Thomas M. Bowman (OH)
Robert W. Fawcett (PA)
Harry J. Glynn (LA)
Dennis C. Rokes (IA)
Brian W. Roughton (MO)
Steven A. Van Raalte (IL)
Brian J. Yole (TX)

The drivers were included in docket number FMCSA–2015–0348. Their exemptions are applicable as of March 10, 2020, and will expire on March 10, 2022.

As of March 13, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (79 FR 1908; 79 FR 14333; 81 FR 20433; 83 FR 6919):

Jackie K. Curlin (KY)
Justin W. Demarchi (OH)
Jimmey C. Harris (TX)
David G. Henry (TX)
Rogelio C. Hernandez (CA)
Jason C. Sadler (KY)
Michael O. Thomas (NC)

The drivers were included in docket number FMCSA–2013–0174. Their exemptions are applicable as of March 13, 2020, and will expire on March 13, 2022.

As of March 15, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (67 FR 68719; 68 FR 2629; 70 FR 7545; 72 FR 40362; 74 FR 64124; 77 FR 10606; 79 FR 14328; 81 FR 20433; 83 FR 6919):

Wayne H. Holt (UT)

The driver was included in docket number FMCSA–2002–12844. The exemption is applicable as of March 15, 2020, and will expire on March 15, 2022.

As of March 17, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following 16 individuals have satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (83 FR 6681; 83 FR 6694; 83 FR 24151; 83 FR 24571):

Rodney P. Barfield (GA)
Michael W. Belknap (VT)
Kenneth W. Blake (KS)
Scott M. Cavanaugh (OK)
Justin D. Craft (AR)
James M. Ferry (OH)
Jacob A. Hehr (IL)
Mike B. Houston (OR)
Marvin R. Knecht (ND)
Randolph W. Lewis (CA)
Curvin L. Martin (PA)
Martin Munoz (TX)
Edwin Quiles (FL)
Robert L. Redding (NC)
Gerald A. Vaughn (OH)
Richard E. Wixom (MI)

The drivers were included in docket numbers FMCSA–2017–0028; and FMCSA–2018–0006. Their exemptions are applicable as of March 17, 2020, and will expire on March 17, 2022.

As of March 23, 2020, and in accordance with 49 U.S.C. 31136(e) and 31315, the following individual has satisfied the renewal conditions for obtaining an exemption from the vision requirement in the FMCSRs for interstate CMV drivers (77 FR 5874; 77 FR 17117; 79 FR 13085; 81 FR 20433; 83 FR 6919):

Glenn R. Theis (MN)

The driver was included in docket number FMCSA–2011–0366. The exemption is applicable as of March 23, 2020, and will expire on March 23, 2022.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Larry W. Minor,
Associate Administrator for Policy.

[FR Doc. 2020–10321 Filed 5–13–20; 8:45 am]
BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2020–0044]

Parts and Accessories Necessary for Safe Operation; Application for an Exemption From K & L Trucking, Inc.

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) requests public comment on an application for exemption from K & L Trucking, Inc. (K & L) to allow the company to secure large metal coils to its trailers for transport using a securement system that differs from that required by the Federal Motor Carrier Safety Regulations (FMCSR).

DATES: Comments must be received on or before June 15, 2020.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket ID FMCSA–2020–0044 using any of the following methods:

- *Website: http://www.regulations.gov.* Follow the instructions for submitting comments on the Federal electronic docket site.
- *Fax:* 1–202–493–2251.
- *Mail:* Send comments to Docket Operations, U.S. Department of Transportation, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.
- *Hand Delivery:* Deliver comments to Docket Operations, Ground Floor, Room W12–140, DOT Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m. e.t., Monday–Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

Instructions: All submissions must include the Agency name and docket number for this notice. For detailed instructions on submitting comments and additional information on the exemption process, see the ''Public Participation'' heading below. Note that all comments received will be posted

without change to *http://www.regulations.gov,* including any personal information provided. Please see the ''Privacy Act'' heading for further information.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or visit Docket Operations, Room W12–140, DOT Building, 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Docket Operations.

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, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Public Participation: The *http://www.regulations.gov* website is generally available 24 hours each day, 365 days each year. You may find electronic submission and retrieval help and guidelines under the ''help'' section of the *http://www.regulations.gov* website as well as the DOT's *http://docketsinfo.dot.gov* website. If you would like notification that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgment page that appears after submitting comments online.

FOR FURTHER INFORMATION CONTACT: Mr. Luke Loy, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 366–0676; *luke.loy@dot.gov.*

SUPPLEMENTARY INFORMATION:

Background

Under 49 CFR 381.315(a), FMCSA must publish a notice of each exemption request in the **Federal Register**. The Agency must provide the public with an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews the safety analyses and the public comments and determines whether granting the exemption would likely achieve a level of safety equivalent to or greater than the level that would be achieved by the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)). If the Agency denies the request, it must state the reason for doing so. If the decision is to grant the exemption, the notice must specify the person or class of persons receiving the exemption and the regulatory provision or provisions from which an exemption is granted. The notice must specify the effective period of the exemption (up to 5 years) and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.315(c) and 49 CFR 381.300(b)).

K & L Application for Exemption

Section 393.120(c) of the FMCSRs requires metal coils that weigh more than 5,000 pounds (either individually or grouped together) and transported with eyes crosswise to be secured using (1) a means (*e.g.,* timbers, chocks or wedges, a cradle, etc.) to prevent the coil from rolling and to support the coil off the deck, (2) at least one tiedown through its eye restricting against forward motion, and (3) at least one tiedown through its eye restricting against rearward motion. Attaching tiedowns diagonally through the eye of a coil to form an X-pattern when viewed from above the vehicle is prohibited. K & L has applied for an exemption from 49 CFR 393.120(c) to allow the use of an alternative securement system consisting of (1) a specialized metal carrier permanently affixed to the flatbed trailer designed to secure the coil and prevent it from rolling, and (2) a single, two-ply, nylon-Kevlar tie down strap routed through the eye of the coil that secures the coil to the coil carrier.

A copy of the application is included in the docket referenced at the beginning of this notice.

Request for Comments

In accordance with 49 U.S.C. 31315(b)(6), FMCSA requests public comment from all interested persons on K & L's application for an exemption from 49 CFR 393.120(c). All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2020–10322 Filed 5–13–20; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities; Information Collection Renewal; Comment Request; Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework

AGENCY: Office of the Comptroller of the Currency, Treasury (OCC).

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

The OCC may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The OCC is soliciting comment concerning the renewal of its information collection titled ''Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework.''

DATES: Comments must be received by July 13, 2020.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible. You may submit comments by any of the following methods:

- *Email: prainfo@occ.treas.gov.*
- *Mail:* Chief Counsel's Office, Attention: Comment Processing, Office of the Comptroller of the Currency, Attention: 1557–0242, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.
- *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–

0242'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

You may review comments and other related materials that pertain to this information collection beginning on the date of publication of the second notice for this collection [1] by any of the following methods:

• *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0242'' or ''Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.

• For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of title 44 requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the OCC is publishing notice of the renewal of this collection.

Title of Information Collection: Supervisory Guidance: Supervisory Review Process of Capital Adequacy (Pillar 2) Related to the Implementation of the Basel II Advanced Capital Framework.

OMB Control No.: 1557–0242.

Frequency of Response: Event-generated.

Affected Public: National banks.

Abstract: In 2008, the agencies [2] issued a supervisory guidance document for implementing the supervisory review process (Pillar 2).[3] Paragraphs 37, 41, 43, and 46 of the guidance contain information collections. Paragraph 37 provides that banks should state clearly the definition of capital used in any aspect of its internal capital adequacy assessment process (ICAAP) and document any changes in the internal definition of capital. Paragraph 41 provides that banks should maintain thorough documentation of ICAAP. Paragraph 43 specifies that the board of director should approve the bank's ICAAP, review it on a regular basis, and approve any changes. Boards of directors, under Paragraph 46, should periodically, and at least annually, review the assessment of overall capital adequacy and analyze how measures of internal capital adequacy compare with other capital measures (such as regulatory or accounting).

Estimated Burden:

Number of Respondents: 19.

Estimated Burden per Respondent: 140 hours.

Total Estimated Annual Burden: 2,660 hours.

Comments: Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on:

(a) Whether the collection of information is necessary for the proper performance of the OCC's functions, including whether the information has practical utility;

(b) The accuracy of the OCC's burden estimates, including the validity of the methodology and assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd,

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2020–10339 Filed 5–13–20; 8:45 am]

BILLING CODE 4810–33–P

[1] Following the close of this notice's 60-day comment period, the OCC will publish a second notice with a 30-day comment period.

[2] The OCC, Board of Governors of the Federal Reserve System, and Federal Deposit Insurance Corporation.

[3] 73 FR 44620 (July 31, 2008).

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Assessment of Fees

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice and request for comment.

SUMMARY: The OCC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, ''Assessment of Fees.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: You should submit written comments by June 15, 2020.

ADDRESSES: Commenters are encouraged to submit comments by email, if possible.

You may submit comments by any of the following methods:

• *Email: prainfo@occ.treas.gov.*

• *Mail:* Chief Counsel's Office, Attention: Comment Processing, 1557–0223, Office of the Comptroller of the

Currency, 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

• *Hand Delivery/Courier:* 400 7th Street SW, Suite 3E–218, Washington, DC 20219.

• *Fax:* (571) 465–4326.

Instructions: You must include ''OCC'' as the agency name and ''1557–0223'' in your comment. In general, the OCC will publish comments on *www.reginfo.gov* without change, including any business or personal information provided, such as name and address information, email addresses, or phone numbers. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0223, U.S. Office of Management and Budget, 725 17th Street NW, #10235, Washington, DC 20503 or by email to *oira_submission@omb.eop.gov.*

You may review comments and other related materials that pertain to this information collection [1] following the close of the 30-day comment period for this notice by any of the following methods:

• *Viewing Comments Electronically:* Go to *www.reginfo.gov.* Click on the ''Information Collection Review'' tab. Underneath the ''Currently under Review'' section heading, from the drop-down menu select ''Department of Treasury'' and then click ''submit.'' This information collection can be located by searching by OMB control number ''1557–0223'' or ''Assessment of Fees.'' Upon finding the appropriate information collection, click on the related ''ICR Reference Number.'' On the next screen, select ''View Supporting Statement and Other Documents'' and then click on the link to any comment listed at the bottom of the screen.

• For assistance in navigating *www.reginfo.gov,* please contact the Regulatory Information Service Center at (202) 482–7340.

• *Viewing Comments Personally:* You may personally inspect comments at the OCC, 400 7th Street SW, Washington, DC. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hearing impaired, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect comments.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, OCC Clearance Officer, (202) 649–5490, Chief Counsel's Office, Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), Federal agencies must obtain approval from the OMB for each collection of information that they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) to include agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The OCC asks that OMB extend its approval of the collection in this document.

Title: Assessment of Fees.

OMB Control No.: 1557–0223.

Affected Public: Business or other for-profit.

Type of Review: Regular review.

Abstract: The OCC is requesting comment on its proposed extension, without change, of the information collection titled, ''Assessment of Fees.'' The OCC is authorized by the National Bank Act (for national banks and Federal branches and agencies) and the Home Owners Loan Act (for Federal savings associations) to collect assessments, fees, and other charges as necessary or appropriate to carry out the responsibilities of the OCC. 12 U.S.C. 16, 481, 482 and 1467. The OCC requires independent credit card national banks and independent credit card Federal savings associations (collectively, independent credit card institutions) to pay an additional assessment based on receivables attributable to accounts owned by the national bank or Federal savings association. 12 CFR 8.2(c). Independent credit card institutions are national banks or Federal savings associations that engage primarily in credit card operations and are not affiliated with a full-service national bank or full-service Federal savings association. 12 CFR 8.2(c)(3)(vi) and (vii). Under 12 CFR 8.2(c)(2), the OCC also has the authority to assess an independent credit card institution that is affiliated with a full-service national bank or full-service Federal savings association if the OCC concludes that the affiliation is intended to evade the requirements of 12 CFR part 8.

The OCC requires independent credit card institutions to report receivables attributable data to the OCC semiannually or at a time specified by the OCC. 12 CFR 8.2(c)(4). ''Receivables attributable'' are the total amount of outstanding balances due on credit card accounts owned by independent credit card institutions (the receivables attributable to those accounts) on the last day of an assessment period, minus receivables retained on the national bank or Federal savings association's balance sheet as of that day. 12 CFR 8.2(c)(3)(viii). The OCC uses the information to calculate the assessment for each national bank and Federal savings association and adjust the assessment rate for independent credit card institutions over time.

Estimated Number of Respondents: 7.

Estimated Total Annual Burden: 14 hours.

Comments: On February 27, 2020, the OCC issued a notice for 60 days of comment concerning this collection, 85 FR 11452. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC's estimate of the information collection burden;

(c) Ways to enhance the quality, utility, and clarity of the information to be collected;

(d) Ways to minimize the burden of the collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Theodore J. Dowd.

Deputy Chief Counsel, Office of the Comptroller of the Currency.

[FR Doc. 2020–10338 Filed 5–13–20; 8:45 am]

BILLING CODE 4810–33–P

[1] On February 27, 2020, the OCC published a 60-day notice for this information collection, 85 FR 11452.

DEPARTMENT OF THE TREASURY

Financial Crimes Enforcement Network

Agency Information Collection Activities; Proposed Renewal; Comment Request; Renewal Without Change of the Bank Secrecy Act Reports of Transactions in Currency Regulations at 31 CFR 1010.310 Through 1010.314, 31 CFR 1021.311, and 31 CFR 1021.313, and FinCEN Report 112—Currency Transaction Report

AGENCY: Financial Crimes Enforcement Network (FinCEN), Treasury.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork and respondent burden, FinCEN invites comments on the proposed renewal, without change, of currently approved information collections relating to reports of transactions in currency. Under Bank Secrecy Act regulations, financial institutions are required to report transactions in currency of more than $10,000 using FinCEN Report 112 (the currency transaction report, or CTR). Although no changes are proposed to the information collections themselves, this request for comments covers a proposed updated burden estimate for the information collection. This request for comments is made pursuant to the Paperwork Reduction Act of 1995 (PRA).

DATES: Written comments are welcome, and must be received on or before July 13, 2020.

ADDRESSES: Comments may be submitted by any of the following methods:

- *Federal E-rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Refer to Docket Number FINCEN–2020–0003 and the specific Office of Management and Budget (OMB) control numbers 1506–0004, 1506–0005, and 1506–0064.
- *Mail:* Policy Division, Financial Crimes Enforcement Network, P.O. Box 39, Vienna, VA 22183. Refer to Docket Number FINCEN–2020–0003 and OMB control number 1506–0004, 1506–0005, and 1506–0064.

Please submit comments by one method only. Comments will also be incorporated into FinCEN's review of existing regulations, as provided by Treasury's 2011 Plan for Retrospective Analysis of Existing Rules. All comments submitted in response to this notice will become a matter of public record. Therefore, you should submit only information that you wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: The FinCEN Regulatory Support Section at 1–800–767–2825 or electronically at *frc@fincen.gov.*

SUPPLEMENTARY INFORMATION:

I. Statutory and Regulatory Provisions

The legislative framework generally referred to as the Bank Secrecy Act (BSA) consists of the Currency and Financial Transactions Reporting Act of 1970, as amended by the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) (Pub. L. 107–56) and other legislation. The BSA is codified at 12 U.S.C. 1829b, 12 U.S.C. 1951–1959, 31 U.S.C. 5311–5314 and 5316–5332, and notes thereto, with implementing regulations at 31 CFR Chapter X.

The BSA authorizes the Secretary of the Treasury, *inter alia,* to require financial institutions to keep records and file reports that are determined to have a high degree of usefulness in criminal, tax, and regulatory matters, or in the conduct of intelligence or counter-intelligence activities, to protect against international terrorism, and to implement counter-money laundering programs and compliance procedures.[1] Regulations implementing Title II of the BSA appear at 31 CFR Chapter X. The authority of the Secretary to administer the BSA has been delegated to the Director of FinCEN.[2]

Under 31 U.S.C. 5313, the Secretary of the Treasury is authorized to require financial institutions to report currency transactions exceeding $10,000. Regulations implementing 31 U.S.C. 5313 are found at 31 CFR 1010.310 through 1010.314, 31 CFR 1021.311, and 31 CFR 1021.313. Generally, information collected pursuant to the BSA is confidential, but may be shared as provided by law with regulatory and law enforcement authorities.

II. Paperwork Reduction Act (PRA)[3]

Title: Reports of Transactions in Currency by Financial Institutions (31 CFR 1010.310 through 1010.314, 31 CFR 1021.311, and 31 CFR 1021.313).

OMB Control Numbers: 1506–0004, 1506–0005, and 1506–0064.[4]

Report Number: FinCEN Report 112—Currency Transaction Report (CTR).

Abstract: FinCEN is issuing this notice to renew the OMB control numbers for the CTR regulations and the CTR report.

Type of Review: Renewal without change of currently approved information collections.

Affected Public: Businesses or other for-profit institutions, and non-profit institutions.

CTR Regulations

Estimated Burden: An administrative burden of one hour is assigned to each of the CTR regulation OMB control numbers in order to maintain the requirements in force.[5] The reporting and recordkeeping burden is reflected in FinCEN Report 112—CTR, under OMB control number 1506–0064. The rationale for assigning one burden hour to each of the CTR regulation OMB control numbers is that the annual burden hours would be double counted if FinCEN estimated burden in each CTR regulation OMB control number and in the FinCEN Report 112—CTR OMB control number.

FinCEN Report 112—CTR

Type of Review:

- Propose for review and comment a re-calculation of the portion of the PRA burden that has been subject to notice and comment in the past.
- Propose for review and comment a method to estimate the portion of the PRA burden that FinCEN previously had not included.

Frequency: As required.

Estimated Reporting and Recordkeeping Burden: The total estimate of the annual reporting and recordkeeping burden contained herein consists of two parts: (a) a re-calculation of the portion of the PRA burden that FinCEN traditionally included in its PRA renewal notices (the ''traditional PRA burden calculation''); and (b) an estimate of the portion of the total burden that FinCEN previously did not include in its PRA calculations (the ''supplemental PRA burden calculation'').

[1] Language expanding the scope of the BSA to intelligence or counter-intelligence activities to protect against international terrorism was added by Section 358 of the USA Patriot Act.

[2] Treasury Order 180–01 (re-affirmed Jan. 14, 2020).

[3] Public Law 104–13, 44 U.S.C. 3506(c)(2)(A).

[4] The reports of transactions in currency regulatory requirements are currently covered under the following OMB control numbers: 1506–0004 (General provisions—31 CFR 1010.310—Reports of transactions in currency, 31 CFR 1010.311—Filing obligations for reports of transactions in currency, 31 CFR 1010.312—Identification required, 31 CFR 1010.313—Aggregation, and 31 CFR 1010.314—Structured transactions), and 1506–0005 (Rules for casinos and card clubs—31 CFR 1021.311—Reports of transaction in currency, and 31 CFR 1021.313—Aggregation). OMB control number 1506–0064 applies to FinCEN Report 112—CTR.

[5] One hour of burden is estimated under each of the following OMB control numbers: 1506–0004 and 1506–0005.

FinCEN's traditional annual PRA burden calculation associated with the CTR previously included only the filer's annual operational burden and cost associated with (a) producing and filing the report, and (b) storing a copy of the filed report. Starting with the current PRA renewal notice, FinCEN intends to add a supplemental PRA burden calculation, reflecting the annual costs involved in (a) obtaining data required by the report that the filer does not need for its own bookkeeping, and (b) maintaining, updating, and upgrading the technological infrastructure required to file and store the report.

Part 1. Breakdown of the 2019 CTR Filings

In 2019, 14,276 individual filers (the filing population) submitted 16,087,182 CTRs (the 2019 CTR submissions). To present a more complete breakdown of the 2019 filing population, FinCEN grouped filers into twelve tranches according to the range of CTRs filed during the year. The tranches are listed in descending order starting with filers accounting for the most CTRs filed annually (''01_LARGEST FILERS''), to filers submitting six or fewer CTRs annually (''12_1–6/YEAR), as set out in Table 1 below.[6]

TABLE 1—2019 FILERS, BY RANGE OF THE NUMBER OF REPORTS FILED (TRANCHES), AND TYPE OF FINANCIAL INSTITUTION

Tranche	Total filers	Total reports	Casino card club		Depository institution		Money services business (MSB)		Other		Securities/futures	
			Filers	Reports	Filers	Reports	Filers	Reports	Filers	Reports	Filers	Reports
01_LARGEST_FILERS	19	7,971,675	.....	.....	19	7,971,675						
02_100–2000/WEEK	287	4,434,506	73	946	507	206	3,393,315	5	33,515	3	61,169	
03_50–99/WEEK	262	925,809	56	198,827	188	656,924	17	67,414	1	2,644		
04_10–49/WEEK	1,562	1,723,657	159	195,821	1,224	1,336,193	167	176,148	12	15,495		
05_5–9/WEEK	1,296	487,224	87	33,547	1,029	387,095	172	63,774	8	2,898		
06_121–259/YEAR	1,632	292,595	77	13,943	1,281	229,059	263	47,459	9	1,749	2	385
07_73–120/YEAR	1,102	104,671	53	5,141	821	78,048	206	19,443	22	2,039		
08_37–72/YEAR	1,531	80,568	66	3,406	1,152	60,985	278	14,432	35	1,745		
09_25–36/YEAR	808	24,433	28	835	588	17,838	170	5,103	21	627	1	30
10_13–24/YEAR	1,323	23,596	41	722	917	16,355	310	5,556	54	946	1	17
11_7–12/YEAR	1,089	10,122	39	369	656	6,138	323	2,975	71	640		
12_1–6/YEAR	3,365	8,326	106	273	1,519	4,098	1,188	2,784	547	1,158	5	13
Grand Total	14,276	16,087,182	785	1,399,301	9,600	14,157,723	3,099	438,603	783	9,110	9	445

Table 1 illustrates that in 2019, 19 filers (all of them depository institutions) filed almost half of the 2019 CTR submissions (7,971,675 reports). These large filers submitted in excess of 2,000 reports per week.[7] Adding these numbers to the submissions of filers that filed between 100 and 2,000 reports per week, totals 306 individual filers (or slightly over 2% of the filing population), accounting for over three-quarters of the 2019 CTR submissions (12,406,181 reports).[8] Furthermore, depository institutions represent two-thirds of the filing population, and filed 88% of the 2019 CTR submissions. The high concentration of filings in a very small fraction of the filing population, and the preponderance of depository institutions at any tranche level will impact the averages of both burden and cost.[9]

All filers submit their reports electronically, either in batch or discrete form.[10] Table 2 below sets out the distribution of the 2019 CTR submissions by tranche, filing method, and type of financial institution.

TABLE 2—BREAK-DOWN OF 2018 CTR SUBMISSIONS, BY TRANCHE, FILING METHOD, AND TYPE OF FINANCIAL INSTITUTION

Tranche	Reports			Casino card club		Depository institution		Money services business (MSB)		Other		Securities/futures	
	Batch	Discrete	Total	Batch	Discrete	Batch	Discrete	Batch	Discrete	Batch	Discrete	Batch	Discrete
01_LARGEST_FILERS	7,937,017	34,658	7,971,675	.....	19	7,937,017	34,658						
02_100–2000/WEEK	4,304,983	129,523	443,4506	924,763	21,744	3,318,491	7,4824	12,621	20,894	49,108	12,061		
03_50–99/WEEK	835,918	89,891	925,809	170,474	28,353	627,595	29,329	37,849	29,565	.....	2644		
04_10–49/WEEK	1,261,192	462,465	1,723,657	133,909	61,912	1,101,645	234,548	24,353	151,795	1,285	14210		
05_5–9/WEEK	265,191	222,033	487,224	16,806	16,651	243,531	143,564	4,854	58,920	.....	2898		
06_121–259/YEAR	111,215	181,380	292,595	5,175	8,768	102,810	126,249	2,971	44,488	.....	2,039	385	
07_73–120/YEAR	29,528	75,143	104,671	1,244	3,897	26,875	51,173	1,409	18,034	.....	2,039		
08_37–72/YEAR	16,042	64,526	80,568	757	2,649	14,430	46,555	855	13,577	.....	1,745		
09_25–36/YEAR	3,289	21,144	24,433	188	647	2,836	15,002	265	4,838	.....	627	.....	30
10_13–24/YEAR	2,993	21,303	23,596	67	655	1,942	14,413	263	5,293	21	925	17	
11_7–12/YEAR	688	9,434	10,122	49	320	503	5,635	136	2,839	640			
12_1–6/YEAR	347	7,979	8,326	34	239	146	3,952	158	2,626	9	1,149	13	
Grand Total	14,767,703	1,319,479	16,087,182	1,253,466	145,835	13,377,821	779,902	85,734	352,869	50,423	40,687	259	186

[6] The category ''Other'' includes filers belonging to other types of financial institutions than the ones identified in the table (such as insurance companies and mutual funds), and some filers where the type of financial institution was undetermined at the time of the tabulation.

[7] The annual range of the number of reports filed by each large filer is between 110,000 and nearly 2,000,000 reports per year.

[8] The 19 largest CTR filers plus 287 filers reporting between 100 and 2,000 CTRs per week, totals 306 filers. 7,971,675 CTRs reported by the 19 largest filers plus 4,434,506 CTRs reported by filers reporting between 100 and 2,000 CTRs per week, totals 12,406,181 reports.

[9] As large filers that are depository institutions account for a very large percentage of the 2019 CTR submissions, the general averages of burden and cost for the filer population will be greatly affected by the characteristics of the filings of depository institutions belonging to the first two tranches.

[10] In batch-filing, a filer submits a single electronic file containing several reports. In discrete-filing, the filer fills in an electronic form individually, using a data entry screen that FinCEN provides. While exceptions apply, batch-filing is generally used by large-volume filers that have automated the filing process, while discrete-filing is generally employed by filers that submit fewer forms per year and rely more on manual data entry methods.

Table 2 shows that, in the aggregate, there is a marked predilection for batch filing among the filing population (92% of the 2019 CTR submissions were batch-filed). However, filers belonging to any tranche combine batch and discrete filing, with the preference shifting from batch filing to discrete filing as the number of reports filed per year goes down. The aggregate percentages also are influenced by the concentration of submissions in the first two tranches, and in the preponderance of depository institutions in the filing population. When focusing on individual types of financial institution, the percentage of batch filings vary significantly (money services businesses (MSBs), for example, file only 20% of their reports in batch form).

The CTR requires the identification of persons (*i.e.,* entities or individuals) that fulfill certain roles in the transaction or group of transactions reflected in each report, either as principals (*e.g.,* a person that conducts a transaction on its own behalf, or a person on whose behalf a transaction is conducted), or non-principals (*e.g.,* a person that conducts a transaction on behalf of another person, or any currency transporters not hired by the filer itself). The number of persons per CTR varies significantly among the 2019 CTR submissions. Breakdowns of those transactions, however, are available where a person operated on its own behalf, or where the person operating on behalf of another did not need to be identified (*e.g.,* transactions conducted through ATMs, night deposit windows, or transported by currency transporters hired by the filer). Table 3 below sets out the breakdowns.

TABLE 3—BREAKDOWN BY TRANCHE AND TYPE OF PERSON IDENTIFIED IN THE CTR

[Number of reports]

Tranche	Conducted on own behalf			Information on transactor not required			Total
	Depository	Non-depository	Total	Depository	Non-depository	Total	
01_LARGEST_FILE	2,289,162		2,289,162	2,279,428		2,279,428	4,568,590
02_100–2000/WEEK	825,683	961,259	1,786,942	660,123	69,132	729,255	2,447,065
03_50–99/WEEK	183,055	227,272	410,327	109,655	5,273	114,928	519,982
04_10–49/WEEK	510,531	277,878	788,409	239,409	23,918	263,327	1,027,818
05_5–9/WEEK	189,273	68,176	257,449	68,963	4,591	73,554	326,412
06_121–259/YEAR	128,231	43,146	171,377	41,436	5,734	47,170	212,813
07_73–120/YEAR	49,264	18,927	68,191	14,223	2,006	16,229	82,414
08_37–72/YEAR	42,521	15,155	57,676	10,321	1,583	11,904	67,997
09_25–36/YEAR	13,242	5,637	18,879	2,545	268	2,813	21,424
010_13–24/YEAR	12,913	5,895	18,808	2,209	326	2,535	21,017
011_7–12/YEAR	5,073	3,398	8,471	625	284	909	9,096
012_1–6/YEAR	3,535	3,456	6,991	379	403	782	7,370
Grand Total	4,252,483	1,630,199	5,882,682	3,429,316	113,518	3,542,834	9,311,998

In general, depository institutions will only accept reportable transactions in currency from established customers subject to the institution's customer identification program (CIP).[11] Therefore, if a depository institution's CTR identifies only one type of person, typically that person is either an established customer operating on its own behalf, or the person on whose behalf the transaction is conducted is an established customer and the transaction is conducted through a transactor that does not need to be identified. In these cases, a depository institution's CIP records for established customers would provide the identifying information needed to complete a CTR. In addition, as a prudential matter and prior to completing a transaction, depository institutions, for example, request identification documents such as a driver's license to verify the identity of the customer to protect against fraud. Table 3 shows that depository institutions filed 7,681,799 reports (or 54% of their 2019 CTR submissions) where the only person identified in the report was the person subject to the filer's CIP requirements.

Part 2. Re-Calculation of the Traditional Annual PRA Burden and Cost

Traditional Annual PRA Burden (Expressed in Hours)

To comply with their BSA currency transaction reporting requirement, filers must implement, operate, and supervise a process that may be broken down into the following steps:

- Step 1: Determine whether the filer must report a currency transaction or group of transactions, based on the amount of a transaction, the aggregation of multiple transactions at the end of the day, and certain characteristics of the established customer, the transaction, or the transactor (such as whether a depository institution filer has exempted an account of an established customer from CTR filing). All these determinations are based on objective parameters.
- Step 2: Obtain the information required by the CTR on parties to the transaction that the filer has not already identified as part of (i) its normal business operations, (ii) another BSA requirement (such as CIP), or (iii) another regulatory requirement that is not BSA-related. Some types of financial institutions filing CTRs (*e.g.,* depository institutions) will already maintain most, if not all, the information on parties to the transaction in their customer database and accounting records.
- Step 3: Complete the CTR with the information on the transaction and the parties involved. The completion of the report will vary, depending on the technology available to the filer, from a fully-automated process requiring no manual data entry, to a process that is nearly entirely manual.
- Step 4: The filer will submit the report electronically, either as a batch or discrete filing. The method of submission does not necessarily indicate the level of automation of a financial institution's CTR filing process. For example, some filers that submit few reports a year batch file, while other filers that submit more reports may use discrete filing because they have incorporated into their CTR

[11] For a description of the customer identification program requirements, see 31 CFR 1001.220 and Subpart B of 31 CFR Chapter X.

filing process software tools that fill in each form automatically and release it after manual review of the content.

• Step 5: After filing, the filer must store the report for the regulatory recordkeeping period. As the submission consists of an electronic file containing one or several reports, the recordkeeping will be done electronically too.

The greater the reliance on automation, the greater the periodic cost involved in maintaining, updating, and upgrading the systems and tools that either link the filer's different applications to obtain the required source data, or that are used for the CTR completion, submission, and storage steps.

FinCEN's estimate of the traditional annual hourly burden of the CTR reporting and recordkeeping requirements only takes into consideration the time required to complete, submit, and store the report (Steps 3 to 5 in the process described above).

FinCEN has maintained the same method to calculate the CTR PRA burden hour estimate since 2002, when paper reports typically were filled in manually, mailed to the Internal Revenue Service, and uploaded individually. Under this method, the burden estimates per CTR were 20 minutes for reporting, and 20 minutes for recordkeeping per report, regardless of the type of financial institution or complexity of the report. Since 2011, CTRs have been filed electronically, either in batch or discrete format. FinCEN has concluded that (a) as either filing method allows the filer to save an electronic copy of the batched or discrete/individual reports, which satisfies the recordkeeping part of the requirement, the recordkeeping portion of the traditional annual PRA burden will be zero, and (b) the reporting portion of the traditional annual PRA burden will be set at a variable number of minutes per report that will reflect the (i) type of financial institution, (ii) range of the number of reports filed per year, and (iii) filing method.

For purposes of calculating PRA burden and cost, FinCEN used the 2019 CTR submissions as a baseline, stipulating that submissions from 2019 are an appropriate representation of the expected composition of the filing population and report submissions for the next three years. FinCEN estimates the time required for reporting a CTR, based on these parameters, as described in Table 4 below:

TABLE 4—TRADITIONAL ANNUAL PRA BURDEN CALCULATIONS

Tranche	Reports				Minutes per report				Total hours		Grand total (hours)
	Batch-filed		Discrete-filed		Batch		Discrete		Batch	Discrete	
	D	ND	D	ND	D	ND	D	ND			
01_LARGEST_FILERS	7,937,017	0	34,658	0	1	1	20	20	132,284	11,553	143,836
02_100–2000/WEEK	3,318,491	986,492	74,824	54,699	1	1	20	20	71,750	43,174	114,924
All other tranches	2,122,313	403,390	670,420	484,878	20	20	20	20	841,901	385,099	1,227,000
Total	13,377,821	1,389,882	779,902	539,577	.....	.....	.....	.....	1,045,934	439,826	1,485,761

D: Depository Institution.
ND: Non-depository Institution.

The traditional annual PRA burden estimated by this new method (1,485,761 hours) is significantly lower than what FinCEN had calculated in the past. Table 4 reflects the following rationale for purposes of the new estimate:

• FinCEN considers the reporting time required by both depository and non-depository financial institutions belonging to the same tranche of filers (based on number of reports filed), to be the same.[12]

• FinCEN stipulates that filers submitting 100 reports per week or more, are doing so in a totally automated way (''fully-automated filers'').

• If a fully-automated filer submits reports through batch filing, the individual reports and the batch file that contains them are produced automatically, without manual intervention. The burden of 1 minute per report represents the administrative burden involved in carrying out, reviewing, and overseeing the process of filing CTRs, and not just the time of preparation and submission per report which would be nearly instantaneous, and therefore far lower than 1 minute per individual report.

• Where the filing does not involve a fully-automated filer submitting reports through batch filing, FinCEN allocates 20 minutes per report to reports filed on (a) a discrete basis by fully-automated filers, or (b) either a batch or discrete basis by any filer submitting fewer than 100 reports per week. The 20 minutes includes the administrative burden and the actual time required to enter the individual report in FinCEN's data entry screen, or to complete the individual report manually before it is added to the batch file. This allocation of time is extremely conservative: FinCEN is stipulating that filers submitting fewer than 100 reports per week are not automated and that, regardless of the filing method, each report will require full manual data entry intervention. Similarly, FinCEN stipulates that fully-automated filers that file discretely will not receive the benefits of any automation, and will incur the same burden per report.

FinCEN intends to conduct more granular studies of the filing population in the future, to arrive at more accurate estimates that take into consideration a more granular breakdown of the degree of automation among CTR filers. The data obtained in these studies may result in significant variations of the estimated annual PRA burden hours.

Cost of the Traditional Annual PRA Burden

To estimate the cost of each hour of the traditional annual PRA burden, FinCEN identified three types of roles and corresponding staff positions involved in the reporting and recordkeeping of CTRs: (1) Remote supervision (general process oversight), (ii) direct supervision (review of the filing process, and cross-check of filings against accounting records), and (iii) operations (actual production, filing, and storage of the reports). FinCEN calculated the fully loaded hourly wage for each of these three roles by taking the median wage for these positions as estimated by the U.S. Bureau of Labor Statistics (BLS), and computing an additional cost of benefits as follows:[13]

[12] However, whether the institution is depository or non-depository will have an effect when combining the traditional annual PRA burden with the supplemental PRA, as described in Part 3 below.

[13] See U.S. Bureau of Labor Statistics, Occupational Employment Statistics-National, May

Continued

TABLE 5—TOTAL HOURLY REMUNERATION (FULLY-LOADED HOURLY WAGE) PER ROLE AND BLS JOB POSITION

Role	BLS-Code	BLS-Name	Median hourly wage	Benefit factor	Fully-loaded hourly wage
Remote Supervision	11–3031	Financial Manager	$62.45	1.502	$93.80
Direct Supervision	13–1041	Compliance Officer	33.20	1.502	49.87
Operations	43–3071	Teller	15.02	1.502	22.56

FinCEN estimates that, on average, each role would spend different amounts of time on the CTR reporting and recordkeeping requirements. FinCEN further estimates that the total number of hours of the traditional annual PRA burden may be allocated to the different roles as follows: 1% of the burden will represent the work of remote supervision, 9% of the burden will represent the work of direct supervision, and the remainder will represent operations work. Multiplying the fully-loaded hourly wage from Table 5 by the proportion of time FinCEN estimates each role spends on the CTR process, FinCEN arrives at a weighted average hourly cost, set out below:

TABLE 6—WEIGHTED AVERAGE HOURLY COST

Component	Remote Supervision		Direct supervision		Operations		Weighted average hourly cost
	% time	Hourly cost	% time	Hourly cost	% time	Hourly cost	
Recordkeeping and reporting	1	$93.80	9	$49.87	90	$22.56	$25.73

FinCEN multiplied the total hours per filer type from Table 4 (1,485,761 hours), by the weighted average hourly cost from Table 6 ($25.73 per hour), and estimated the cost of the traditional annual PRA burden to be $38,228,631.

Part 3. Estimate of the Supplemental Annual PRA Burden

FinCEN intends to add a supplemental PRA burden calculation, reflecting the annual PRA burden and cost involved in (a) obtaining data required by the CTR that the filer does not need for its own bookkeeping, and (b) maintaining, updating, and upgrading the technological infrastructure required to file and store the CTRs.

Annual Hourly PRA Burden of Obtaining Source Data

For purposes of estimating the annual burden of obtaining and verifying information on the parties to a reportable transaction or group of transactions (the ''ID-related annual PRA burden''), FinCEN consolidates the types of financial institution filing CTRs into two major groups, depository and non-depository institutions, and stipulates the following:

1. Depository institutions report CTRs where the principal—the person on whose behalf the transaction is conducted (either when the person is operating by itself or through a different person)—is an established customer subject to CIP.[14] All depository institutions verify and record the customer identification information on the principals required by the CTR. Therefore, FinCEN assigns no PRA burden to obtaining, verifying, and recording the information on principals of currency transactions reported by depository institutions (''ID-related PRA burden'').[15]

2. Non-depository institutions may or may not restrict their reportable currency transactions to established customers. Conservatively, FinCEN assigns an ID-related PRA burden of three minutes per person for a non-depository institution to obtain, verify, and record the required information to file a CTR on any principal (either a person conducting a currency transaction on its own behalf, or a person on whose behalf the transaction was conducted).

3. Neither depository nor non-depository institutions likely maintain in their records the information required by a CTR about a person conducting a transaction on behalf of another person. Therefore, FinCEN assigns an ID-related PRA burden of three minutes per person for an institution to collect the required information to file a CTR on a person conducting a transaction on behalf of another person.

4. The CTR requires the reporting of currency transporters operating on behalf of any party that is not the filer.[16] The information required involves the legal person (for example, the armored car service company), and not the individual natural person performing the physical transportation. There are a limited number of currency transporters conducting transactions with depository or non-depository institutions whose information must be on file for physical security reasons (such as controlling access to the vault). Therefore, FinCEN assigns an ID-related PRA burden of one minute per currency transporter for an institution to collect the required information to file a CTR on the currency transporter.

To arrive at the estimate of the total ID-related annual PRA burden, FinCEN counted the number of each of the four types of persons (*i.e.,* a person operating on its own behalf, a person on whose behalf the transaction is conducted, a person conducting the transaction on

2019, available at *https://www.bls.gov/oes/tables.htm. The most recent data from the U.S. Bureau of Labor Statistics corresponds to May 2019.* For benefits component of total compensation, see U.S. Bureau of Labor Statistics, Employer's Cost per Employee Compensation as of December 2019, available at *https://www.bls.gov/news.release/ecec.nr0.htm.* The ratio between benefits and wages for financial activities, credit intermediation and related activities is $15.80 (hourly benefits)/$31.45 (hourly wages) = 0.502. The benefit factor is 1 plus the benefit/wages ratio, or 1.502. Multiplying each hourly wage by the benefit factor produces the fully-loaded hourly wage per position.

[14] For the regulatory definition of 'established customer', see 31 CFR 1010.100(p).

[15] This stipulation is grounded in FinCEN's review of the 2019 CTR submissions. In CTRs filed by depository institutions, the filer reported a transactional account belonging to either the person conducting the transaction on its own behalf, or to the person on whose behalf the transaction was conducted, in over 98% and 94% of the cases, respectively, while the remaining reports had incomplete information in the respective sections.

[16] See FIN–2013–R001, ''Treatment of Armored Car Service Transactions Conducted on Behalf of Financial Institution Customers or Third Parties for Currency Transaction Report Purposes'', July 12, 2013.

behalf of another, and a currency transporter operating on behalf of a person other than the filer) in each 2019 CTR submission, and multiplied the total of each type of person identified in each report by the corresponding individual ID-related PRA burden, as defined above. The breakdown of the total ID-related PRA annual burden is described in Table 7 below.[17]

TABLE 7—TOTAL ANNUAL PRA BURDEN OF OBTAINING AND VERIFYING PERSONAL INFORMATION

[Minutes and hours]

TRANCHE	Depository		Non-depository		Total minutes	Total hours
	Principals	Non-principals	Principals	Non-principals		
01_LARGEST_FILERS	0	12,905,258	0	0	12,905,258	215,087
02_100–2000/WEEK	0	6,973,483	3,179,679	60,264	10,213,426	170,224
All other tranches	0	4,928,268	2,846,334	640,998	8,415,600	140,260
Total	0	24,807,009	6,026,013	701,262	31,534,284	525,571

The total ID-related annual PRA burden estimated by this method is 525,571 hours.

Cost of Annual PRA Burden of Obtaining Source Data

FinCEN multiplied the total hours per filer type from Table 7 (525,571 hours), by the weighted average hourly cost from Table 6 ($25.73),[18] and estimated the cost of the total ID-related PRA annual burden to be $13,522,942.

Annual PRA Cost and Burden of Maintaining and Upgrading Hardware and Software

It is difficult for FinCEN to separately estimate the annual cost and hourly burden a financial institution bears in maintaining the hardware and software for the CTR requirement itself (the ''technology-related annual PRA cost'' and the ''technology-related annual PRA burden'' of the CTR, respectively). FinCEN understands that most large financial institutions maintain highly integrated software and hardware systems for anti-money laundering and safety and soundness purposes that leverage the existing need to maintain records and information about customers and transactions for business reasons. Given the difficulties of calculating such a cost estimate, FinCEN attempted to estimate a percentage of the supplemental burden for this report using data collected in a previous rulemaking effort. While not exact, this is the best information FinCEN currently has to prepare an estimate which likely represents the outer limit of the technology-related costs relative to the total cost.

In 2008, FinCEN surveyed certain depository institutions and money transmitters to assess the costs to set up and maintain the reporting of cross-border electronic transmittal of funds (CBETF) data above certain thresholds (the ''2008 Survey'').[19] Seventy-five depository institutions and six money transmitters involved in international transmittals of funds responded to the survey. In the case of depository institutions, the survey identified proportionally each type of cost involved in setting up the reporting process, and the ongoing cost involved in complying annually with the proposed CBETF reporting obligation.[20]

The breakdown of the annual ongoing reporting compliance costs is reflected in Table 8 below.

TABLE 8—PROPORTION OF COMPONENTS OF ANNUAL PRA BURDEN

PERSONNEL	45%	85.00%	COST COMPONENTS INCLUDED IN TRADITIONAL AND ID-RELATED ANNUAL PRA BURDEN
ONGOING MANAGEMENT	23.00%		
OTHER	12.00%		
TESTING	2.00%		
TRAINING	2.00%		
CONSULTING	1.00%		
HARDWARE	6.00%	15.00%	COST COMPONENTS NOT INCLUDED IN TRADITIONAL AND ID-RELATED ANNUAL PRA BURDEN
IT	6.00%		
SOFTWARE DEVELOPMENT	3.00%		
TOTAL	100.00%	100.00%	

The absolute ongoing cost per component estimated by the 2008 Survey respondents relate to the CBETF reporting, and therefore cannot be used to extrapolate the costs of another reporting or recordkeeping requirement.

[17] The column ''Principals'' includes the PRA burden of ''persons conducting a transaction on their own behalf'', and ''persons on whose behalf the transaction was conducted'' by somebody else. The column ''Non_Principals'' includes the PRA burden of ''persons conducting a transaction on behalf of others'' and ''currency transporters working for a person other than the filer.'' Principals carry a zero PRA burden for depository institutions, and a 3-minute PRA burden per individual person identified in each report for non-depository institutions. In the case of Non-Principals, ''persons conducting a transaction on behalf of others'' carry a 3-minute PRA burden per person identified in each report, regardless of the filer type, and ''currency transporters working for a person other than the filer'' carry a PRA burden of one minute per individual currency transporter identified in each report, regardless of the filer type.

[18] FinCEN stipulates that the weights used to calculate the weighted average costs in Table 6 are appropriate weights for the calculation of the weighted average costs for the obtaining of source data.

[19] FinCEN's 2008 Cross-Border Electronic Funds Transfer Survey Final Report is set out in Appendix C of FinCEN's January 2009 study on the Implications and Benefits of Cross-Border Funds Transmittal Reporting, available at *https://www.fincen.gov/sites/default/files/shared/ImplicationsAndBenefitsOfCBFTR.pdf* (''January 2009 Study'').

[20] Appendix C of the January 2009 Study, page 15.

While the absolute costs may not be extrapolated to another requirement, the proportion of the annual ongoing compliance costs provided by the depository institution respondents to the 2008 Survey can be used to extrapolate an estimate of the technology-related PRA cost (15% of the total cost) for fully-automated filers. FinCEN assesses such a method is valid because the CTR and CBETF reporting and recordkeeping requirements are similar with respect to the objective nature of the reporting triggered by threshold amounts of transactions. Given the limited information at its disposal regarding the technology-related costs associated with the filing of CTRs, FinCEN is using the proportions of the cost components reported by depository institutions to extrapolate the total annual technology-related PRA cost, as CTRs filed by depository institutions represent 88% of all CTRs filed in 2019. In addition, FinCEN believes the proportionality of ongoing costs derived from the 2008 Survey is still useful today notwithstanding changes in costs over time. Not only has the cost of hardware dropped considerably between 2008 and 2019, but the personnel cost associated with software development and information technology management has increased on par with, or slightly less than, the cost of personnel included in the traditional PRA estimate; in other words, the changes in costs of the different components of the information technology investment have grown at a slower pace than the traditional annual PRA cost estimate.[21]

Based on the revised estimate of the traditional annual PRA burden (as described in Part 2 above), and the estimate of the additional ID-related annual PRA burden described in the earlier sections of this Part, the PRA burden and cost for all filers (without including a technology component) are described in Table 9 and Table 10 below, respectively.

Table 9 - Traditional and ID-related annual hourly PRA burden, per tranche, filing method, and filer type

TRANCHE	FILING METHOD	FILER TYPE	TRADITIONAL PRA HOURS	ADDIT ID PRA HOURS	TOTAL HOURS	TOTAL HOURS AUTOMATED	TOTAL HOURS NON-AUTOMAT
FULLY-AUTOMATED FILERS	BATCH	DEPOSITORY	187,592	328,615	516,207	516,207	0
	BATCH	NON_DEPOSITORY	16,442	50,108	66,550	66,550	0
	DISCRETE	DEPOSITORY	36,494	2,697	39,191	39,191	0
	DISCRETE	NON_DEPOSITORY	18,233	3,890	22,123	22,123	0
NON-AUTOMATED FILERS	ANY METHOD	DEPOSITORY	930,911	82,137	1,013,048	0	1,013,048
	ANY METHOD	NON_DEPOSITORY	296,089	58,122	354,211	0	354,211
TOTAL			1,485,761	525,571	2,011,332	644,071	1,367,259

Table 10 - Traditional and ID-related annual PRA cost, per tranche, filing method, and file type

TRANCHE	FILING METHOD	FILER TYPE	TRADITIONAL PRA $	ADDIT ID PRA $	TOTAL $	TOTAL $ AUTOMATED	TOTAL $ NON-AUTOMATED
FULLY-AUTOMATED FILERS	BATCH	DEPOSITORY	$4,826,744	$8,455,263	$13,282,007	$13,282,007	$0
	BATCH	NON_DEPOSITORY	$423,053	$1,289,278	$1,712,331	$1,712,331	$0
	DISCRETE	DEPOSITORY	$938,991	$69,393	$1,008,384	$1,008,384	$0
	DISCRETE	NON_DEPOSITORY	$469,135	$100,089	$569,224	$569,224	$0
NON-AUTOMATED FILERS	ANY METHOD	DEPOSITORY	$23,952,340	$2,113,385	$26,065,725	$0	$26,065,725
	ANY METHOD	NON_DEPOSITORY	$7,618,370	$1,495,479	$9,113,849	$0	$9,113,849
TOTAL			$38,228,631	$13,522,941	$51,751,572	$16,571,946	$35,179,574

Traditional and ID-related annual PRA costs result from multiplying the hourly PRA burdens in Table 9 by the Weighted Average Hourly Cost from Table 6 ($25.73)

Based on the proportions described in Table 8 above, the traditional and ID-related annual PRA costs of fully-automated filers estimated in Table 10 (the ''Table 10 PRA cost'') constitute 85% of the total annual PRA cost of reporting and recordkeeping incurred by such filers, with the remaining 15% of costs corresponding to the technology-related PRA cost (*i.e.,* maintenance, updates and upgrades of software, general information technology support, and hardware replacement). To estimate the total annual PRA costs for fully-automated filers to file CTRs (a calculation that adds the cost of the traditional and ID-related annual PRA burden to the newly estimated technology-related PRA cost), FinCEN discounts the Table 10 PRA cost by its contribution to the total annual PRA cost ($16,571,966/0.85), resulting in a total annual PRA cost for fully-automated filers of $19,496,430.

Determining the hourly burden of some cost components of the technology-related annual PRA burden, such as the price of new hardware, is not straightforward. The method FinCEN followed to estimate the technology-related annual PRA cost does not provide a definitive way for deriving the burden hours attributable to each cost component. To produce such an estimate, FinCEN would have needed information not provided in the 2008 Survey (such as the participation of different levels of technology-related labor and their fully-loaded compensation rates). FinCEN, however, believes that it is appropriate to estimate the total annual PRA hourly burden for fully-automated filers using a calculation similar to the one employed for the total annual PRA cost. FinCEN stipulates that the traditional and ID-related PRA burden for fully-automated filers set out in Table 9 above (the ''Table 9 PRA burden'') also constitutes 85% of the total annual PRA burden of such filers. FinCEN discounts the Table 9 PRA burden by its contribution to the total annual PRA burden (644,072 hours/0.85), and arrives at a total annual

[21] See footnote 8. See also, Bureau of Labor Statistics, Occupational Employment Statistics-National, May 2008, available at *https://www.bls.gov/oes/tables.htm.* Between 2008 and 2019, for example, the median hourly wage for financial managers, compliance officers, and tellers went up 17.41%, 28.43%, and 28.82%, respectively, while the same metric went up only 8.27% and 20.03% for software developers and programmers and network and computer system administrators, respectively.

PRA burden for fully-automated filers of 757,732 hours.[22] This equals the sum of the traditional annual PRA burden and the ID-related annual PRA burden (644,072 hours or 38,644,260 minutes), and the technology-related annual PRA burden (113,660 hours or 6,819,583 minutes).

In the future, FinCEN intends to conduct studies of the filing population to more accurately estimate the contribution of technology-related costs to the total annual PRA burden. These future studies will incorporate a more granular breakdown of the degree of automation among CTR filers, and may result in significant variations of the estimated annual PRA burden. Among other things, FinCEN will need to segregate the technology costs associated exclusively with BSA reporting, recordkeeping, and monitoring requirements, from the technology costs involved in (i) complying with other regulatory frameworks, and/or (ii) processing data used for the filer's other business purposes.

Estimated Reporting and Recordkeeping Burden: The average estimated PRA burden, measured in minutes per report, is 8 minutes, as described in Table 11 below:

Table 11 - Total annual PRA burden, per tranche, filing method, and file type, expressed as minutes per report

TRANCHE	FILING METHOD	FILER TYPE	REPORTS	TRADITIONAL PRA (MINUTES)	ID PRA (MINUTES)	TECH PRA (MINUTES)	TOTAL MINUTES	MINUTES PER REPORT
FULLY-AUTOMATED FILERS	BATCH	DEPOSITORY	11,255,508	11,255,508	19,716,909	5,465,721	36,438,138	3.24
		NON_DEPOSITORY	986,492	986,492	3,006,534	704,652	4,697,678	4.76
	DISCRETE	DEPOSITORY	109,482	2,189,640	161,832	414,966	2,766,438	25.27
		NON_DEPOSITORY	54,699	1,093,980	233,409	234,245	1,561,634	28.55
NON-AUTOMATED FILERS	ANY METHOD	DEPOSITORY	2,792,733	55,854,660	4,928,268	0	60,782,928	21.76
		NON_DEPOSITORY	888,268	17,765,360	3,487,332	0	21,252,692	23.93
TOTAL			16,087,182	89,145,640	31,534,284	6,819,583	127,499,507	7.93

Estimated Number of Respondents: 14,276 financial institutions.[23]

Estimated Total Annual Responses: 16,087,182.[24]

Estimated Total Annual Reporting and Recordkeeping Burden: The estimated total annual PRA burden is 2,124,992 hours, as described in Table 12 below.

Table 12 - Total annual PRA burden, in hours, per tranche, filing method, and file type

TRANCHE	FILING METHOD	FILER TYPE	REPORTS	TRADITIONAL PRA (HOURS)	ID PRA (HOURS)	TECH PRA HOURS	TOTAL HOURS
FULLY-AUTOMATED FILERS	BATCH	DEPOSITORY	11,255,508	187,592	328,615	91,095	607,302
		NON_DEPOSITORY	986,492	16,442	50,109	11,744	78,295
	DISCRETE	DEPOSITORY	109,482	36,494	2,697	6,916	46,107
		NON_DEPOSITORY	54,699	18,233	3,890	3,904	26,027
NON_AUTOMATED FILERS	ANY METHOD	DEPOSITORY	2,792,733	930,911	82,138	0	1,013,049
		NON_DEPOSITORY	888,268	296,089	58,122	0	354,212
TOTAL			16,087,182	1,485,761	525,571	113,660	2,124,992

Estimated Total Annual Reporting and Recordkeeping Cost: At the weighted average hourly cost of $25.73 described in Table 6 above, the cost of the estimated total annual PRA reflected in Table 12 (2,124,992 hours) is $54,676,044.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Records required to be retained under the BSA must be retained for five years.

Request for Comments

a. Specific Requests for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on the calculation of the total PRA burden of filing the CTR, under the current regulatory requirements. Specifically, comments are invited on the following issues:

1. FinCEN has broken down the process required to comply with the CTR requirement into several steps, from identifying a transaction that must be reported, to maintaining and upgrading software required for the completion, submission, and storage of the report. In general, do these steps reflect the filer's own general experience? Is there a need to include a more granular breakdown of the process to describe what, *on average,* a CTR filer must do?

2. For purposes of calculating PRA burden and cost, FinCEN has taken the 2019 CTR submissions number as a baseline, stipulating that it is an

[22] This calculation uses the cost per burden hour estimate of $25.73 per hour derived through the previous estimates even though the costs per hour in the context of maintaining, updating, and upgrading the hardware and software are different. Of importance here is FinCEN's confidence in the overall costs reflected in this assessment, even if there is less confidence in the notional number of burden hours associated with the supplemental cost.

[23] See Part 1-Table 1 for a breakdown of the types of financial institutions that filed CTRs in 2019. Note that all banks, casinos and card clubs, MSBs, brokers or dealers in securities, mutual funds, futures commissions merchants and introducing brokers in commodities are required to comply with the CTR regulatory requirement, however, not all financial institutions conduct transactions that would trigger the CTR filing requirements. See 31 CFR 1020.310 (banks), 31 CFR 1021.310 (casinos and card clubs), 31 CFR 1022.310 (MSBs), 31 CFR 1023.310 (brokers or dealers in securities), 31 CFR 1024.310 (mutual funds), and 31 CFR 1026.310 (futures commissions merchants and introducing brokers in commodities).

[24] Numbers are based on actual 2019 filings as reported by the BSA E-Filing System as of 12/31/2019. This number reflects the total number of filings for both the legacy CTR and CTRC and the new FinCEN Report 112—CTR.

appropriate representation of the expected composition of the filing population and report submissions for the next three years. Is that an appropriate assumption? Are there expected changes in either the composition of the filing population or the breakdown of the report submissions over the next three years that should be factored into FinCEN's estimates?

3. FinCEN estimates that, *on average,* the time involved in the reporting of a CTR varies in accordance with the range of the total number of reports filed per year (*i.e.,* filers filing 100 reports or more per week are totally automated), the type of financial institution and type of transaction (*i.e.,* depository financial institutions engaging in reportable currency transactions that only involve established customers), and filing method (*i.e.,* completion of reports filed on a discrete basis generally involve more manual data entry than those batch-filed, regardless of the filer's level of automation). Are these assumptions reasonable? Are there other factors that may affect the amount of time involved in preparing, reviewing, and filing the report, *which FinCEN could quantify by analyzing the contents of the BSA database and without conducting a formal survey of the reporting financial institutions*?

4. FinCEN estimates that the completion, review, and submission of a CTR will demand a certain number of minutes per report, depending on the factors listed above. *On average,* is the estimated number of minutes per report reasonable, by degree of automation of the filer, type of financial institution the filer is, method of filing, types of financial institution labor positions involved, and allocated time per labor position?

5. FinCEN estimates that, *on average,* the cost of labor involved in the completion, review, and submission of a CTR will depend on at least three different levels of staff involvement within the filer's organization (*i.e.,* remote supervision, direct supervision, and operations) participating in the process for different portions of the CTR process. *On average,* is the allocation of time and hourly cost plus benefits per organizational level reasonable? Has FinCEN identified the right level of involvement and the right type of labor position per role?

6. FinCEN estimated the ID-related PRA burden by stipulating that depository institutions conduct reportable transactions only with established customers, while non-depository institutions conduct transactions with non-established customers. Is this stipulation reasonable? Is there another factor that would allow FinCEN to determine when a non-depository institution conducts a transaction with an established customer, and therefore its ID-related PRA cost is lower than the current estimate? FinCEN allocated an ID-related PRA cost of three minutes to persons conducting a transaction on behalf of another, for any type of financial institution. Is this allocation always required, or are there instances where the filer has already obtained, verified, and retained the personal data of the transactor, and therefore the allocation could be lower, or even eliminated altogether?

7. FinCEN estimated the technology-related PRA burden on the assumption that, *on average,* the percentage breakdown of the total cost among different cost factors is mostly constant among analogous reporting obligations. Based on a previous industry survey, FinCEN based the estimates of total annual PRA burden on the premise that traditional and ID-related annual PRA costs amount to 85% of the total annual PRA cost of fully-automated filers, while software, hardware, and systems-related costs, including maintenance, updates and upgrades represent the remaining 15%. Is there existing evidence that may indicate that one or both of these assumptions are not reasonable? Is there another factor or combination of factors that would assist FinCEN in determining which filers that file fewer than 100 reports a week may also be fully or partially automated, and therefore adjust the technology-related PRA cost?

8. The estimate of the technology-related PRA burden relies on the principle that the system maintenance, hardware maintenance and replacement, and other technological costs included in the estimate relate to hardware and software resources used exclusively for CTR filing. If such resources are used for multiple purposes, only a fraction of their cost that represents their use for complying with this BSA obligation should be included in the PRA burden estimate. Is this assumption correct? Is this assumption provable by objective methods? Has your financial institution determined what percentage of its technology is used for CTR purposes? How can FinCEN determine which resources, if any, are used for purposes other than BSA compliance, and therefore adjust the PRA estimate?

9. Please provide any other comments on calculation methods, assumptions, stipulations, or any other issues that may impact the total PRA burden calculation of the regulations or the report.

b. General Request for Comments

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: May 8, 2020.

Derek Baldry,

Deputy Chief of Staff, Financial Crimes Enforcement Network.

[FR Doc. 2020–10310 Filed 5–13–20; 8:45 am]

BILLING CODE 4810–02–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0021]

Agency Information Collection Activity: VA Loan Electronic Reporting Interface (Valeri) System

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it includes the actual data collection instrument.

DATES: 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. Refer to ''OMB Control No. 2900–0021.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: VA Loan Electronic Reporting Interface (VALERI) System.

OMB Control Number: 2900–0021.

Type of Review: Extension of a currently approved collection.

Abstract: VA provides the authority for VA-guaranteed mortgage servicers to assist veteran borrowers and their families experiencing financial difficulty. VA then provides oversight of the servicers' actions by collecting specific documentation and data. In today's environment, this collection is done via the VALERI application. Federal Regulations under 38 CFR 36.4300 require specific, critical information be provided to VA and without the collection of such documentation and data, the number of foreclosures of VA-guaranteed loans and homeless veterans would potentially increase.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on February 24, 2020 at 85 FR 10512, pages 10512–10513.

Affected Public: Business or other for profit.

Estimated Annual Burden: 70 hours.

Estimated Average Burden per Respondent: 1 minute.

Frequency of Response: One time.

Estimated Number of Respondents: 967.

By direction of the Secretary.

Danny S. Green,

VA PRA Clearance Officer, Office of Quality, Performance and Risk Department of Veterans Affairs.

[FR Doc. 2020–10318 Filed 5–13–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0877]

Agency Information Collection Activity: Freedom of Information Act (FOIA) or Privacy Act (PA) Request, Priority Processing Request, and Document/Evidence Submission

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 previously 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 July 13, 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. 2900–0877'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Danny S. Green, (202) 421–1354 or email *Danny.Green2@va.gov.* Please refer to ''OMB Control No. 2900–0877'' in any correspondence.

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: Freedom of Information Act (FOIA) or Privacy Act (PA) Request (VA Form 20–10206), Priority Processing Request (VA Form 20–10207), and Document/Evidence Request (VA Form 20–10208).

OMB Control Number: 2900–0877.

Type of Review: Extension of a previously approved collection.

Abstract: VA Form 20–10206 is be used by a claimant to request access to Federal agency records as long as the record is not exempt from release by one of nine FOIA exemptions. This form standardizes submission of Freedom of Information Act (FOIA) requests and Privacy Act (PA) requests received from claimants in order to facilitate the identification and retrieval of requested records. VA Form 20–10207 is used by claimants to notify VA of an urgent or immediate need due to change in status or circumstance for priority processing of claim. VA Form 20–10208 is used to identify and associate additional evidence or information in support of claim.

Affected Public: Individuals or households.

Estimated Annual Burden: 50,000 hours.

Estimated Average Burden per Respondent: 6 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 500,000.

By direction of the Secretary.

Danny S. Green,

VA Clearance Officer, Office of Quality, Performance and Risk, Department of Veterans Affairs.

[FR Doc. 2020–10355 Filed 5–13–20; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0252]

Agency Information Collection Activity: Application for Authority to Close Loans on an Automatic Basis Nonsupervised Lenders (VA Form 26–8736)

AGENCY: Loan Guaranty Service, Veterans Benefits Administration.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Loan Guaranty Service, Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and it

includes the actual data collection instrument.

DATES: 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. Refer to ''OMB Control No. 2900–0252.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 104–13; 44 U.S.C. 3501–3521.

Title: Application for Authority to Close Loans on an Automatic Basis Nonsupervised Lenders (VA Form 26–8736).

OMB Control Number: 2900–0252.

Type of Review: Extension of an approved collection.

Abstract: VA Form 26–8736 is used by non-supervised lenders requesting approval to close loans on an automatic basis. The form contains information and data considered crucial for making acceptability determinations as to lenders who shall be approved for this privilege. Upon receipt of the form, the VA Regional Loan Centers will process and evaluate the information. They will then advise the lender-applicant of their decision. Without this information, VA would not be able to determine if lender-applicants meet the qualifications for processing loans on an automatic basis.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published on March 4, 2020 at 85 FR 12823, page 12823.

Affected Public: Individuals or households.

Estimated Annual Burden: 50 hours.

Estimated Average Burden per Respondent: 25 minutes.

Frequency of Response: One time.

Estimated Number of Respondents: 120.

By direction of the Secretary.

Danny S. Green,

VA PRA Clearance Officer, Office of Quality, Performance and Risk Department of Veterans Affairs.

[FR Doc. 2020–10319 Filed 5–13–20; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

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Part II

Environmental Protection Agency

40 CFR Parts 79, 80, 86, et al.
Fuels Regulatory Streamlining; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 79, 80, 86, 1037, and 1090

[EPA–HQ–OAR–2018–0227; FRL–10007–52–OAR]

RIN 2060–AT31

Fuels Regulatory Streamlining

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This action proposes to update the Environmental Protection Agency's (EPA) existing gasoline, diesel, and other fuels programs to improve overall compliance assurance and maintain environmental performance, while reducing compliance costs for industry and EPA. EPA is proposing to streamline its existing fuel quality regulations by removing expired provisions, eliminating redundant compliance provisions (*e.g.,* duplicative registration requirements that are required by every EPA fuels program), removing unnecessary and out-of-date requirements, and replacing them with a single set of provisions and definitions that will apply across all gasoline, diesel, and other fuels programs that EPA currently regulates. This action does not propose to change the stringency of the existing fuel quality standards.

DATES:

Comments. Comments must be received on or before June 29, 2020. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before June 15, 2020.

Public Hearing. EPA will announce the public hearing date and location for this proposal in a supplemental **Federal Register** document.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2018–0227, at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. 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. 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.*

FOR FURTHER INFORMATION CONTACT: Nick Parsons, Office of Transportation and Air Quality, Assessment and Standards Division, Environmental Protection Agency, 2000 Traverwood Drive, Ann Arbor, MI 48105; telephone number: 734–214–4479; email address: *parsons.nick@epa.gov.* Comments on this proposal should not be submitted to this email address, but rather through *http://www.regulations.gov* as discussed in the **ADDRESSES** section.

SUPPLEMENTARY INFORMATION:

Does this action apply to me?

Entities potentially affected by this proposed rule are those involved with the production, distribution, and sale of transportation fuels, including gasoline and diesel fuel. Potentially affected categories include:

Category	NAICS [1] Code	Examples of potentially affected entities
Industry	211130	Natural gas liquids extraction and fractionation.
Industry	221210	Natural gas production and distribution.
Industry	324110	Petroleum refineries (including importers).
Industry	325110	Butane and pentane manufacturers.
Industry	325193	Ethyl alcohol manufacturing.
Industry	325199	Manufacturers of gasoline additives.
Industry	424710	Petroleum bulk stations and terminals.
Industry	424720	Petroleum and petroleum products wholesalers.
Industry	447110, 447190	Fuel retailers.
Industry	454310	Other fuel dealers.
Industry	486910	Natural gas liquids pipelines, refined petroleum products pipelines.
Industry	493190	Other warehousing and storage—bulk petroleum storage.

[1] North American Industry Classification System (NAICS).

This table is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this proposed action. This table lists the types of entities that EPA is now aware could potentially be affected by this proposed action. Other types of entities not listed in the table could also be affected. To determine whether your entity would be affected by this proposed action, you should carefully examine the applicability criteria in 40 CFR part 80. If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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I. Executive Summary

A. Overview of Fuels Regulatory Streamlining

1. Why EPA Is Taking This Action

As part of our continual effort to update our regulations to ensure that fuel quality standards established under the Clean Air Act (CAA) continue to be met in-use, while minimizing the burden associated with doing so, we are proposing to streamline and modernize our existing 40 CFR part 80 (''part 80'') fuel quality regulations by transferring them into a new proposed set of regulations in 40 CFR part 1090 (''part 1090''). In this action, we are taking a wholistic look at the existing part 80 regulations in an attempt to consolidate the many different and overlapping regulations into the proposed part 1090 regulations that will also better reflect how fuels, fuel additives, and regulated blendstocks are produced, distributed, and sold in today's marketplace.

2. What Is and Is Not Covered in This Action

This action focuses primarily on streamlining and consolidating our existing gasoline and diesel fuel programs that currently reside in part 80.[1] To accomplish this, we are proposing to remove expired provisions and consolidate the remaining provisions from multiple fuel quality programs into a single set of requirements. This action covers almost all fuel programs and related provisions currently in part 80. These programs include, but are not limited to, the reformulated gasoline (RFG) program, the anti-dumping program, the diesel sulfur program, the gasoline benzene program, the gasoline sulfur programs, the E15 misfueling mitigation program, and the national fuel detergent program. This proposed streamlining effort aims to combine these separate, now fully-implemented programs, all of which affect the same regulated parties, into a single, national fuel quality program.

While this action proposes changes to many aspects of our fuel quality programs, there are several areas of the existing part 80 regulations that would remain unchanged. Most importantly, this action does not change the stringency of the existing fuel quality standards. We are simply proposing to streamline and consolidate the existing part 80 fuel quality programs into a single streamlined fuel quality program that would make compliance with the existing fuel quality standards under part 80 more straightforward, and as a result potentially improve fuel quality through increased compliance with our fuel quality standards. This action proposes to transfer the part 80 fuel quality standards mostly unchanged to part 1090, though in some cases we are proposing to modify the form of the standards to translate them into a format more conducive to streamlining the regulations and ensuring in-use compliance.

We recognize that while we are not proposing changes to the standards, in some cases, the proposed consolidation of certain provisions may slightly, indirectly affect in-use fuel quality. For example, proposed changes to how parties record and report test results that fall below the test method's lower limits of detection might cause parties to have to report slightly higher sulfur and benzene levels in gasoline, effectively improving in-use fuel quality by slightly decreasing the sulfur national annual average. On the other hand, the proposal to make it easier for fuel manufacturers of conventional gasoline (CG) to account for oxygenates (*e.g.,* ethanol) added downstream of the manufacturing facility, thereby allowing for a slightly lower reported level of gasoline benzene and sulfur levels, might be perceived as slightly decreasing in-use fuel quality. There are many such minor impacts of changes in part 1090 and we believe that on balance the proposed program would maintain the same overall level of fuel quality as the current part 80 standards. Throughout this preamble, we have tried to identify such cases and we discuss the cumulative costs and benefits of these changes in more detail in Section XIV.

We are also proposing some slight modifications to the Renewable Fuel Standard (RFS) program in subpart M of part 80, primarily for administrative purposes that follow from the proposed changes to our other fuel programs. These subpart M regulations are mostly unique to the RFS program, and

[1] Under the current regulations, EPA's fuels regulations are in 40 CFR parts 79 and 80. Part 79 contains provisions related to the registration of fuel and fuel additives under CAA sections 211(a), (b), (e), and (f), while Part 80 contains provisions for fuel quality (*e.g.,* fuel controls and prohibitions established under CAA section 211(c) and the RFG program requirements promulgated under CAA section 211(k)) and the RFS program. This action is limited to the provisions related to EPA's fuel quality standards in part 80, as the registration requirements in part 79 and the RFS program in part 80 are significantly different in scope and would involve different considerations to update those regulatory requirements.

therefore do not need to be consolidated with the other part 80 fuel standard regulations. One of the goals of this action is to help ensure consistency in how parties comply with our regulatory requirements and report information to EPA. Since the RFS program uses similar, if not the same, reporting systems and compliance mechanisms for parties to demonstrate compliance, we are proposing changes to help ensure that this consistency is maintained or enhanced as a result of this action. We will treat public comments received suggesting substantive changes to the RFS program as outside the scope of this rulemaking.

Finally, this action does not propose to remove any statutory requirement for fuels specified by the CAA. For example, this action does not propose to remove limits on lead levels in gasoline under CAA section 211(n), remove the requirement that all gasoline be additized with detergents under CAA section 211(l), or cetane index limits for diesel fuel under CAA section 211(g) and (i). While this action does update some of the provisions put in place to implement many provisions of the CAA, and in some cases substantially streamline the implementing regulations (*e.g.,* for the gasoline detergents program), we are not proposing to eliminate any requirement under the CAA for fuels and parties that make, distribute, and sell such fuels.

The majority of this action's proposed changes relative to part 80 focus on consolidating and streamlining compliance provisions currently in part 80, not on adding new compliance requirements for regulated parties. This action also does not propose to impose new standards on fuels. As such, this action is mostly a compilation of numerous, relatively minor proposed changes to the existing provisions under part 80. Many of these proposed changes may appear disconnected from one another, as they are addressing a specific technical area that needs consolidation, streamlining, and/or updating. Together, however, these proposed changes will lead to a more effective, efficient EPA fuels program.

3. Program Design

The new part 1090 is designed to reduce compliance burdens for both industry and EPA, potentially lower fuel costs for consumers, and maintain fuel quality. To accomplish these goals, we have identified three key elements that are included in part 1090:

- A simplification of the RFG summer VOC standards.
- A consolidation of the regulatory requirements across the part 80 fuel quality programs.
- Improving oversight through the leveraging of third parties to ensure in-use fuel quality.

First, we are proposing to simplify the RFG standards by translating the current summer RFG VOC standard into an RVP per-gallon cap of 7.4 psi. This proposed change would allow us to remove the use of the Complex Model [2] as a requirement to certify batches of gasoline and remove all the provisions associated with demonstrating compliance on average. This proposed change would also allow for us to minimize the restrictions on the commingling of RFG and CG, allowing for a more fungible and efficient gasoline distribution system.

The main remaining difference between RFG and CG is that in the summer, RFG's volatility is functionally controlled through a summer VOC performance standard determined with the Complex Model instead of through the RVP per-gallon maximum standards established for CG under CAA section 211(h). EPA has previously aligned the treatment RFG and CG for NO_X performance through the Tier 2 gasoline sulfur program and toxics performance through the national gasoline benzene program.[3] This action would align treatment for RFG and CG by translating the existing RFG VOC performance standard into an RVP per-gallon cap standard, as is the case for CG in the summer. In Section V.A.2, we describe how the proposed summer RVP per-gallon cap of 7.4 psi equates to the existing RFG summer VOC standards. This change alone allows for the removal of the sampling, testing, and reporting requirements associated with several Complex Model parameters, greatly simplifying compliance with our fuel standards. With this proposed translation of the RFG summer VOC performance standards into a summer RFG RVP per-gallon maximum standard, the required controls on fuel properties for RFG would be identical to the control of fuel properties for CG, even though the standards would remain different.

Second, since the standards for volatility, benzene, and sulfur would be treated similarly between RFG and CG, this would allow for the streamlining and consolidation of the compliance and enforcement provisions of the various part 80 fuel quality programs into a single fuel quality program. This consolidation would improve consistency, remove duplication, and ultimately reduce compliance burden on regulated parties and EPA. For example, we are proposing to consolidate the various gasoline reporting requirements into a single, unified annual reporting requirement. Under part 80, we require quarterly batch reports for RFG, versus annual reports for CG. We also require separate batch reports for the gasoline benzene and gasoline sulfur programs.

Third, the proposed streamlined fuel quality program aims to improve oversight of our fuel quality programs. We hope to accomplish this by updating and improving the third-party oversight programs we already use in part 80. We are proposing to consolidate the existing three in-use survey programs into a single national in-use fuel quality survey. This proposed program would help ensure that all fuels nationwide continue to meet EPA fuel quality standards when dispensed into vehicles and engines, not just at the refinery gate. We are also proposing to replace the RFG independent lab testing requirement with a voluntary national oversight program. This proposed sampling oversight program would impose substantially lower costs across industry than the current regulations while helping to ensure the consistency of sampling and testing across industry. Finally, we are proposing to update and modernize the annual attest engagement program. These updated procedures will help ensure that the quality and consistency of reported information. Taken together, we believe these proposals will help improve oversight of our fuel quality programs.

B. Summary of Stakeholder Involvement and Rule Development

We have actively engaged stakeholders throughout the development of this action to help maximize its potential effectiveness. Due to the number of affected stakeholders, the complexity surrounding the production and distribution of fuels, and the broad scope of this action, active stakeholder involvement was necessary to help ensure that the proposed fuels regulatory streamlining program achieved its goals.

[2] The Complex Model is a predictive model that estimates emissions performance of gasoline based on measured fuel parameters against a statutory baseline in model year 1990 vehicles (see 40 CFR 80.45 and CAA section 211(k)(10)). Under part 80, refiners and importers are required to use the Complex Model to demonstrate compliance with RFG standards. The Complex Model is available at: *https://www.epa.gov/fuels-registration-reporting-and-compliance-help/complex-model-used-analyze-rfg-and-anti-dumping.*

[3] See 72 FR 8428 (February 26, 2007).

As part of the proposal development process, we provided advance notice through four discussion drafts of the proposed regulations.[4] In doing so, we solicited feedback from stakeholders to: (1) Help ensure that any gaps in our regulatory requirements were filled prior to proposal; and (2) identify potential issues with the streamlined regulations. We also held a three-day public workshop on a variety of topics in Chicago on May 21–23, 2018.[5] During this workshop, EPA staff discussed a variety of issues related to the development of this action to an audience of over 120 affected stakeholders. We also reached out on at least two separate occasions to a broad spectrum of interested stakeholders, including parties that make and distribute fuels, states, environmental non-governmental organizations, and other affected stakeholders. The proposed streamlined fuel quality program in this action is intended to reflect the input of all of those who participated in these activities and events.

C. Timing

As discussed in more detail in Section III.B, we are proposing that the part 1090 regulations would mostly replace the existing part 80 regulations on January 1, 2021. We believe that having an implementation date at the beginning of a new compliance period would provide for a smooth transition to new regulatory requirements.

D. Costs and Benefits

We do not anticipate much, if any, change in air quality as a result of this action. This is largely due to the fact that we are not proposing changes to the existing fuel quality standards. As such, we do not expect that regulated parties would need to make significant changes to how fuels are made, distributed, and sold, which are the factors EPA typically considers when determining the costs associated with imposing or changing fuel quality standards.

However, we do believe that this proposal could result in savings to regulated parties and EPA by simplifying compliance with our fuel quality standards and by allowing greater flexibility in the manufacture and distribution of fuels. These savings would largely arise from the reduction of the administrative costs on regulated parties and EPA in complying with and implementing the existing fuel quality standards. We estimate the annualized total costs savings in administrative cost savings to industry to be $32.9 million per year. Other savings associated with improving the fungibility of fuel and providing greater flexibility could potentially be even more significant but are much more difficult to quantify. Section XIV of the preamble discusses in more detail the potential costs and benefits of this action.

II. Changes to Part 80

We are transferring several provisions in part 80 that are currently in effect to part 1090.[6] These provisions are all discussed in the subsequent sections of this preamble and are now drafted in a manner that makes them easier to understand. We are also proposing to remove subparts B, D, E, F, G, H, I, J, K, L, N, and O and appendices A and B to part 80. Some of these subparts have either expired (*e.g.,* designate and track provisions for diesel fuel) or have been replaced by newer subparts (*e.g.,* subpart K (RFS1) was superseded by subpart M (RFS2), subpart H (Tier 2 Sulfur) was supplanted by subpart O (Tier 3 Sulfur), and subpart J (MSAT1) was supplanted by subpart L (MSAT2)).

We are not transferring some provisions from part 80 to part 1090. First, we are retaining the existing Renewable Fuel Standard (RFS) provisions in subpart M. We are proposing minor edits to subpart M that are intended to ensure consistency with the new language used in part 1090. These edits will not affect any of the actual requirements in subpart M, but rather will homogenize the language used across all of our fuels programs.

Second, because we are retaining the RFS program in part 80, we need to maintain certain general provisions contained in subpart A that will continue to apply to the RFS program. We are also revising several sections within subpart A to remove requirements, such as definitions that would no longer be applicable to part 80. In addition, we are reorganizing and consolidating the definitions in 40 CFR 80.2 to place them in alphabetical order, as this would make it consistent with part 1090 and much easier to find terms.

Finally, we are also retaining the Oxygenated Gasoline provisions in subpart C in part 80. This subpart contains a single section related to a requirement for labeling of oxygenated gasoline at retail pumps, as mandated by CAA section 211(m)(4). We are maintaining this requirement in part 80 because some state oxygenated fuel programs may reference the labeling requirements in part 80 and we want to minimize the amount of changes needed by states to revise regulations and update state implementation plans.

III. Structure of Proposed Regulations and General Provisions

This section describes the general structure of the proposed part 1090 regulations (*i.e.,* how we propose to structure the regulations to make them more accessible to users and readers of the regulations). This section also describes the proposed implementation dates, how we intend to deal with prior approvals made under part 80, and our proposed approach to consolidating the hundreds of definitions in the part 80 regulations. Finally, this section discusses key proposed provisions (*e.g.,* the definition of gasoline) in more detail to solicit public feedback on terms fundamental to the proposed streamlined fuel quality program.

A. Structure of the Regulations

We are proposing a structure for part 1090 that differs from the structure of our current part 80 regulations. Part 80 includes a variety of fuel quality programs that, while designed to operate together, appear as distinct programs in the regulations. Historically, we have codified new fuel quality programs by adding a new subpart at the end of part 80. This was often done because each new fuel quality program implemented new regulatory requirements that augmented the prior fuel quality programs. These new additions also helped provide interim requirements needed to implement the new program. As a result, part 80 includes numerous similar sections that either create multiple methods of complying with certain regulatory requirements (*e.g.,* submitting multiple gasoline batch reports for the RFG, antidumping, gasoline benzene, and Tier ⅔ gasoline sulfur programs) or create what might appear to be contradictions in the regulations. Rather than have subparts with all the provisions associated with a given fuel standard (*e.g.,* a subpart that contains all provisions related to gasoline benzene and a separate subpart that contains all provisions related to gasoline sulfur), part 1090 contains dedicated subparts according to the various functional elements of our fuel regulations (*e.g.,* subparts that contain all gasoline standards or contain all reporting requirements).

As proposed, subpart A contains general requirements that apply

[4] The four discussion drafts are available in the docket for this action and on our website at: *https://www.epa.gov/diesel-fuel-standards/fuels-regulatory-streamlining.*

[5] See 83 FR 20812 (May 8, 2018).

[6] Note that if we update these provisions in part 80 as part of a separate EPA action after this proposal, we plan to incorporate those updated provisions to part 1090 in the final rule.

throughout the rest of part 1090. Subpart A includes regulatory language that generally outlines the applicability and scope of the regulation, defines key terms, and outlines when the part 1090 requirements come into effect. Subpart A also describes how requirements under part 1090 interact with other parts of the regulations that affect fuels—parts 79 and 80. Many of these sections are described elsewhere; for example, rounding of data is discussed in the reporting section (see Section VIII), and batch numbering is discussed in the designation and product transfer document section (see Section VIII).

We are also proposing to include a list of general regulatory requirements for parties in subpart B. This subpart would lay out the general regulatory requirements for regulated parties. This helps inform the regulated community of what is generally expected of them in a succinct manner and provides references to the specific requirements in the appropriate places in the regulations. While the roadmap in subpart B does not remove or modify any of the regulatory obligations required throughout the rest of part 1090, we believe it will serve as a helpful guide. During the development of this proposed rule, we received feedback from several stakeholders that such a roadmap would not only be helpful for them to follow the part 1090 regulations, but would especially help those new to the regulations more easily identify general regulatory requirements.

We are also proposing to keep the standards for different fuels in separate subparts so as to make it easier for parties to identify the specific standards that apply to fuels, regulated blendstocks, and additives. For part 1090, we have put the gasoline-related standards and the diesel-related (plus IMO marine fuel) standards in their own individual subparts. We are also leaving a subpart reserved after the gasoline and diesel standards, as we may need to use that subpart for future standards and this would enable us to not have to move subsequent subparts in a manner that would cause unnecessary confusion on the part of the regulated community.

The next block of subparts (E through P) involve the provisions and requirements that regulated parties are expected to follow to demonstrate compliance with the applicable standards. We have consolidated the specific types of compliance activities where possible. For example, we have consolidated all the registration sections of part 80 into a single registration subpart in part 1090 (subpart I). For these subparts, we have included general provisions that apply to all regulated parties, with sections devoted to specific requirements for individual groups of regulated parties (*e.g.,* gasoline refiners or oxygenate blenders).

Subpart Q includes the liability, compliance, and violation provisions that EPA enforcement staff would use to enforce the program. This subpart consolidates the similar sections from across part 80 into a single streamlined subpart.

Finally, subpart R includes the attest engagement procedures that independent auditors would need to use to conduct annual auditing of reports and records for gasoline refiners. These procedures are updated versions of the those already included in part 80.

We believe that this new structure would make the fuel quality regulations more accessible to all stakeholders, help ensure compliance by making requirements more easily identifiable by activity, and help future participants in this regulated space understand our fuel quality regulations in the future. We seek comment on this proposed structure of the regulations.

B. Implementation Dates

We are proposing that regulated parties would begin complying with most provisions of part 1090 on January 1, 2021. This proposed date would result in the first compliance reports for the 2021 compliance period being due March 31, 2022, and the first attest engagement reports for the 2021 compliance period being due June 1, 2022.

We believe that this action minimizes the need for immediate changes to how regulated parties comply with our fuel quality regulations, and therefore, this proposed implementation schedule will allow sufficient time for regulated parties to modify their current business practices whenever it makes the most business sense for the individual regulated party's situation. In general, we have tried to minimize changes to existing requirements for regulated parties so as to avoid unnecessary burden. However, to consolidate the RFG program with the other fuel quality programs and maximize fuel fungibility, some changes to the program design would result from consolidating the programs into a single national program. Where possible, we wrote the proposed requirements to allow flexibility for regulated parties to adjust as needed.

While we believe a January 1, 2021, implementation date provides regulated parties enough time to come into compliance since we are not requiring changes that would necessitate substantive investments to meet new or modified fuel quality standards, we received feedback during the rule development process that we may need to provide regulated more time to implement some of the proposed provisions. In particular, some stakeholders noted that modifying product transfer document (PTD) language and adjusting to some of the proposed changes for sampling and testing may not be possible by January 1, 2021. One potential solution is to allow more time for these specific provisions to phase in. For example, we could allow regulated parties to continue to use the part 80 PTD requirements until the beginning or end of the high ozone season (June 1 and September 15, respectively). A similar approach could be allowed for other provisions that potentially need more lead time. We seek comment specifically on what provisions may require additional lead time to implement.

C. Prior Approvals

We are proposing to allow regulated parties with existing approvals under part 80 to maintain those approvals under part 1090. For example, parties registered under part 80 would not need to reregister under part 1090. We believe that making regulated parties resubmit information already reviewed and approved by EPA would be duplicative and burdensome on both the regulated parties and EPA staff. However, this action would require that any new requests or updates to approvals currently necessary under part 80 would have to meet the new proposed regulatory requirements of part 1090.

For existing approvals under part 80, regulated parties would not need to update a previously approved submission under part 1090. For example, we have approved alternative E15 labels under part 80. Parties would not need to have these labels reapproved in order to use them under part 1090. One notable exception is for in-line blending waivers. As discussed more in Section XIII.G, we are proposing significant changes to the in-line blending waiver provisions for RFG (mostly to remove provisions related to parameters that would no longer need to be reported) and for CG, which are designed to make consistent with the proposed RFG in-line blending waiver provisions. As such, we are proposing to require resubmission of all in-line blending waiver requests to ensure that they meet the new requirements.

D. Definitions

We are proposing to streamline and update the definitions contained

throughout part 80, as well as add and remove terms as needed to write the proposed part 1090 regulations. How we define key terms in the regulations has a significant effect on how regulated parties comply with the regulations. As our fuel quality programs have expanded in scope, definitions in part 80 have expanded as well. Additionally, as we added new subparts to the part 80 regulations for each program, we have added subpart specific definitions. We have also defined terms in the context of specific sections of the regulations. This has created situations where sometimes there are differences in definitions for the different standards, which makes it more difficult for parties to comprehend and comply with the regulations. In part 1090, we have consolidated all the applicable definitions into a single section. We have tried to avoid having a definition section in individual subparts; however, some infrequently-used terms may still be defined in the context of the regulatory text. We believe this approach would help the regulated community and the public at large to more easily comprehend the regulations.

For the most part, we are proposing to transfer the existing part 80 definitions into part 1090 with minor proposed changes to specific terms for consistency. However, in some cases, we are proposing to redefine or reclassify key terms as part of part 1090. Specifically, these areas include the defined terms for the types of regulated products (discussed in Section III.D.1) and the descriptions of regulated parties (discussed in Section III.D.2). We are also proposing revisions to the definition of ''gasoline'' and ''diesel fuel'' (discussed in Section III.D.3). While we believe these three areas of the proposed definitions warrant significant discussion, we seek comment on all of the proposed definitions.

1. Fuels, Fuel Additives, and Regulated Blendstocks

In order to improve the clarity and consistency of our regulations, we are proposing changes regarding how to classify products regulated under our fuel quality regulations. In part 80, most fuel programs were written as a separate fuel program rather than a single, consolidated fuel quality program. For example, 40 CFR part 80, subpart I, almost exclusively deals with distillate fuels and 40 CFR par 80, subpart N, deals with gasoline-ethanol blended fuels. Since part 1090 would attempt to consolidate all fuel quality programs under part 80 into a single, consolidated fuel quality program, a consistent nomenclature for regulated products is needed.

This action describes requirements for fuel quality on three categories of products: Fuels, regulated blendstocks, and fuel additives. We further classify these products into bins based on the type of vehicle or engine that the fuel is used (*i.e.,* gasoline-fueled, diesel fueled, or in a vessel subject to MARPOL Annex VI requirements (*e.g.,* vessels that must use ECA or IMO marine fuel)). For gasoline-fueled engines, we not only define the term gasoline (discussed in detail in Section III.D.2), but we also define and place requirements on specific types of gasoline based on its ethanol content (*e.g.,* E0, E10, and E15), whether the gasoline is intended for use or used as summer or winter gasoline, and in the summer, what RVP standard the fuel is subject to (*i.e.,* 9.0 psi, 7.8 psi, or the proposed RFG 7.4 psi standard). For diesel-fueled engines, since the requirement to use 15 ppm diesel fuel (or ultra-low-sulfur diesel (ULSD)) is now required in almost all motor vehicle, non-road, locomotive, and marine applications (called MVNRLM diesel fuel in part 80), we are defining this fuel simply as ULSD, as it is more commonly known in the market. 500 ppm diesel fuel continues to be allowed for certain locomotive and marine applications.

Regarding regulated blendstocks, we have historically not imposed quality specifications on blendstocks, choosing instead to focus compliance requirements on finished fuels that are ultimately used in vehicles and engines. However, as the fuels marketplace has continued to evolve, this structure has become increasingly difficult to accommodate the complexity of manufacturing and distributing fuels practices today. Therefore, we are proposing alternative provisions, which are all currently permissible under part 80, for gasoline manufacturers to demonstrate compliance with our fuel quality requirements by imposing requirements on certain blendstocks that are added to previously certified gasoline (PCG) if certain conditions are met. We are referring to blendstocks for which we have proposed standards collectively as ''regulated blendstocks.'' For example, under both part 80 and the proposed part 1090 regulations, we allow gasoline refiners to blend butane into gasoline and to rely on test results from the producers of the butane if the butane meets more stringent sulfur and benzene per-gallon standards.[7] These butane blenders can use these provisions in lieu of certifying the finished gasoline and having to meet sulfur and benzene annual standards as these provisions are designed to ensure that the national sulfur and benzene pool do not increase as a result of blending these feedstocks. Under part 1090, we are proposing the same flexibilities as under part 80 for gasoline manufacturers that wish to blend butane that has been certified to meet specifications (differences between parts 80 and 1090 are discussed in Section V.A.3). We believe that this will also allow more opportunities for parties to make cost-effective compliant fuels in the future.

This action also includes the current part 80 specifications for gasoline and diesel additives, mostly unchanged. Except for oxygenates in gasoline, additives are added to fuels in low amounts (less than 1.0 volume percent of the fuel total) and often serve to help improve fuel performance (*e.g.,* to control deposits on intake valves). All diesel fuel additives are subject to sulfur limitations. Under both part 80 and part 1090, gasoline additives are also subject to sulfur limitations, but the term ''gasoline additives'' also includes gasoline detergents and oxygenates. Also under both part 80 and part 1090, gasoline detergents and oxygenates (including denatured fuel ethanol or DFE) have specific requirements that apply in addition to the sulfur requirements that apply for all gasoline additives.

2. Fuel Manufacturers, Regulated Blendstock Producers, and Fuel Additive Manufacturers

In part 80, a refinery is defined as '' any facility, including but not limited to, a plant, tanker truck, or vessel where gasoline or diesel fuel is produced, including any facility at which blendstocks are combined to produce gasoline or diesel fuel, or at which blendstock is added to gasoline or diesel fuel,''[8] while a refiner is ''any person who owns, leases, operates, controls, or supervises a refinery.''[9] When these terms were first defined, virtually all finished fuels were produced at a crude oil refinery. As we have permitted greater flexibility in the production of fuels through the blending of regulated blendstocks to make new fuels and the market has moved to allowing fuels to be produced downstream of crude oil

[7] Under part 80, for summer CG, a butane blender must test the finished gasoline (*i.e.,* the resultant fuel from the combined PCG and added butane) for the RVP; for RFG, butane blenders cannot blend butane into summer RFG. This provision is not changing in part 1090.

[8] 40 CFR 80.2(h).

[9] 40 CFR 80.2(i).

refineries, the use of the term ''refiner'' to encompass all parties that make fuels has become less appropriate. Additionally, the differences in terminology between part 79 and part 80 have caused confusion among those required to or potentially required to comply with the requirements of both parts. Refiners and importers of on-highway motor vehicle gasoline and diesel fuel are fuel manufacturers under part 79 and required to register under EPA's fuel and fuel additive registration (FFARs) requirements. Under part 79, parties that make gasoline or diesel fuel through the blending of blendstocks or blending of blendstocks into PCG are also considered fuel manufacturers and must registered under part 79. Part 79 also includes importers of on-highway motor vehicle gasoline and diesel fuel as fuel manufacturers for purposes of FFARs. Part 80 generally requires that importers of gasoline and diesel fuel meet the same requirements as refiners, with some additional requirements on importers depending on the situation.

This action uses the term fuel manufacturer to describe any party that owns, leases, operates, controls, or supervises a facility where fuel is produced, imported, or recertified, whether through a refining process (*e.g.,* through the distillation of crude oil), through blending of blendstocks or blending blendstocks into a previously certified fuel to make fuel, or through the recertification of products not subject to our fuel quality standards to fuels that are subject to our fuel quality standards (*e.g.,* redesignating heating oil to ULSD). Importers of fuels would continue to be fuel manufacturers consistent with parts 79 and the CAA. We are also proposing to further distinguish between parties that refine feedstocks to make fuels (more commonly known as ''crude refiners'') and blending manufacturers who make fuels through blending blendstocks together to make a fuel or into an existing fuel to make a new fuel.[10] This action includes requirements specific to the type of fuel manufacturer, and the proposed nomenclature makes it easier for us to describe the proposed requirements for the types of fuel manufacturers and for parties to understand what requirements apply specifically to whom. However, while we are proposing to modify the terminology used in part 1090 for these parties, generally, these parties would have the same obligations and responsibilities under the regulations.

We are proposing to define producers of regulated blendstocks as regulated blendstock producers. For example, these parties would include certified butane/pentane producers and oxygenate producers (including DFE producers).

As is the case currently under parts 79 and 80, parties that only blend fuel additives into fuels are not fuel manufacturers. Any party that adds a compound (other than oxygenate or transmix) that is 1.0 percent or more of the finished fuel would be a blending manufacturer, as the compound added would be considered a blendstock and parties that add blendstocks into fuel are considered fuel manufacturers and would need to meet all the applicable regulatory requirements. Consistent with part 79, oxygenate blenders that only add oxygenates at levels permissible under the CAA section 211(f) continue to be considered additive blenders and not fuel manufacturers.

3. Definition of Gasoline

This action includes a new definition of gasoline. When we define what constitutes a fuel, this determines which fuels are subject to our fuel quality standards. The goal of our fuel quality programs is to ensure that compliant fuel is ultimately used in vehicles, engines, and equipment. To achieve this goal, we believe that the definition of gasoline needs to reflect changes in the fuels marketplace that have occurred over the last 40 years, as well as potential changes on the horizon. While petroleum refineries still have the most direct impact on gasoline fuel quality by volume, every party downstream of the refinery can affect fuel quality, and in today's marketplace many of these downstream parties are now the determinant of the quality of the fuel that actually goes into the vehicle. For example, these parties may add oxygenates (primarily ethanol) or augment the volume of gasoline through the blending of various blendstocks into PCG to produce new fuels.

To ensure that gasoline meets fuel quality standards from the petroleum refinery until it is dispensed into a gasoline-fueled vehicle or engine, in light of the changing fuels marketplace, we believe that the definition of gasoline should contain three elements. First, when a party represents a fuel as meeting our fuel quality standards, such fuel is subject to our standards regardless of whether the fuel meets the standard. Were this not the case, then anytime a fuel failed to meet our standards, we could not hold anyone accountable for failing to meet the standards. In the proposed definition of gasoline, we define gasoline as anything commonly and commercially known as gasoline. This portion of the proposed definition is consistent with the existing parts 79 and 80 definitions of gasoline.

The second element of the definition of gasoline is whether the product is made available for use or used in a gasoline-fueled vehicle or engine. Since the ultimate purpose of our fuel standards is to ensure that compliant fuel is used in vehicles and engines, if a person makes a product available for use by designating it as gasoline or placing it in the fuel distribution system, or if the product is used in a gasoline-fueled vehicle or engine, the product should be subject to EPA standards. We have used this terminology when describing other fuels under part 80, notably in definitions related to motor vehicle diesel fuel[11] and ECA marine fuel.[12]

The third element of the definition of gasoline is the product's physical and chemical characteristics. Whether a fuel is subject to our standards cannot be solely based on whether a regulated party calls or labels a product it produces as gasoline. This would create an incentive for parties to simply label fuel intended for use as gasoline by another name to avoid having to meet our fuel standards. Therefore, when a manufacturer produces a fuel that is chemically and physically similar to gasoline, the fuel should be subject to our gasoline fuel standards. To address this element, we are proposing that gasoline is any product that meets the voluntary consensus standards body (VCSB) industry specifications for gasoline (ASTM D4814).

For the discussion drafts of the regulations,[13] we presented definitions of gasoline that attempted to conservatively capture any product that could be used in vehicles and engines designed to operate on gasoline. We received feedback from stakeholders suggesting that this definition of gasoline was too broad, especially concerning the third element, which would have resulted in blendstocks that are never intended to be sold in their pure form as gasoline being subject to our fuel quality standards. These stakeholders argued that some higher quality blendstocks (*e.g.,* alkylates) used to make gasoline would meet the ASTM D4814 specifications for gasoline and may therefore be subject to EPA

[10] Under this approach, transmix processors are also considered fuel manufacturers.

[11] See 40 CFR 80.2(y).

[12] See 40 CFR 80.2(ttt).

[13] EPA–420–D–18–001, EPA–420–D–18–002, and EPA–420–D–19–001, available in the docket for this action.

standards. To address this feedback, we have excluded those blendstocks of concern that are not made available as gasoline but may otherwise meet the definition of gasoline by meeting ASTM D4814 specifications. Since there is an economic incentive for parties to keep these high value blendstocks segregated from gasoline in the fuel distribution system, these products will not generally be made available for use in gasoline-fueled vehicles and engines and would not, therefore, be considered gasoline. We seek comment on this approach.

We have taken a similar approach in the part 80 definitions for diesel fuel and largely mirror the three elements proposed for the definition of gasoline in the definition of diesel fuel. We seek comment on these definitions.

IV. General Requirements for Regulated Parties

As part of the streamlined fuel quality program, we are proposing a subpart dedicated to outlining the general regulatory requirements for each regulated party (subpart B). We received feedback during the rule development process that due to the layout of the regulations in part 80, parties need to read the entire subpart to make sure they have identified all applicable regulatory requirements. The current regulations in part 80 are almost 1,000 pages long, and many regulated parties spend a substantial amount of resources to comprehend and interpret them or ask EPA staff through the help desk to identify applicable regulatory requirements.

To make the streamlined regulations more accessible, we are proposing to make subpart B a roadmap for regulated parties, directing them to those subparts that are most likely to affect them and their business. We first outline the general requirements applicable to all parties that make and distribute fuels, fuel additives, and regulated blendstocks. These requirements include keeping records and being subject to regulatory requirements under the proposed subpart if a party makes and distributes fuels, fuel additives, and regulated blendstocks.

We then describe the requirements that apply to each group of regulated parties based on their business activities. Examples of these categories are fuel manufacturers, detergent blenders, oxygenate blenders, and retailers. We believe this would help these parties more easily identify regulatory provisions that apply to their specific activities. For example, retailers are typically small businesses that have greater difficulty affording consultants to help them understand their regulatory requirements. Retailers also have a relatively small number of regulatory requirements under the part 80 and part 1090 regulations. By identifying the generally applicable requirements that apply to all retailers, these small businesses could more easily identify those regulatory requirements that apply to them, helping them to more easily comply with our fuel quality regulations.

It is important to note that parties may have more than one regulated activity, and, as is the case today, these parties would be required to satisfy all regulatory requirements for each regulated activity. Regulated parties would still need to comply with all applicable requirements contained in part 1090, regardless of whether they are identified for them in subpart B. EPA cannot predict every possible situation a party may be in within the market place now or in the future. Accordingly, regulated parties, as always, should pay careful attention to all the applicable regulatory requirements to ensure compliance.

We request comment on the proposed structure of subpart B, as well as whether the subpart would be helpful to regulated parties in general. We also request comment on how we can improve the streamlined regulations to further improve the understandability and navigation of part 1090.

V. Standards

A. Gasoline Standards

1. Overview and Streamlining of Gasoline Program

We are proposing to consolidate the various gasoline-related standards into a single subpart in part 1090 (subpart C). We are not proposing to change the lead, phosphorous, sulfur, benzene standards or the RVP gasoline standards in the summer, nor are we proposing to change the standards for oxygenates (including denatured fuel ethanol), certified ethanol denaturant, gasoline additives, and standards for certified butane and pentane. These standards are simply being moved and consolidated into subpart C. Any comments on these standards will be treated as beyond the scope of this rulemaking.

However, to streamline the gasoline program, we are proposing some changes in the form of the RFG VOC performance standards. These changes are not expected to change the stringency of the gasoline standards. We do, however, expect that these changes would greatly simplify the gasoline program, resulting in: (1) Reduced burden associated with demonstrating compliance with the gasoline standards; (2) improved fungibility of gasoline, allowing the market to operate more efficiently; and (3) reduced costs to consumers. First, we are proposing to translate the RFG standard from the demonstration of the VOC performance standard via the complex model into an equivalent maximum RVP per-gallon standard, which would allow us to greatly simplify the compliance demonstration requirements for RFG. Of all the provisions being proposed, this is the key provision enabling considerable streamlining of our existing gasoline regulations.

Second, we are also proposing to consolidate the two grades of butane and the two grades of pentane specified in part 80 for use by butane and pentane blenders into a single grade each of certified butane and certified pentane. This would greatly simplify the registration and reporting of activities related to blending certified butane and certified pentane.

Finally, we are proposing certain regulations related to summer gasoline, as well as procedures for states to relax the federal 7.8 psi RVP standard. These changes are discussed more thoroughly in the following sections.[14]

2. Reformulated Gasoline Volatility Standard

The RFG program was created by EPA in the 1990s in response to a directive from Congress in the CAA Amendments of 1990 with the express purpose of providing cleaner burning gasoline to the most polluted metropolitan areas of the country. The program was very successful in that regard. However, since that time, a series of additional fuel quality standards and other market changes have resulted in CG meeting or exceeding most of the performance requirements for RFG, with the primary difference between CG and RFG now being only the lower RVP of the RFG during the summer months. At the same time, the extensive RFG regulations remain, constraining gasoline fungibility, increasing costs, complicating compliance oversight, and limiting the sale of certain biofuel blends. Consequently, we are proposing to: (1) Replace the existing compliance mechanism used for RFG batch certification—the Complex Model—with a summer RVP maximum per-gallon standard; (2) apply that same single RVP standard to all RFG nationwide; (3) provide greater

[14] The proposed changes to the transmix provisions for gasoline and diesel fuel are addressed in Section XIII.E.

flexibility for blending of oxygenates (ethanol and biobutanol) and E0 in RFG areas; and (4) remove a number of other restrictions that now create a distinction without a difference between RFG and CG.

We intend these proposed changes to maintain the stringency of all standards associated with RFG while alleviating unnecessary compliance mechanisms by simplifying the recordkeeping and reporting requirements. We acknowledge that the CAA requires the existence of RFG in specified nonattainment areas [15] and certification procedures to certify RFG as complying with the requirements.[16] This action proposes to simplify and translate those requirements while still maintaining the same level of VOC emissions reductions as currently required. This would be accomplished by translating the current VOC emissions reductions demonstrated through the Complex Model into an RVP standard that would be used to demonstrate RFG VOC compliance in lieu of the Complex Model.[17]

CAA section 211(k)(3)(B) provides that during the high ozone season, ''the aggregate emissions of ozone forming volatile organic compounds from baseline vehicles when using the reformulated gasoline shall be 15 percent below the aggregate emissions of ozone forming [VOCs] from such vehicles when using baseline gasoline.'' This section also provides for increasing stringency beginning in 2000 of at least 25 percent, based on technological feasibility and costs. We are achieving that demonstration through the use of an RVP standard.

The proposed RFG summer RVP standard of 7.4 psi was specifically chosen in order to maintain the summer VOC performance required by the statute,[18] and this RVP is currently observed in the RFG fuel pool; this approach also aligns the RFG compliance provisions with the much simpler and more easily enforced provisions currently in place for CG. In doing so, we are also acting on the Energy Policy Act of 2005 (EPAct) directive to consolidate the RFG VOC Regions into a single set of RFG standards by applying the southern RFG requirements (VOC control region 1) to all RFG areas, as discussed further in Section V.A.2.d. This consolidation of RFG VOC Regions, along with other proposed changes in this action, would provide greater fungibility in the RFG pool and eliminate antiquated restrictions in order to provide greater flexibility to fuel manufacturers and distributors, reduce cost for those parties, and reduce compliance and enforcement oversight costs.

Additional benefits from this proposed action are potentially wide reaching and could create opportunities for broader availability of fuels and reduced consumer costs. With the introduction of a summer RVP standard for RFG, in situations of fuel shortage in RFG areas, gasoline from other RFG areas or from state low-RVP fuel programs could now be moved to affected areas without recertification so long as the RFG RVP standard is observed. This increase in gasoline fungibility should serve to reduce scarcity and promote lower prices for consumers in affected areas. Additionally, the desire for ethanol-free gasoline for marine use in RFG areas has regularly been expressed by both citizens and elected officials of areas where RFG is required. Under the current RFG compliance provisions in part 80, it is difficult for distributors to provide ethanol-free gasoline to consumers in RFG areas. Under part 1090, it would be easier for distributors to provide ethanol-free gasoline to consumers in these areas.

a. Review of RFG

The definition and use of RFG is stipulated in CAA section 211(k). The RFG program was established in response to exceedances of the National Ambient Air Quality Standards (NAAQS) for ozone being experienced in many metropolitan areas across the U.S. in the late 1980s.[19] Gasoline motor vehicle emissions were and continue to be a major contributor to the inventory of air pollutants in metropolitan areas. The RFG program is implemented through a set of gasoline standards demonstrated to reduce emissions from vehicles of that era.[20] The demonstration of emissions reductions was predicated on changing fuel properties from a baseline fuel composition used in the baseline vehicle fleet. The 1990 statutory baseline fuel and fleet codified in the RFG regulations in part 80 are presented in Table V.A.2.a–1.

TABLE—V.A.2.a–1—STATUTORY BASELINE FUEL COMPOSITION

	Summer	Winter
RVP (psi)	8.7	11.5
Benzene (vol%)	1.53	1.64
Aromatics (vol%)	32.0	26.4
Olefins (vol%)	9.2	11.9
Sulfur (ppm)	339	338
E200 (%)	41.0	50.0
E300 (%)	83.0	83.0
Oxygen (wt%)	0.0	0.0

Summer = June 1–September 15.

The compliance of RFG in comparison to the baseline fuel was originally demonstrated by refiners using the Simple Model.[21] An improved version of the compliance model was created and designated the Phase II Complex Model after the initial phase of the RFG program. The Complex Model has been used by refiners to certify RFG

[15] CAA section 211(k)(1).

[16] CAA section 211(k)(4)(A).

[17] Currently, refiners use the Complex Model to demonstrate compliance with the RFG provisions. We are proposing that refiners instead could demonstrate compliance by testing the RVP of the fuel, along with benzene and sulfur as currently required.

[18] The VOC performance standard specifies that reductions are as compared to baseline vehicles using baseline gasoline. CAA section 211(k)(10) defines ''baseline vehicles'' as representative of 1990 vehicles and ''baseline gasoline'' as those with parameters specified in Table V.A.2.a–1. Our proposed translation of the VOC performance standard uses the statutorily specified points of comparison (*i.e.,* 1990 vehicle technology using baseline gasoline as specified in the CAA).

[19] See ''National Air Quality and Emissions Trends Report, 1988,'' EPA–450/4–90–002, March 1990.

[20] Gorse, R.A. et al. (1997). Auto/Oil Air Quality Improvement Research Program Final Report. 10.13140/RG.2.2.20882.35521.

[21] See 40 CFR 80.42.

under the Phase II RFG program and to meet the emission reduction standards outlined in Table V.A.2.a–2.

TABLE V.A.2.a–2—PHASE II STANDARDS AND REQUIREMENTS FOR COMPLIANCE

Phase II Complex Model Averaged Standards	
VOC Emission Performance Reduction (%):	
Region 1 standard	≥ 29.0
Region 1 per-gallon standard	≥ 27.5
Region 2 standard	≥ 27.4
Region 2 per-gallon standard	≥ 25.9
Region 2 (Chi/Milw) standard	≥ 25.4
Region 2 (Chi/Milw) per-gallon standard	≥ 23.9
Toxic Air Pollutants Emission Performance Reduction (%)	≥ 21.5
NO_X Emission Performance Reduction (%):	
Gasoline designated as VOC-controlled	≥ 6.8
Gasoline not designated as VOC-controlled	≥ 1.5
Benzene (vol%):	
Standard	≤ 0.95
Per-gallon maximum	≤ 1.30

The Complex Model required refiners to sample and test RFG for 11 parameters that would then be entered into the model. Refiners could either demonstrate compliance on a per-gallon basis or on an average basis across the year. Despite the added flexibility associated with the Complex Model over the Simple Model, refiners tended to focus changes on just a few parameters. To comply with the VOC emissions performance standard, refiners primarily lowered the RVP of their RFG as was anticipated at the time of the rule. For the NO_X standard, refiners primarily lowered the sulfur content of RFG, and to comply with the toxics standard, benzene and aromatics content was reduced in their RFG. Additionally, there have been three different RFG VOC regions designated under the Phase II standards; each with slightly different required levels of VOC emissions reduction as compared to the baseline fuel. The RFG program operated under these standards and resulted in a gasoline composition that was vastly different from CG when the program was phased in from 1995 through 2000.

b. Gasoline Regulation Changes

Since 2000, however, through a series of gasoline regulations and marketplace changes, the environmental performance of CG has improved to equal that of RFG in all respects except for summer VOC emission performance (as estimated using the Complex Model).

We established the Tier 2 gasoline sulfur program to limit the average sulfur content in gasoline to 30 ppm beginning in 2004,[22] with an 80 ppm per-gallon maximum standard (95 ppm at any location downstream of a refinery or import facility).[23] A reduction in fuel sulfur would reduce NO_X emissions on its own accord (as expressed in the Complex Model), but fuel sulfur reduction was also paramount to protecting the exhaust aftertreatment systems necessitated by the more stringent vehicle emission standards established as part of the same Tier 2 program rulemaking. By the end of 2007, after the conclusion of all early credit, small refinery hardship extensions, and other program flexibilities, the sulfur level of all gasoline was reduced to less than 30 ppm in-use. The Tier 2 gasoline sulfur standards reduced VOC, NO_X, and air toxics emissions, and brought down RFG and CG sulfur levels to a low enough level that the NO_X emission performance standard determined using the Complex Model were met and exceeded for any compliant RFG. Consequently, the NO_X emission performance standard was thereafter deemed met for both RFG and Antidumping (*i.e.,* CG) if the Tier 2 gasoline sulfur standard was met. This represented the first time that gasoline standard for CG exceeded an RFG performance standard (the NO_X performance standard in this case) on average, but it also heralded the convergence in gasoline quality between CG and RFG that would continue to occur over the next decade.

In 2007, EPA revised the original Mobile Source Air Toxics (MSAT) Rule with the MSAT2 Gasoline Benzene Program.[24] This rulemaking established an annual average standard of 0.62 volume-percent benzene on refiners and importers of gasoline.[25] This standard took effect starting January 1, 2011, for non-small refiners and January 1, 2015, for small refiners. The standard was fully phased-in on January 1, 2018. The result was that the air toxics performance standards for RFG were surpassed by the MSAT2 benzene standards for CG. Consequently, fuels that met MSAT2 benzene standards were deemed compliant with the air toxics emission performance standard otherwise calculated using the Complex Model. The rationale held, as with Tier 2, that any fuel meeting the new standard would meet or exceed the reductions required by the statute. The MSAT2 rulemaking also eliminated the NO_X emissions performance reduction demonstration in the Complex Model as a result of the gasoline sulfur program.[26]

The combined effect of the sulfur and benzene gasoline standards has been that the use of the Complex Model has been narrowed to only demonstrating compliance with the summer VOC emission performance standard for RFG. While all of the Complex Model fuel parameters (except benzene) play a role in determining VOC emission performance, by far the primary lever for refiners to use to comply with the VOC emission performance standard is RVP.[27] Given that the changes to all the

[22] See 65 FR 6698 (February 10, 2000).

[23] See 40 CFR 80.195 and 40 CFR 80.210, respectively.

[24] See 72 FR 8428 (February 26, 2007).

[25] See 40 CFR 80.815.

[26] See 40 CFR 80.41(e)(2) and 72 FR 8428, 8498 (February 26, 2007).

[27] The VOC performance standard is made up of two components: Non-exhaust and exhaust VOCs. Under the Complex Model, 100 percent of the non-exhaust VOCs are calculated using RVP, which also plays a significant role in determining exhaust VOC reductions under the Complex Model. In both non-exhaust and exhaust VOCs, the Complex Model

Continued

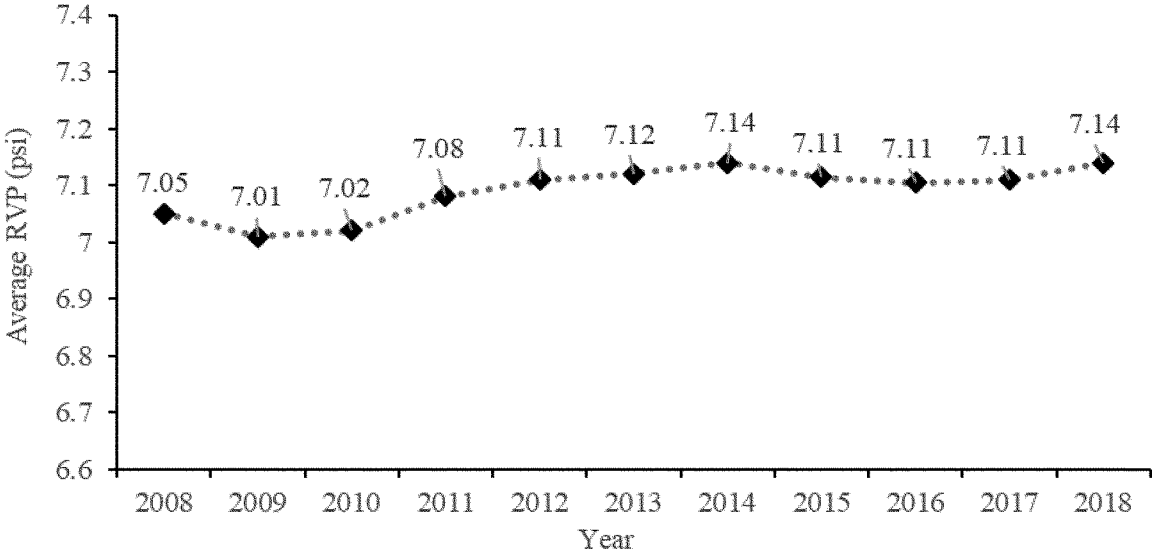
other fuel parameters are dictated by other vehicle standards and market requirements, refiners today primarily only lower RVP to the degree necessary (due to cost reasons) in order to meet the VOC emission performance standard of RFG. However, the degree to which refiners have needed to reduce the RVP of RFG to demonstrate compliance using the Complex Model has relaxed slightly over time with other changes, mandated and market, to gasoline.

In 2014, EPA finalized the Tier 3 gasoline sulfur program to further limit the average sulfur content in gasoline to 10 ppm beginning in 2017.[28] All refineries and importers, including small refiners and small volume refineries, must comply with the 10 ppm Tier 3 sulfur standard starting January 1, 2020. The Tier 3 sulfur standard resulted in further reductions in VOC, NO_X, and air toxics emissions predicted by the Complex Model.

Beginning in the early 2000s, the amount of gasoline blended with 10 percent ethanol also increased markedly as a result of MTBE bans, rising crude oil prices, tax incentives, and the Renewable Fuel Standard (RFS) mandates. The addition of ethanol reduced the aromatic, olefin, T50, and T90 levels of gasoline, which together with the oxygen content reduced the VOC, NO_X, and air toxics emissions predicted by the Complex Model. Similarly, since about 2009, reduced natural gas prices brought on by the proliferation of hydraulic fracturing technology has allowed refiners to more economically back off on gasoline reforming, continuing to reduce gasoline aromatic levels and in turn reducing VOC, NO_X, and air toxics emissions predicted by the Complex Model.

The progression in gasoline sulfur, benzene, and aromatic content, RVP, distillation, and other Complex Model parameters is documented in the Fuel Trends Report released by EPA in 2017.[29] The evolution of these other Complex Model parameters over the past decade has allowed for a slight increase in RVP, as seen in Figure V.A.2.b–1.

Figure V.A.2.b-1: Summer RFG RVP Trends



RVP is the only one of the Complex Model parameters that affects evaporative emissions; the other fuel parameters (except benzene and including RVP) impact VOC exhaust emissions under the Complex Model. As a result, there are limits to the extent that these other fuel parameters can impact VOC emissions performance under the Complex Model and corresponding limits to the extent that RVP can be increased within the Complex Model and still result in a compliant RFG.[30] Figure V.A.2.b–2 shows the 95th percentile of RVP levels from the batch compliance data EPA receives.

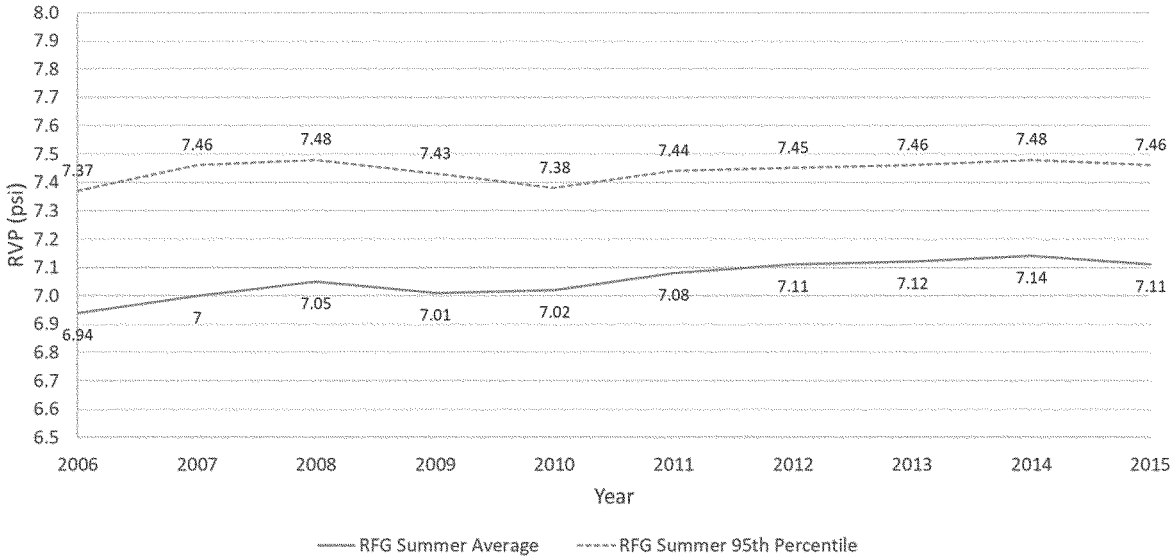
estimates an increase in performance of the fuel on 1990 vehicle technology relative to the 1990 baseline gasoline specifications.

[28] See 40 CFR 80.1603.

[29] See ''Fuel Trends Report: Gasoline 2006—2016,'' EPA–420–R–17–005, October 2017.

[30] In the RFG final rule, we found that a fuel with an RVP of 7.2 would meet the Region 1 VOC performance standards. See 59 FR 7716, 7721 (February 16, 1994).

Figure V.A.2.b-2: Summer RFG RVP 95th Percentile (Batch Data)



c. Proposed RVP Standard for VOC Performance Determination

With the importance of RVP in the Complex Model for VOC emissions performance and the combination of MSAT2 and Tier ⅔ for reducing benzene and sulfur, respectively, RFG compliance is now almost completely determined by the RVP of the fuel. Consequently, an opportunity for greatly simplifying the certification process for RFG has presented itself. The 11 parameters required to certify RFG under the Complex Model could be reduced to just three (sulfur, benzene, and RVP) if a summer RVP standard were adopted along with the existing sulfur and benzene content standards.[31] Therefore, we are proposing that any RFG batch meeting a summer RVP standard of 7.4 psi RVP would be deemed in compliance with the RFG VOC emission performance reduction standard. Along with RVP, benzene concentration for MSAT2 compliance, and sulfur content for Tier 3 compliance would also be reported to EPA. Thus, all three of the emission reduction standards for RFG would be covered by just three parameters: RVP, benzene, and sulfur. This would reduce the compliance and reporting burden for fuel manufacturers by reducing the number of parameters they need to test and report from 11 to as few as three in the summer.[32]

In Section V.A.2.e, we lay out the process and rationale for the proposed summer RVP per-gallon standard of 7.4 psi for RFG. The primary intent in proposing to translate the VOC performance standards into an RVP maximum per-gallon standard is to maintain the status quo and to ensure that the emission reduction targets for RFG would continue to be achieved. During the selection process of the proposed summer RVP standard, we operated under the statutory constraints that were, and remain, present for the formulation of the Complex Model—namely, the 1990 baselines for both fuel composition and vehicle technology. Thus, the proposed 7.4 psi RVP standard for RFG would maintain the gasoline quality and its associated emission performance as calculated consistent with the statutory requirements and the Complex Model.

Although it will no longer be required for demonstration of RFG batch compliance, the Complex Model will be retained by EPA for compliance oversite purposes in conjunction with the proposed national fuel survey program. Continued adherence to the VOC emission performance reduction standard will be monitored through samples collected from RFG areas as part of the survey. This oversite function will help ensure that the emission reductions the Complex Model was intended to certify at the refinery gate are being maintained in use.

d. Consolidation of RFG Areas

Translating the VOC emissions performance standard into a summer RVP standard would enable EPA to simplify the RFG program significantly. Additionally, the creation of a single summer RVP standard for all RFG areas would further simplify the RFG program and automatically consolidate the VOC regions as required under section 1504(c) of EPAct.[33] Section 1504(c) directs EPA to revise the RFG regulations to consolidate the regulations for the VOC-Control Regions by eliminating the less stringent requirements.

In practice, there have been three sets of VOC emission performance standards for the VOC Regions of the RFG program: VOC-Control Regions 1 and 2, along with the adjustment to Region 2 provided for the Chicago/Milwaukee areas. To date, EPA has not taken action to consolidate the VOC regions as directed by EPAct. However, the creation of a single summer RVP standard provides both an opportunity and a mechanism by which to act on this requirement. A benefit of this consolidation would be the increased fungibility of RFG amongst historically distinct VOC-control regions.

We find that the EPAct language provides EPA with an additional source of authority to take this action to

[31] As discussed in Section IX, manufacturers that certify batches of oxygenated gasoline would need to test for oxygenates, while manufacturers of BOBs would need to follow hand blending procedures for batch certification.

[32] As discussed in sections VIII and IX, manufacturers would need to sample, test, and report for additional fuel.

[33] EPA ''shall . . . revise the [RFG] regulations . . . to consolidate the regulations applicable to VOC-Control Regions 1 and 2 . . . by eliminating the less stringent requirements applicable to gasoline designated for VOC-Control Region 2 and instead applying the more stringent requirements applicable to gasoline designated for VOC-Control Region 1.'' See Energy Policy Act of 2005, Public Law 109–58, 119 Stat. 1079. See also USEPA Office of Transportation and Air Quality. Assessing the Effect of Five Gasoline Properties on Exhaust Emissions from Light-Duty Vehicles Certified to Tier 2 Standards: Analysis of Data from EPAct Phase 3 (EPAct/V2/E–89): Final Report. EPA–420–R–13–002. Assessment and Standards Division, Ann Arbor, MI. April 2013.

translate the VOC performance standard into a single RVP standard.

e. Translating the VOC Performance Standard to a Summer RVP Standard

In order to translate the VOC performance standard into an RVP cap, we utilized the Complex Model and the 1990 baseline fuels and vehicles to determine the corresponding RVP. In accordance with EPAct, the VOC-Control Region 1 emission reduction standards were used to establish the consolidated RVP standard. More specifically, the per-gallon reduction requirements for VOC-Control Region 1 from 40 CFR 80.41 were used as the basis for determining the summer RVP standard. Given that we are proposing a per-gallon standard, it was deemed the most appropriate point of reference for determining the required VOC reduction from the statute. We recognize that the current RFG summer VOC performance standards under part 80 allow for refiners and importers to meet either a per-gallon summer VOC performance standard or an annual average summer VOC performance standard. We are proposing to replace all RFG summer VOC performance standards with a maximum RVP per-gallon standard translated from the RFG Region 1 summer VOC performance per-gallon standard. Under this proposal, fuel manufacturers would no longer comply through an annual average standard and must instead demonstrate compliance on a per-gallon basis during the summer.

The intention of this proposed action is to maintain the level of stringency observed in the RFG pool while transitioning away from using the Complex Model to demonstrate compliance to instead demonstrate compliance with a summer RVP standard. To that end, the starting point for our analysis was the batch reports submitted to EPA in the course of certifying batches of RFG. Several years were evaluated, but the most recent full year of data at the time the analysis was carried out was 2018. Summary statistics, based upon volumetrically weighting the batches, for the Complex Model parameters for this data are presented in Table V.A.2.e–1.

TABLE V.A.2.e–1—SUMMARY STATISTICS FOR 2018 RFG

	Weighted 5%	Weighted 25%	Weighted median	Weighted 75%	Weighted 95%	Volume weighted average
Oxygen (wt%)	3.37	3.46	3.51	3.57	3.65	3.52
Sulfur (ppm)	4	10	18	26	42	19.3
Aromatics (vol%)	6.2	12.7	16.3	20	26.6	16.3
Olefins (vol%)	1.5	5.9	10.9	14.3	17.8	10.25
Benzene (vol%)	0.19	0.38	0.5	0.67	0.93	0.53
Ethanol (vol%)	9.23	9.46	9.61	9.77	10	9.62
E200 (%)	41.7	45.7	48.5	50.7	55.4	48.4
E300 (%)	81.4	84.1	86.5	88.9	92.6	86.6

There are only eight fuel parameters reported in Table V.A.2–5 because the remaining three parameters in the Complex Model (MTBE, ETBE, and TAME) have become negligible in the past 15 years, in part due to the removal of the RFG minimum oxygenate content requirement. The reported eight fuel parameters were then used to statistically construct ''percentile'' fuels based on how each of the eight parameters affected VOC performance in the Complex Model. For instance, the ''5th'' percentile is comprised of the 5th percentile values of Ethanol, E200, and E300 along with the 95th percentile values for aromatics, olefins, sulfur, and benzene. This combination results in the strictest set of parameters for RVP control and consequently the lowest, or ''5th'' percentile of allowable RVP. The parameter values for the 5th, 50th, and 95th percentile [34] RFG are reported in Table V.A.2.e–2, along with the volume-weighted average for each of the parameters for 2018 RFG.

TABLE V.A.2.e–2—MEETING THE PHASE II VOC PERFORMANCE STANDARD FOR 2018 RFG

Fuel	Oxygen (wt%)	Sulfur (ppm)	Aromatics (vol%)	Olefins (vol%)	Benzene (vol%)	E200 (vol%)	E300 (vol%)
5th	3.37	42	26.6	17.8	0.93	41.7	81.4
50th	3.51	18	16.3	10.9	0.5	48.5	86.5
95th	3.65	4	6.2	1.5	0.19	55.4	92.6
Average	3.51	19.3	16.3	10.3	0.53	48.4	86.6

Each of the four fuel compositions in Table V.A.2.e–2 was then exercised in the Complex Model in order to solve for the maximum allowable RVP while still meeting the VOC emissions reduction requirement. The maximum allowable RVP was calculated for both the average and per-gallon standards for VOC-Control Region 1 and are reported for each of the four compositions in Table V.A.2–7.

[34] We chose the 5th and 95th percentile to exclude cases of misreporting or reported non-compliance from affecting the analysis.

TABLE V.A.2.e–3—MAXIMUM ALLOWABLE RVP LEVEL IN THE COMPLEX MODEL FOR 2018 RFG PERCENTILE FUEL COMPOSITIONS

	Percentile			Volume-weighted average
	5th	50th	95th	
VOC-Control Region 1 Maximum Allowable RVP Level				
Average Standards	6.7	7.14	7.24	7.12
Per-Gallon Standards	6.90	7.30	7.40	7.29

As would be expected, the volume-weighted average allowable RVP of 7.12 is nearly identical to the 7.11–7.14 range that was observed in the 2012–2017 batch report data presented in Figure V.A.2.b–1. This reflects the widespread use of the average standards by most RFG fuel manufacturers under the current program. The per-gallon standards would have theoretically allowed for a ~0.15 psi higher RVP across the average RFG fuel pool, but fuel manufacturers have predominantly used the average standards. The percentile fuel compositions demonstrate that there is the potential for approximately a half-pound variation in RVP for a compliant RFG fuel depending on the balance of the other fuel parameters. However, there are two important results from this analysis: (1) Solving for maximum allowable RVP for the volume-weighted average fuel yields a very similar RVP as observed in the batch reports (~7.1 psi); and (2) the per-gallon standards would have allowed for a pool average RVP of nearly 7.3 psi with no changes to RFG fuel composition.

Therefore, we believe that the proposed 7.4 psi RVP standard for RFG is appropriate.[35] The proposed standard equates to a 27.5 percent reduction in VOC emissions performance as compared to baseline gasoline used in baseline vehicles (*i.e.,* 1990 vehicles) using the Complex Model. We seek comment on the proposed 7.4 psi RVP standard.

f. Conventional Gasoline Batch Data Analysis

In order to translate the existing RFG VOC performance standard as an RFG summer RVP maximum per-gallon standard, it is necessary to evaluate how RVP per-gallon maximum standards are treated in practice. In order to evaluate the treatment of an RVP per-gallon maximum standard, we examined the RVP levels in relation to the 9.0 psi standard for CG in 2016.[36] To conduct the analysis, the batch reports were submitted to thorough quality control and assurance in order to ensure that only batches adhering to the 9.0 psi standard (boutique, federal 7.8 psi, etc. were all removed) and that contained less than one percent ethanol were considered.[37] The summary statistics for the 2016 summer CG batches are presented in Table V.A.2.f–1.

TABLE V.A.2.f–1—CG SUMMARY STATISTICS FROM THE 2016 BATCH REPORTS

Summer CG			
Percentile	RVP	Volume above	Volume below
5th	7.32	27,187,626,247	1,420,043,309
50th	8.67	12,984,692,750	15,622,976,806
95th	8.99	1,194,383,604	27,413,285,952
Mean	8.47	18,762,397,380	9,845,272,176
Standard	9.0	489,040,207	28,118,629,349

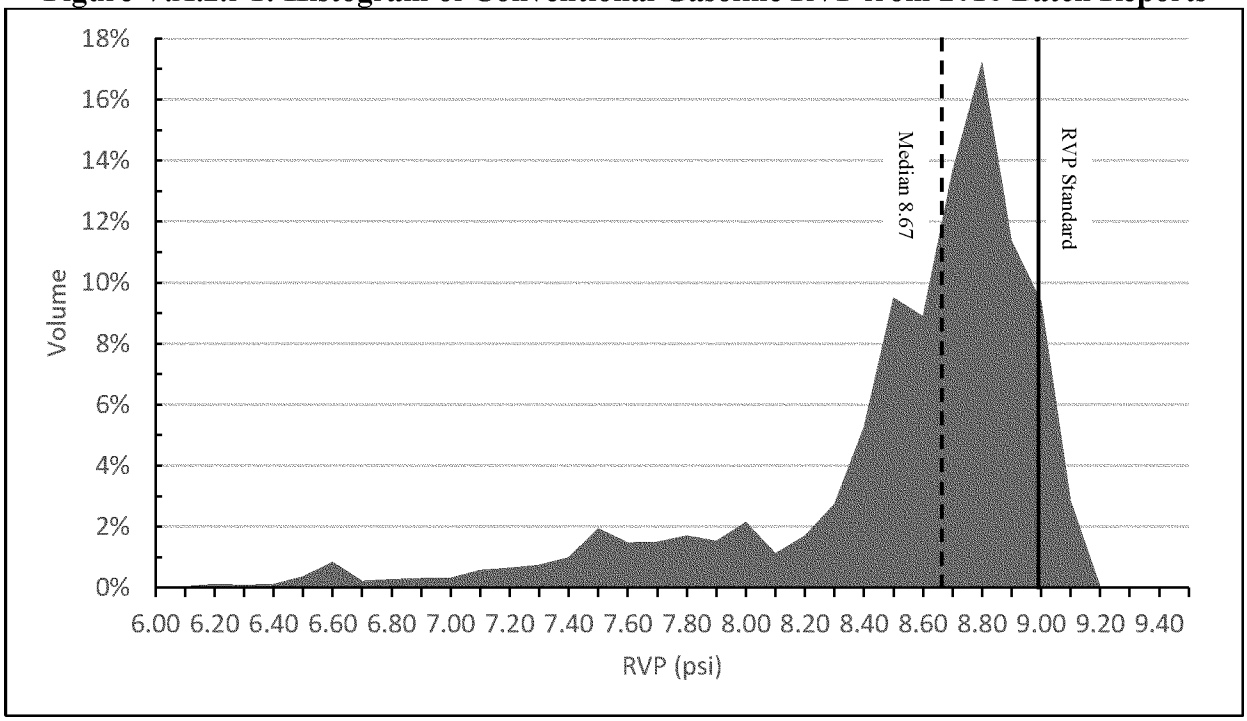
The CG batch data is represented in histogram form in Figure V.A.2.f–1. The graduations of 0.1 psi on the x-axis allow for a clearer representation of where the bulk of the fuel resides in relation to the 9.0 psi RVP standard.

[35] The data used for this analysis was based on the most current information available to EPA at the time (*i.e.,* the 2018 gasoline batch information). Should new information become available, we intend to perform the same analysis using the updated information, which may result in a small change in the standard.

[36] 2016 was the most recent year for which clean, batch report data was available at the time of analysis. We intend to update this analysis with the most recent data available for the final rule.

[37] The presence of ethanol can result in an increase in the RVP of the gasoline-ethanol blended fuel. The purpose of this analysis is to evaluate how refiners make fuels relative to the 9.0 psi RVP maximum per-gallon standard without the addition of ethanol.

Figure V.A.2.f-1: Histogram of Conventional Gasoline RVP from 2016 Batch Reports



The data from the CG batch reports show that the median RVP (8.67 psi) is approximately 0.3 psi below the 9.0 psi RVP standard. As would be expected, there is variability in the fuel batches, but the mode of the data is 0.2 psi below the standard and more than 95% of the CG fuel volume is below the standard. For CG, the mode fell 0.2 psi below the standard and the median fell 0.3 psi below the standard. This information was taken along with the average RVP of 7.12 psi for 2018 RFG discussed in Section V.A.2.e to conclude that a summer RVP standard for RFG of 7.4 psi would meet the goal of preserving the current environmental performance of RFG, while imposing little to no additional industry burden based upon the batch reports for CG. We seek comment on whether there would be additional industry burden associated with the proposed 7.4 psi RVP RFG standard.

g. Additional Changes Related to RFG

We are also proposing regulations intended to allow for greater compliance flexibility and increased gasoline fungibility for the RFG program. Specifically, in Section VIII.G we are proposing to address several provisions regarding fuel certification and recertification that are now commonplace due to the gasoline quality standards implemented since the onset of the RFG program. For instance, RFG is statutorily required to be used in certain ozone nonattainment or maintenance areas in both summer and winter. The differences between RFG and CG that require the respective fuels to be segregated in the summer (*i.e.,* RFG and CG must meet different standards in the summer) are not present during the winter season, where RFG and CG must meet identical standards under part 80. However, a similar prohibition on co-mingling RFG and CG in the winter exists.

To address this situation, we are proposing to allow all winter gasoline to be used in RFG areas without recertification. Distributors of gasoline would be allowed to designate winter gasolines without recertification as RFG or CG to comport with state or pipeline specifications, which may require those distinctions. We are also proposing provisions to allow California manufacturers and distributors the flexibility to ship California gasoline and diesel fuel to the rest of the U.S. due to their state specifications meeting or exceeding EPA's standards. Lastly, new recertification standards are being proposed to facilitate end-of-season recertification, emergency fuel waivers, and allow greater downstream flexibility. These provisions are discussed in more detail in Section VIII.G. We seek comment on the proposed approach.

3. Certified Butane and Pentane

We are proposing to streamline the provisions for gasoline blending manufacturers that blend butane and pentane of certified quality (certified butane and certified pentane, respectively) into PCG.[38] Under part 80, these flexibilities allow gasoline blending manufacturers to rely on test results by the butane or pentane producer rather than testing each batch of butane or pentane received as would otherwise be required of a gasoline blender manufacturer to demonstrate compliance with EPA standards. This approach would be maintained in part 1090.

We are proposing to combine these grades into single grades of ''certified butane'' and ''certified pentane.'' Part 80 currently has two grades of butane and pentane (commercial and noncommercial) that can be used by gasoline blender manufacturers under these provisions. During the rule development process, many stakeholders highlighted the burden of demonstrating compliance with the part 80 butane and pentane blending provisions. We believe that, coupled with other changes to the specifications for certified butane and certified pentane described in this section, there is an opportunity to consolidate the grades of butane and pentane. This would allow for a streamlining of the compliance demonstrations needed for certified butane and certified pentane blenders to produce gasoline using certified butane and certified pentane.

[38] See 40 CFR 80.82 and 80.85, respectively.

The current standards in part 80 for commercial and noncommercial grades of butane and pentane contain specifications on the maximum sulfur, benzene, olefin, and aromatics content. Consistent with the proposed changes to RFG certification,[39] we are proposing to remove the maximum olefin and aromatics standards from the specifications for certified butane and certified pentane as we are proposing to no longer require those parameters for the certification of gasoline, as discussed in Section V.A.2, and because we do not expect issues to occur with other regulated parameters. Both certified butane and pentane would be subject to a maximum 10 ppm sulfur standard and maximum 0.03 volume percent benzene standard as are the commercial and noncommercial grades of butane and pentane today. The sulfur and benzene specifications are still needed to ensure that certified butane and certified pentane blenders do not increase the amount of sulfur and benzene in the national gasoline pool.

Under part 80, commercial grade pentane is subject to both 95 volume percent pentane purity specification and a maximum 5 volume percent C6 [40] and higher carbon number hydrocarbons specification.[41] Non-commercial grade pentane is subject to 95 volume percent pentane purity specification but is not subject to specifications on the amount of C6 and higher carbon number hydrocarbons that may be present. We are proposing to not include a standard on C6 and higher hydrocarbon content in part 1090 for certified pentane given that compliance with the proposed 95 volume percent pentane purity specification would ensure that no more than 5 volume percent C6 and higher hydrocarbons are present.

Unlike the current standard for non-commercial grade pentane, the current standards for commercial and non-commercial grade butane do not include a specification on minimum butane purity. With the proposed removal of the maximum olefin and aromatics specifications for certified butane, it is appropriate to propose controls on the purity of certified butane that are consistent with the purity specification for certified pentane. During the rule development process, we requested input from industry on applying a 95 volume percent purity specification to certified butane similar to the proposed purity specification for certified pentane. Butane blenders stated that implementing a minimum 95 percent purity specification would cause unnecessary additional processing costs to remove pentane that is often present. They noted that the presence of pentane would not be an environmental concern because of the clean burning properties of pentane and the lower volatility of pentane compare to butane. Butane blenders suggested that implementing a minimum 92 volume percent purity specification for certified butane would accomplish our intended goal of ensuring that undesirable chemical species do not contaminate certified butane while providing the necessary flexibility. We agree that a 92 volume percent purity specification would not result in increased emissions from the use of certified butane compared to a 95 volume percent purity specification and would reduce the burden to industry; therefore, we are proposing a minimum 92 volume percent purity specification for certified butane. We request comment on whether the proposed 92 volume percent purity specification for certified butane would provide sufficient flexibility to allow for the presence of pentane in certified butane while still preserving gasoline quality or whether a more or less stringent purity specification would be appropriate.

We are also proposing to simplify the quality assurance requirements for certified butane and pentane blenders. Under part 80, butane and pentane blenders are required to conduct periodic quality assurance testing of the batches of butane or pentane they receive. For butane, the current frequency of sampling and testing for the butane received from each butane supplier must be one sample for every 500,000 gallons of butane received, or one sample every three months, whichever is more frequent. For commercial-grade pentane, the sampling and testing frequency is once for every 350,000 gallons of pentane, or one sample every three months, whichever is more frequent. Noncommercial-grade pentane is currently subject to a more frequent sampling and testing frequency of once every 250,000 gallons or one sample every three months, whichever is more frequent.

To simplify these quality assurance requirements, we are proposing to require the same sampling and testing frequency for certified butane and pentane of once every 500,000 gallons of butane or pentane received, or one sample every three months, whichever is more frequent. We believe that a more frequent sampling and testing is not needed for certified pentane versus certified butane given that they are subject to similar standards. To the extent that there may be heightened concern with the potential presence of high boiling range hydrocarbons that are typically only found in full boiling range gasoline (such as C7–C20 hydrocarbons) in certified pentane versus certified butane due to difference in manufacturing processes,[42] we believe that such concerns are adequately mitigated by the existing registration requirements for certified pentane producers.

4. State and Local Fuel Standards

a. Overview

We are transferring and consolidating the part 80 regulations that relate to RVP, RFG, and other summer gasoline requirements to part 1090. For example, we are removing outdated provisions and making it easier to identify the RVP standard that applies in a given location. We are also proposing changes that are intended to update and simplify existing regulations and reflect our experience in implementing these provisions in partnership with states and industry. For example, we are proposing procedures for states that request a relaxation of the federal RVP limit of 7.8 psi. This is similar to the existing procedures used for RFG opt-out by states. We are not proposing any regulatory revisions for current fuel programs that apply in several states. The following sections detail the changes we are proposing.

We are also using this action to announce that an updated boutique fuel list is currently posted on our website.[43] Section 1541(b) of EPAct requires EPA to remove any fuel from the published list if the fuel either ceases to be included in a state implementation plan (SIP) or is identical to a federal fuel.[44] Several fuels have ceased to be included in SIPs since the boutique fuel list was originally published in 2006.[45] The boutique fuel list on our website, however, provides up-to-date information on where such fuels are currently used.

b. Consolidating Gasoline Volatility Standards

We are transferring summer gasoline requirements related to RVP limits that

[39] See Section V.A.2.

[40] C6 refers to a hydrocarbon molecule that contains six carbon atoms.

[41] Pentane has 5 hydrocarbons (*i.e.,* it is C5).

[42] Pentane that is produced from NGLs historically has been the bottom distillation cut from the NGL fractionation process, and hence contains all heavier hydrocarbons as well as pentane. Since butane is more volatile than pentane, butane produced by distillation from NGLs is unlikely to contain heavy hydrocarbons that may be a concern with respect to increased emissions.

[43] See *http://www.epa.gov/gasoline-standards/state-fuels.*

[44] See CAA section 211(c)(4)(C)(v)(III).

[45] See 71 FR 78195 (December 28, 2006).

are currently in part 80 to part 1090. Summer gasoline for use in the continental U.S. must comply with either the federal maximum RVP limit of 9.0 psi or the more stringent RVP limit of 7.8 psi, unless it is either a federal RFG covered area, is subject to California's RFG regulations, or EPA has waived preemption and approved a state request to adopt a more stringent RVP into a SIP.[46] [47] [48] The proposed regulatory text would simplify and clarify regulatory text currently in 40 CFR 80.27(a) and 80.70, and would not change the current federal RFG and summer gasoline RVP requirements nationwide.

c. Reformatting the List of Areas Where Federal Low RVP Standard Applies

We are also transferring the current RVP standards in 40 CFR 80.27(a)(2), which sets out the current federal RVP limits to part 1090. Areas subject to the federal 7.8 psi RVP limit are listed in a table in 40 CFR 1090.215(a)(1), describing the geographic areas subject to the 7.8 psi RVP limit. The regulatory text specifies that any gasoline that is not subject to a lower RVP limit is subject to the federal 9.0 psi RVP limit. We are not proposing any changes or revisions to applicable RVP limits. Specifically, we are:

- Removing the regulatory text in 40 CFR 80.27(a)(1) because it is outdated and has not applied since 1991.
- Replacing the regulatory text, table, and footnotes that are currently in 40 CFR 80.27(a)(2) with a reformatted table in part 1090 that lists the areas where the federal 7.8 psi RVP limit for summer gasoline currently applies.

The table in 40 CFR 1090.215(a)(1) includes the name of the area and the county or counties in the area where the federal 7.8 psi RVP limit applies, rather than the current table in part 80 that dates back to the initial one-hour ozone standard, is overly complex and has caused confusion among states and industry. The new table would also include a description of the boundaries for areas that include partial counties where RVP standards are currently in effect. Under the current regulations in part 80, interested parties must search 40 CFR part 81 in order to identify these specific boundaries of the area where the 7.8 psi RVP limit applies. As previously noted, this action does not change any existing requirements.

d. Reformatting Federal RFG Applicability and Covered Areas

As part of transferring part 80 requirements relating to federal RFG to part 1090, we are reformatting how the information on current RFG covered areas is presented. Specifically, in 40 CFR 1090.270 we are presenting the description of RFG covered areas in a table format and grouping the covered areas by the process under which the area became a covered area. There are four ways in which an area could have become an RFG covered area:

- It was included in the original RFG covered areas under CAA section 211(k)(10)(D) because its 1987–1989 ozone design value was among the nine highest design values and its 1980 population was greater than 250,000;
- It was subsequently reclassified to Severe for an ozone NAAQS;
- It was a classified ozone nonattainment area that opted into the RFG program; or
- It was an attainment area in the ozone transport region that opted into the RFG program.

The tables in part 1090 list the areas in each of these groups. As previously explained, we are not changing the geographic applicability of federal RFG.

We are also transferring the existing regulatory processes by which an area may become a federal RFG covered area in the future, which are if: (1) An area is reclassified to Severe nonattainment for an ozone NAAQS; (2) a governor requests that a classified ozone nonattainment area become a covered area; or (3) a governor requests that an attainment area in the ozone transport region be included as a federal RFG covered area.

We are also including two California areas on the list of covered areas in part 1090 because the areas became federal RFG covered areas when they were reclassified as Severe ozone nonattainment areas.[49] The two areas are the Sacramento Metro area and the San Joaquin Valley area.[50] We have provided information on these RFG covered areas on our website but had not previously included them in the list of covered areas in 40 CFR 80.70. This does not impact California's regulations that require the sale of California RFG in these areas, but should California's regulations no longer apply in the future, the federal RFG regulations would still apply in keeping with the CAA.

e. Continuation of Federal RFG Requirements in Covered Areas When Revised Ozone NAAQS Are Implemented

In the Phase 2 Implementation Rule for the 1997 Ozone NAAQS, we stated that areas that became RFG covered areas pursuant to CAA section 211(k)(10)(D) would remain RFG covered areas at least until they were redesignated to attainment for the 1997 ozone NAAQS. We also stated that areas that became covered areas because they opted into RFG would remain covered areas until they opt out of RFG pursuant to our opt-out regulations. We also included regulatory text in 40 CFR 80.70(m),[51] parts of which are now outdated and unnecessary because they were specific to the transition from the 1-hour ozone NAAQS to the 1997 ozone NAAQS and to redesignations to attainment for the 1-hour ozone NAAQS. Both the 1-hour and 1997 ozone NAAQS have been revoked.

We are maintaining and clarifying in this action our intention and existing practice with regard to applicable RFG requirements for the implementation of revised ozone NAAQS. Our intention is consistent with our past approach and fuel program implementation to date. Specifically, for purposes of implementing revised ozone NAAQS, RFG will continue to apply in all covered areas (*i.e.,* both areas that opted into RFG under CAA section 211(k)(6) and covered areas under CAA section 211(k)(10)(D)). As previously explained, this is consistent with how the federal RFG program has been implemented during the transition to the 1997, 2008, and 2015 ozone NAAQS. As also previously explained, part 1090 includes procedures for either removing a prohibition on or opting out of RFG requirements, consistent with CAA requirements; thus, states should be able

[46] Some states where the federal low RVP standard is required have chosen instead to apply federal RFG or another state fuel regulation that limits RVP to less than 7.8 psi. Such a practice is consistent with the CAA. If a state with such an area decided to remove its fuel program, the state should work closely with EPA to ensure that the state's SIP demonstration also supports removal of multiple fuel programs, if desired. See Section V.A.4.g for more information.

[47] California has set requirements for gasoline sold throughout the entire state, and these requirements include limits on the gasoline RVP. See Title 13, sections 2250–2273.5 of the California Code of Regulations. These standards apply in lieu of federal RVP standards.

[48] In the absence of California's RFG regulation, either federal RVP standards or federal RFG would apply in California. Some areas would be federal RFG covered areas because either they were among the original nine RFG covered areas or they were reclassified to Severe nonattainment for an ozone NAAQS. See CAA section 211(k)(10)(D).

[49] See CAA section 211(k)(10)(D).

[50] The Sacramento Metro area was reclassified as a severe ozone nonattainment area on June 1, 1995 and became a federal RFG covered area on June 1, 1996. See 60 FR 20237 (April 25, 1995). The San Joaquin Valley area was reclassified as a severe ozone nonattainment area on December 10, 2001 and became a federal RFG covered area on December 10, 2002. See 66 FR 56476 (November 8, 2001).

[51] See 70 FR 71684–9 (November 29, 2005).

to change their RFG programs under certain cases.

f. Clarifying When Mandatory RFG Covered Nonattainment Areas Can Be Removed From the List of Covered Areas

In the Phase 2 Implementation Rule for the 1997 Ozone NAAQS, we reserved for future consideration the continued applicability of RFG requirements in mandatory RFG covered areas pursuant to CAA section 211(k)(10)(D) (*i.e.,* they were among the areas with the nine highest 1-hour ozone design values from 1987–1989 or they have been reclassified to Severe for an ozone NAAQS) in the future.[52]

We are proposing a new provision in part 1090 that would allow mandatory RFG covered area pursuant to CAA section 211(k)(10)(D) to remove the applicability of the RFG program if certain requirements are met. Under this proposed provision, a state could request the removal of its RFG program if the RFG area was either redesignated to attainment for the most stringent ozone NAAQS in effect at the time or initially designated as attainment for the most stringent ozone NAAQS in effect. For example, the 2015 ozone NAAQS of 70 ppb is currently the most stringent ozone NAAQS. Therefore, in order for a mandatory RFG area to remove its RFG program, it would have to be either redesignated to attainment for the 2015 ozone NAAQS (if had initially been designated as attainment for that NAAQS) or be initially designated as an attainment area for the 2015 ozone NAAQS. If the area is initially designated as an attainment area for the most stringent ozone NAAQS in effect, under the proposed requirement the area would have to be redesignated to attainment for the prior ozone NAAQS before the RFG program could be removed. For example, under this proposal an area would either have been designated as an attainment area for the 2015 ozone NAAQS with an approved maintenance plan for the 2008 ozone NAAQS or be redesignated to attainment for the 2015 NAAQS to be eligible for consideration for removal of the RFG program. In either case, we are proposing to require that any request to remove the federal RFG requirements must include an approved maintenance plan that demonstrates maintenance of the ozone NAAQS throughout the period of time addressed by the maintenance plan without the emission reductions from the federal RFG program. Additionally, the proposed provision would require a state to also demonstrate that the removal of the requirement for the federal RFG program would not interfere with reasonable further progress requirements or attainment or maintenance of any other NAAQS or interfere with any other CAA requirement.[53] We seek comment on this proposed requirement.

We are proposing to allow states with current mandatory RFG covered areas to remove those programs in the future when all ozone NAAQS are attained and maintained. Although the CAA requires RFG in certain ozone nonattainment areas, it is important that states can use limited resources for programs that are necessary for attainment, rather than require the implementation of RFG indefinitely simply because such a covered area had the highest ozone design values 30 years ago or were reclassified as Severe for a prior ozone NAAQS. This proposal is premised on our view that once a covered area attains the most stringent ozone NAAQS, states should be able to determine whether an emission reduction strategy should either continue or be removed.

We believe that a mandatory RFG covered area should have the ability to determine if it is necessary to continue as an RFG covered area once it has attained the most stringent ozone NAAQS that is in effect and can demonstrate maintenance of the ozone NAAQS without the emissions reductions attributable to RFG in the approved CAA section 175A maintenance plan for the area. Requiring that an area attain the most stringent ozone NAAQS and demonstrate maintenance of the ozone NAAQS without the emissions reductions from RFG provides adequate safeguards with respect to protecting air quality improvements and public health, while providing states with the flexibility to determine the best course for maintaining the ozone NAAQS.

This proposed provision is in addition to the current RFG opt-out procedures that apply to areas that opted-in to RFG under CAA section 211(k)(6)(A) or (B) unless an opt-in area under CAA section 211(k)(6)(A) has been reclassified as a Severe ozone nonattainment area. These procedures, which were established in 1996 and 1997, are currently in 40 CFR 80.72 and are also being transferred to part 1090.[54] We are not changing them except for removing obsolete regulatory text and minor clarifications, such as requirements that applied for specific periods of time that are now in the past.

g. Providing Streamlined Procedures for Areas Relaxing the Federal Low RVP Standard

We are proposing to include a new streamlined process for state requests to relax the federal 7.8 psi RVP standard for gasoline sold between June 1st and September 15th of each year. This action would provide procedures similar to those that are currently used when states opt out of the RFG program.[55]

The current federal 7.8 psi RVP limit took effect in 1992 and was initially required in certain 1-hour ozone NAAQS nonattainment areas. We have also allowed for state relaxation requests and since 2014 we have approved relaxations of the federal 7.8 psi RVP standard for 12 areas in the states of Alabama, Florida, Georgia, Louisiana, North Carolina, and Tennessee.[56] As discussed in Section V.A.4.c, we are providing a new table in part 1090 that sets out where the federal 7.8 psi RVP standards currently applies.

Under our current regulations, the process for accomplishing low RVP relaxation requires two EPA approval actions before a state's request can be effective. First, the EPA Regional Office needs to approve a state's revision to an area's SIP, such as a maintenance plan, for the relevant ozone NAAQS. After that rulemaking is completed, a second rulemaking by EPA Headquarters is necessary to remove the subject area(s) from the federal low RVP regulations in 40 CFR 80.27(a)(2).[57] The current process of requiring both of these approval actions before a state's request is effective is cumbersome and time consuming given the number of linear steps involved. There is also an element of confusion and uncertainty to states, local businesses, industry, and the

[52] See 70 FR 71687 (November 29, 2005).

[53] See CAA section 110(l).

[54] See 61 FR 35673 (July 8, 1996) and 62 FR 54552 (October 20, 1997).

[55] The current RFG opt-out procedures apply to areas that opted into RFG under CAA section 211(k)(6)(A) or (B) unless an area that opted in under CAA section 211(k)(6)(A) has been reclassified as Severe. These procedures are currently in 40 CFR 80.72 and were established in 1996 and 1997. See 61 FR 35673 (July 8, 1996) and 62 FR 54552 (October 20, 1997). We are not changing these RFG opt-out procedures except for removing obsolete regulatory text and minor clarifications.

[56] For more information on EPA's actions, see *www.epa.gov/gasoline-standards/federal-gasoline-regulations.*

[57] In some circumstances, a revision to an approved maintenance plan has not been necessary because the subject area was beyond the period of time covered by any approved ozone maintenance plan under either CAA section 110(a) or 175A. For an example, refer to the RVP relaxation for several parishes in Louisiana (82 FR 60886, December 26, 2017).

public concerning the effective date of an RVP relaxation.

Based on our experience since 2014, we have concluded that the current RFG opt-out regulatory procedures provide a better model for considering state requests to relax the federal 7.8 psi RVP standard. Our proposed regulations for relaxing the federal 7.8 psi RVP standard in part 1090 mirrors the current part 80 RFG opt-out procedures, and are as follows:

- The Governor of the state or his/her designee would request in writing that EPA relax the federal 7.8 psi RVP standard.
- The state would continue to be required to revise its approved SIP for the area (*e.g.,* the ozone maintenance plan for the area) to appropriately account for the change in emissions due to the increase in the RVP limit and to address the CAA section 110(l) non-interference requirements.
- The EPA Regional Office would have to approve that SIP revision and CAA section 110(l) demonstration.
- Once, the Regional Office's action is complete, we would establish an effective date for the relaxation, which would be no less than 90 days after the effective date of the Regional Office's approval. We would notify the Governor in writing, typically through a letter, of the effective date and publish a notice in the **Federal Register**. Gasoline meeting the 7.8 psi RVP standard would not be required to be sold after that effective date.
- Subsequently, we would publish a separate final rule to remove the area from the list of areas where the 7.8 psi RVP limit continues to apply (*i.e.,* from the list of areas in part 1090). We believe that notice-and-comment rulemaking would no longer be necessary for relaxation actions because it merely codifies a change that has been made through a process that is included in our regulations and would be merely administrative in nature.

Use of this proposed process would eliminate the need for EPA to complete a notice-and-comment rulemaking each time EPA acts on a request to relax a low volatility gasoline standard to remove the subject area from the list of areas subject to that standard. Under this proposed process, similar to the current RFG opt-out procedures, the effective date of the federal low RVP relaxation would be known shortly after the EPA Regional Office's rulemaking on the state's SIP revision becomes effective. We believe that using similar procedures for acting on state requests to change either federal low RVP or RFG programs would avoid unnecessary confusion and still continue to provide the same level of environmental protection. Under both the current regulations in part 80 and the proposed regulations in part 1090, the state's SIP revision must include revisions to the on-road and nonroad mobile source NO_X and VOC inventories to reflect the removal of the federal low RVP fuel. The SIP must also demonstrate that the area would continue to maintain the relevant ozone NAAQS and that the change would not negatively impact the area's compliance with other CAA requirements.[58] Further, we would continue to act on such a SIP revision and CAA section 110(l) non-interference demonstration through notice-and-comment rulemaking. Finally, this proposed process, which streamlines the RVP relaxation program, would result in the conservation of limited government resources and bring certainty for states, the public and gasoline suppliers as to when a state's request to relax RVP would take effect.

h. Transitioning From Federal RFG or a Boutique Fuel Program to the Federal RVP Standard in Certain States

We are providing information to states that decide to either opt out of federal RFG or remove a state SIP fuel rule that regulates gasoline RVP (*i.e.,* a boutique fuel) that the state in its SIP revision (*e.g.,* maintenance plan revision) may request that EPA apply the 9.0 psi RVP standard rather than the federal 7.8 psi RVP standard.[59] The SIP revision will have to document that increasing the summer RVP standard to 9.0 psi will not interfere with attainment or maintenance of the relevant ozone NAAQS or with requirements for reasonable further progress, attainment, or maintenance of any other NAAQS.[60] This reflects our experience in working with states that have decided to change their fuel programs in areas where the federal 9.0 psi RVP standard could be applied.

In such cases, the ultimate goal of these states has been to allow the sale of gasoline that meets the federal 9.0 psi RVP standard. States have previously accomplished this goal by first submitting a SIP revision (*e.g.,* a maintenance plan revision) based on the application of the federal 7.8 psi standard and then later submitting a second SIP revision to initiate the process to relax the federal 7.8 psi RVP standard to 9.0 psi. We are providing this information to ensure that the relevant states are aware that they can accomplish the goal of relaxing the federal RVP standard to 9.0 psi as long as the associated SIP revision meet the CAA section 110(l) non-interference requirements for the relevant ozone NAAQS and all other pollutants. Accomplishing the goal of allowing the sale of gasoline that meets the federal 9.0 psi RVP standard with one SIP revision, EPA approval of one SIP revision, and one EPA action to update the lists areas subject to the specific gasoline standards will conserve state and federal resources.

This proposal allowing the transition to the federal RVP standard of 9.0 psi through one SIP revision continues to protect air quality and public health because the state must demonstrate through its SIP revision and CAA section 110(l) non-interference demonstration that air quality goals are met as required by the CAA when gasoline that complies with the federal RVP standard of 9.0 psi is sold in the area. In addition, EPA must then approve that SIP revision and CAA section 110(l) demonstration through notice-and-comment rulemaking. This approach also provides fuel suppliers with certainty and stability. Under part 1090, fuel suppliers in such areas would not be required to switch from supplying federal RFG or a state fuel to federal 7.8 psi RVP gasoline for a short period of time only to ultimately switch to supplying gasoline that meets the federal 9.0 psi RVP standard.

We note, however, that if such a state wants EPA to apply the federal 7.8 psi RVP limit, that state could document this intention in its SIP revision, and the associated emissions modeling should be based on application of the federal 7.8 psi RVP limit. In such a case, EPA Headquarters would also complete a rulemaking to revise the list of areas where the federal 7.8 psi RVP standard applies (*i.e.,* add such an area to the list in part 1090).

i. Announcing Updates to the Boutique Fuels List

We are also using this action to announce that an updated boutique fuel list is currently posted on our website. Section 1541(b) of EPAct required EPA, in consultation with the Department of Energy (DOE), to determine the total number of fuels approved into all SIPs

[58] See CAA section 110(l).

[59] In rulemakings on June 11, 1990 (55 FR 23658) and December 12, 1991 (56 FR 64704), EPA promulgated regulations that established a gasoline RVP standard of 7.8 psi from June 1st to September 15th in nonattainment areas for the 1-hour ozone NAAQS in the following states: Alabama; Arizona; Arkansas; California; Colorado; Florida; Georgia; Kansas; Louisiana; Maryland; Mississippi; Missouri; Nevada; New Mexico; North Carolina; Oklahoma; Oregon; South Carolina; Tennessee; Texas; Utah and Virginia; and the District of Columbia. The federal 9.0 psi RVP standard applies in the remaining states in the continental U.S.

[60] See CAA section 110(l).

as of September 1, 2004, under section 211(c)(4)(C), and publish a list of such fuels, including the state and Petroleum Administration for Defense District (PADD) in which they are used for public review and comment. EPA originally published the required list on 2006.[61]

Additionally, we are required to remove any fuels from the published list if the fuel either ceases to be included in a SIP or is identical to a federal fuel.[62] Since the original list was published, a number of fuels have been removed from approved SIPs and have thus ceased to exist in SIPs.[63] In Table V.5.h–1 we are providing an updated list of boutique fuels that includes all of the boutique fuels that are currently in approved SIPs. We also maintain a current list of boutique fuels on our State Fuels website.[64] We will continue to update that website as changes to boutique fuels occur and periodically announce updates in the **Federal Register** for fuels that are either removed or added.

TABLE V.5.h–1—TOTAL NUMBER OF FUELS APPROVED IN SIPS UNDER CAA SECTION 211(C)(4)(C)

Type of fuel control	PADD	Region-state
RVP of 7.8 psi	2	5—Indiana.
	3	6—Texas (May 1–October 1).*
RVP of 7.0 psi	2	7—Kansas.
	2	5—Michigan.
	2	7—Missouri.
	3	4—Alabama.[65]
	3	6—Texas.
Low Emission Diesel	3	6—Texas.
Cleaner Burning Gasoline (Summer)	5	9—Arizona (May 1–September 30).*
Cleaner Burning Gasoline (Non-Summer)	5	9—Arizona (October 1–April 30).
Winter Gasoline (aromatics & sulfur)	5	9—Nevada.[66]

* Dates refer to summer gasoline programs with different RVP control periods from the federal RVP control period, which runs from May 1st through September 15th for fuel manufacturers and June 1st through September 15th for downstream parties.

5. Substantially Similar

CAA section 211(f)(1)(B) prohibits the introduction into commerce of ''any fuel or fuel additive for use by any person in motor vehicles manufactured after model year 1974 which is not substantially similar to any fuel or fuel additive utilized in the certification of any model year 1975, or subsequent model year vehicle, or engine.'' While this provision has always applied to fuel and fuel additive manufacturers by virtue of it being a statutory requirement, we did not listed it in our part 80 regulations among the requirements for fuel.[67] We are proposing to address the substantially similar requirements of the CAA in part 1090 for gasoline and gasoline fuel additives as part of our effort to consolidate fuels compliance requirements and make it easier for regulated parties to understand their obligations.[68] We are proposing to include a requirement in the regulation that that all gasoline, BOBs, and gasoline fuel additives must be substantially similar under CAA section 211(f)(1)(B) or have a waiver under CAA section 211(f)(4). We seek comment on this approach.

EPA has issued two coexisting definitions of substantially similar for gasoline, one in 2008[69] and one in 2019,[70] and several CAA section 211(f)(4) waivers. The regulations proposed today refer to the statutory provisions (CAA section 211(f)(1)(B) and (4)), and the conditions associated with CAA section 211(f)(4) waivers and the parameters associated with the 2019 definition of substantially similar.

B. Diesel Fuel

1. Overview and Streamlining of Diesel Fuel Program

Similar to our approach for the gasoline standards, we are proposing to consolidate the diesel fuel standards into a single subpart in part 1090 (subpart D). We are not proposing any changes to the sulfur or cetane/aromatics standards for diesel fuel, the sulfur standards for diesel fuel additives, or the ECA marine fuel standards. We are removing expired provisions that were needed to support the phase-in of the diesel fuel sulfur program. The phase-in period was completed in 2014; however, these now expired phase-in provisions are imbedded throughout the diesel program regulations, adding burden to regulated parties in identifying their compliance duties and confusing other stakeholders. As part of the transfer of current part 80 regulations to part 1090, we are also consolidating identical provisions for highway and other diesel fuels into a single regulatory requirement to improve clarity.

We are proposing the following revisions to existing part 80 regulations in the following sections. First, we are proposing to remove the requirement that motor vehicle diesel fuel be free of red dye because we believe this requirement no longer provides an effective means of evaluating compliance with the diesel sulfur standards. Second, we are proposing to streamline the requirements that pertain to importation of diesel fuel that does not meet EPA standards. Third, we are proposing to remove the registration requirement for ECA marine fuel distributors and associated requirements to include a registration number on PTDs. Finally, we are proposing

[61] See 71 FR 78192 (December 28, 2006).

[62] See CAA section 211(c)(4)(C)(v)(III).

[63] Since December 2006, the following fuels have been removed from approved SIPs: Pennsylvania—7.8 psi RVP; Maine—7.8 psi RVP; Illinois—7.2 psi RVP; and Georgia—7.0 psi RVP with sulfur provisions.

[64] See *https://www.epa.gov/gasoline-standards/state-fuels.*

[65] EPA has approved Alabama's request to move its SIP approved 7.0 psi RVP program to the contingency measure portion of the SIP for the Birmingham area. Because the fuel rule was retained as a contingency measure it remains on the boutique fuel list (see 77 FR 23619, April 20, 2012).

[66] Nevada's winter gasoline (aromatics and sulfur) fuel rule was retained as a contingency measure and therefore remains on the boutique fuel list (see 75 FR 59090, September 27, 2010).

[67] The fuel and fuel additive registration requirements do, however, require that manufacturers of fuels and fuel additives demonstrate that fuels and fuel additives are either substantially similar under CAA section 211(f)(1) or have a waiver under CAA section 211(f)(4). See 40 CFR 79.11(i) and 79.21(h).

[68] See 81 FR 80877–8 (November 16, 2016).

[69] See 73 FR 22277 (April 25, 2008).

[70] See 84 FR 26980 (June 10, 2019).

streamlined means for downstream parties to redesignate heating oil, kerosene, and jet fuel as ULSD that would require specific documentation from the original fuel manufacturer.

We expect that these proposed changes, when finalized, would simplify the diesel fuel programs, resulting in reduced burden associated with demonstrating compliance with the applicable sulfur standards and maximize the fungibility of diesel fuel, allowing the market to operate more efficiently. These changes are not expected to change the stringency of the diesel fuel and IMO marine fuel standards.

2. Removing the Red Dye Requirement

Part 80 currently requires that motor vehicle diesel fuel must be free of visible evidence of dye solvent red 164 (which has a characteristic red color in diesel fuel), except for motor vehicle diesel fuel that is used in a manner that is tax exempt under section 4082 of the Internal Revenue Code.[71] This EPA requirement is consistent with a parallel requirement in the Internal Revenue Code that is intended to support compliance with diesel fuel tax requirements. Under the Internal Revenue Code, NRLM diesel fuel, heating oil, and exempt highway diesel fuel[72] must contain red dye before leaving a fuel distribution terminal to indicate its tax-exempt status.

When the sulfur standards for off-highway diesel fuel were less stringent than those for motor vehicle diesel fuel, the presence of red dye was a useful screening tool for EPA to identify potential noncompliance with the sulfur standards for highway diesel fuel. However, the presence of red dye has become a much less useful indicator of sulfur noncompliance as other distillate fuels have become subject to the same 15 ppm sulfur standard that applies to highway diesel fuel. With the completion of the phase-in of our diesel fuel sulfur program in 2014, all highway, nonroad, locomotive, and marine diesel fuel must meet a 15 ppm sulfur standard except for a limited volume of locomotive and marine (LM) diesel fuel produced by transmix processors, which is subject to a 500 ppm sulfur standard. The distribution of 500 ppm LM diesel fuel is subject to separate compliance provisions to ensure that is not misdirected for use in highway, nonroad, locomotive, or marine engines that require the use of 15 ppm diesel fuel (ULSD).

The other potential source of red-dyed high-sulfur diesel fuel that might inappropriately be diverted as highway diesel has been heating oil. However, the vast majority of heating is currently subject to a 15 ppm standard.[73] Therefore, we believe that the requirement that red dye should not be present in motor vehicle diesel fuel no longer provides meaningful added assurance of compliance with highway diesel ULSD standards. Rather, the existence of this requirement complicates the process of providing alternate sources of diesel fuel when supplies of highway diesel fuel are constricted due to extreme and unusual supply circumstances. State authorities are currently required to request a waiver from EPA and the Internal Revenue Service (IRS) from the respective agency's red dye requirements to enable the use of 15 ppm NRLM diesel fuel on highway during such circumstances. Eliminating our red dye requirement would reduce state officials' waiver requests to just an IRS waiver during such events without substantially affecting the ability of EPA to enforce highway ULSD standards. Therefore, we are proposing to remove the EPA requirement that motor vehicle diesel fuel must be free from visual evidence of red dye.[74] This proposed change would not alter the Internal Revenue Code requirement that NRLM diesel fuel, heating oil, and exempt motor vehicle diesel fuel must contain red dye before leaving a fuel distribution terminal to indicate its tax-exempt status.

3. Importation of Off Spec Diesel Fuel

We are proposing to replace the provisions for the importation of diesel fuel treated as blendstock (DTAB)[75] with a streamlined procedure to handle imported off-spec diesel fuel. Under part 80, most of the DTAB provisions are designed to account for the DTAB in compliance calculations that have not been used since 2010. The part 80 provisions require importers to include DTAB in compliance calculations that are no longer applicable, to keep DTAB segregated from other diesel fuel, and limit the importer's ability to transfer title of DTAB. Under part 1090, importers could import diesel fuel that does not comply with EPA standards if certain provisions (which are a subset of those currently required under part 80) are met. Under the proposed provisions, the importer would be required to offload the imported diesel fuel into one or more shore tanks containing diesel, sample and test the blended fuel to confirm that it meets all applicable per-gallon standards before introduction into commerce, and keep all applicable records. We believe that this simplification provides the needed flexibility for importers while providing improved clarity.

4. Annex VI Marine Fuel Standards

In this action, we are mostly proposing to transpose without change the regulations in subpart I of part 80 for distillate diesel fuel that complies with the 0.10 percent (1,000 ppm) and 0.50 percent (5,000 ppm) sulfur standards contained in Annex VI to the International Convention for the Prevention of Pollution from Ships (MARPOL Annex VI). The U.S. ratified MARPOL Annex VI and became a Party to this Protocol on October 8, 2009. MARPOL Annex VI requires marine vessels operating globally to use fuel that meets the 0.50 percent sulfur standard starting January 1, 2020, rather than the current standard of 3.50 percent (35,000 ppm) sulfur (''global marine fuel''). The MARPOL Annex VI standard is 0.10 percent sulfur for fuel used in vessels operating in designated Emission Control Areas (ECAs).[76]

In a separate action, we modified our diesel fuel regulations in part 80 to allow fuel manufacturers and distributors to sell distillate diesel fuel meeting the 2020 global marine fuel standard instead of the ULSD or ECA marine standards.[77] We are incorporating those provisions into part 1090 with minor changes to be consistent with the proposed part 1090 structure.

Regarding ECA marine fuel, we are including the provisions from part 80 in part 1090 without change save one major exception. Under part 80, distributors of ECA marine fuel from the refiner to the point of transfer to a vessel are currently required to register with EPA and must include this registration number on PTDs.[78] Distributors of other

[71] See 40 CFR 80.520(b).

[72] Such as diesel fuel used in school buses.

[73] The vast majority of heating oil is used in the Northeast where states require that heating oil meet a 15 ppm sulfur standard. See ''Guidance, Exemptions And Enforcement Discretion For New England's ULSHO Transition,'' New England Fuel Institute (NEFI), available at *https://nefi.com/regulatory-compliance/new-englands-ulsho-transition.*

[74] See 40 CFR 80.520(b)(1).

[75] See 40 CFR 80.512.

[76] Designated Emission Control Areas for the U.S. include the North American ECA and the U.S. Caribbean Sea ECA. More specific descriptions may be found in EPA fact sheets: ''Designation of North American Emission Control Area to Reduce Emissions from Ships,'' EPA–420–F–10–015, March 2010; and ''Designation of Emission Control Area to Reduce Emissions from Ships in the U.S. Caribbean,'' EPA–420–F–11–024, July 2011.

[77] See 84 FR 69335 (December 18, 2019).

[78] See 40 CFR 80.597(d)(3).

distillate and residual fuels had similar ''designate and track'' requirements during the phase-in of the ULSD standards for highway and nonroad diesel fuel to allow the temporary use of limited volumes of 500 ppm highway and nonroad diesel fuel under the program's small refiner and credit provisions.[79] The majority of these requirements gradually expired with the phase-out of the ULSD program's small refiner and credit provisions that ended in 2014, which allowed the production of limited volumes of 500 ppm highway diesel fuel. Beginning in 2014, the only fuel distributors that must register with EPA are those that handle ECA marine fuel and 500 ppm LM diesel fuel produced by transmix processors.[80]

We believe that the benefit associated with having ECA marine fuel distributors register with EPA may not outweigh the burdens associated with this requirement. Like distributors of other regulated fuels, distributors of ECA marine fuel would be required to identify themselves on the PTD. This information could be used by EPA to help determine what parties in the ECA marine fuel distribution chain may be responsible for fuel represented as ECA marine fuel in the distribution system that does not meet the requisite fuel quality standards. While having a registration number on the ECA marine fuel PTD facilitates this process, we do not believe that it is necessary. Therefore, we are proposing to remove the requirement that distributors of ECA marine fuel must register with EPA and include this registration number on ECA marine fuel PTDs. We believe that this would meaningfully reduce the burden to fuel distributors and would avoid potential delays in the transportation of ECA marine fuel due to potential distributors not being registered with EPA, while not diminishing the air quality benefits of the ECA marine fuel program. Any person who produces diesel fuel, including ECA marine fuel, by mixing blendstocks is a blender manufacturer and must continue to register and comply with all applicable requirements; this is consistent with the current regulatory under part 80 and would be unchanged in part 1090. We request comment on the benefits and costs of the current registration requirement for ECA marine fuel distributors.

5. Heating Oil, Kerosene, and Jet Fuel

Under part 80, we first established the diesel sulfur program that required only on-highway or motor vehicle diesel to meet the 15 ppm sulfur standard. We designed most of the provisions related to designating, segregating, and labeling distillate fuels to avoid the contamination of ULSD with higher sulfur distillate fuels, which at the time were non-road diesel, heating oil, kerosene, and jet fuel. Now a federal 15 ppm standard applies for motor vehicle, non-road, locomotive, and marine diesel fuel, and, as discussed in Section V.B.2, a state or local 15 ppm sulfur standard applies to most of the heating oil used in the U.S. The provisions designed to avoid contamination of ULSD with higher sulfur distillate fuels now exist where there is no difference between most distillate fuels; however, the provisions have remained in place despite this change in the distillate fuel market. These obsolete provisions contribute to inefficiency in the distribution system leading to higher costs, and barriers to the free movement of fuel during times of unforeseen supply disruptions (*e.g.,* refinery fires, hurricanes, etc.). Therefore, we are proposing to allow heating oil, kerosene, and jet fuel certified to ULSD standards to be redesignated downstream as ULSD for use in motor vehicles and NRLM engines without recertification by the downstream party if certain conditions are met.

Under these proposed provisions, downstream parties could rely upon documentation from pipelines or fuel manufacturers that the heating oil, kerosene, or jet fuel was certified to meet the 15 ppm ULSD sulfur standard and cetane/aromatics specifications to fungibly transport, store, and dispense all 15 ppm sulfur distillate fuels downstream. We are also proposing provisions in part 1090 that would also allow ULSD to be used as heating oil, kerosene, jet fuel, or ECA marine fuel without recertification as long as records are kept demonstrating that the ULSD had been redesignated. We believe that these provisions would maximize the fungibility of distillate fuels, resulting in substantially reduced distributional costs and greater efficiency in the fuels market.

During the rule development process, several stakeholders asked that we address issues regarding accounting for distillate fuels under the RFS program. We believe that this is outside the scope of this action. We recognize that this proposal could impact RFS compliance and have finalized provisions to help clarify how obligated parties (*i.e.,* refiners and importers of gasoline and diesel fuel) account for distillate fuels under the RFS program in a separate action.[81]

We believe these proposed changes could help increase the efficiency with which distillate fuels are distributed, resulting in significant cost savings to stakeholders and consumers. We seek comment on whether this is the case and on how to quantify the associated cost savings.

VI. Exemptions, Hardships, and Special Provisions

A. Exemptions

We are also transferring provisions that exempt fuels from applicable standards that are currently contained in part 80 to part 1090. We are proposing minor revisions for purposes of modernizing these exemptions as well as removing obsolete exemption provisions, and any exemptions that were granted under part 80 will remain in effect with their original conditions as applicable under part 1090. As a result, instead of being scattered through various subparts as is the current practice in part 80, these provisions would be consolidated into a single subpart in part 1090 (subpart G) for all exemptions. This includes those exemptions that require a petition such as the hardship exemption and those that do not such as the for export exemption. This structure is designed to increase their accessibility and usability. Consistent with current provisions, exempted fuels, fuel additives, and regulated blendstocks do not need to comply with the standards of part 1090, but remain subject to other requirements (*e.g.,* registration, reporting, and recordkeeping) that are now also proposed to be moved to part 1090.

We are not proposing any revisions to exemptions nor the related requirements that apply to fuels used for national security and military purposes, temporary research and development (R&D), racing, and aviation. Similarly, we are not proposing to change the exemption that applies to fuel in Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. Summer gasoline in Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands would also continue to be exempt from the federal volatility regulations.

We are, however, proposing minor revisions to these exemptions for consistency and as a result of consolidating the various part 80

[79] See 40 CFR 80.597 regarding the distributor registration requirements and 40 CFR 80.590(a)(6)(i) for the associated PTD requirements.

[80] The production of 500 ppm LM diesel fuel is discussed in Section XIII.E.4.

[81] See 85 FR 7054–57 (February 6, 2020).

exemptions. We are proposing that exemptions granted under part 80 would remain in effect under part 1090, and as previously explained removing exemption provisions that are no longer active.

We are proposing some changes to modernize the exemption provisions. First, we are proposing to include language that would impose conditions on parties operating under a research and development (''R&D'') test program to prevent the inadvertent use of test fuels exempted under a temporary R&D exemption by participants not included in the test program. Recently, we have received requests for R&D exemptions that focus on the effects of a certain fuel's use in more real world operation conditions (as opposed to a contained laboratory type situation). This often requires the test fuel be made available in a way that could result in vehicles or engines not included as part of the R&D program inappropriately using the test fuel. We believe it is appropriate for applicants requesting such an R&D exemption to take reasonable precautions to prevent consumers not participating in the test program from fueling with the test fuel. We are requesting comment on procedures that could be applied to fuels being tested under an R&D exemption when the test includes consumer participation that could result in the aforementioned misfueling.

Second, we are proposing to allow certain exemptions for fuel additives and regulated blendstocks. Under part 80, it was unclear whether some exemptions applied to fuel additives and regulated blendstocks under certain programs, such as the gasoline sulfur program. Under 1090, fuel additives and regulated blendstocks would now be exempt from applicable requirements if certain conditions are met. For example, the military use exemption would now explicitly exempt fuels, fuel additives and regulated blendstocks used in either military vehicles or in support of military operations.

Third, we are proposing that parties that transport and store exempt aviation and racing fuel take reasonable precautions to avoid the contamination of exempt fuels when using the same tanker trucks and tanks to transport and store exempt and non-exempt fuels. Aviation and racing gasoline can often contain lead additives that can harm emission controls on vehicles and engines designed to operate on unleaded gasoline. For example, when a tanker truck carrying exempt racing gasoline is later used to transport non-exempt gasoline, residual exempt racing gasoline could remain in the tanker truck and contaminate the non-exempt gasoline. We believe it is prudent for parties to follow established voluntary consensus-based standards for the cleaning out of tanker trucks. As such, part 1090 lists two such examples for cleaning tanker trucks to avoid contamination.[82] We seek comment on this proposed requirement and whether there are other voluntary consensus-based standards we should reference.

California gasoline and diesel fuel are currently exempt from the part 80 standards in separate provisions under the various subparts. We are consolidating these existing exemptions for California fuels into a single comprehensive section. This reorganization eliminates the redundancy that resulted as new programs were implemented with California exemptions and old programs sunset but remained in the regulations with their original California fuels exemption. Additionally, housing all the provisions for the California fuels exemption in one section facilitates compliance with its requirements, as regulated parties need not scour part 1090 for hidden exemption provisions. We are also proposing provisions that clarify how California gasoline and diesel fuels may be used in states other than California in the consolidated California exemption section that explains the provisions. Under the current part 80 regulations, fuel manufacturers that make California gasoline and California diesel fuel must recertify those fuels in order to sell them outside the state of California. We are retaining this recertification requirement in part 1090. Fuel manufacturers of California gasoline may recertify their fuels under the applicable standards of this part in order to sell such gasoline outside California. When manufacturers of California gasoline recertify their gasoline, they may participate in the Federal Averaging, Banking, and Trading (''ABT'') programs for gasoline sulfur and benzene. In addition to maintaining the option of recertifying, we are proposing to allow California gasoline manufacturers or distributors of California gasoline to simply redesignate the fuel as CG or RFG, so long as the California gasoline meets all the requirements for California reformulated gasoline under Title 13 of the California Code of Regulations and the manufacturer or distributor meets applicable designation and recordkeeping requirements.[83] Under this proposal, parties that redesignate California gasoline for use outside of California would not be permitted to generate sulfur or benzene credits from the redesignated fuel. Similarly, California diesel fuel used outside of California would be deemed in compliance with the standards of this part if it meets all the requirements Title 13 of the California Code of Regulations and the manufacturer or distributor meets applicable designation and recordkeeping requirements.[84]

B. Exports

We are transferring the current part 80 exemption from applicable standards for fuels, fuel additives, and regulated blendstocks that are designated for export to part 1090. Additionally, we are transferring requirements for designation, product transfer documents, and gasoline segregation for fuels designated for export that currently apply under part 80 to part 1090. Diesel fuels not designated for export could be exported without restriction as long as those fuels meet the applicable fuel quality standards. However, the fuel remains subject to the provisions of this part while in the U.S. For example, fuel designated as ULSD must meet the applicable sulfur standards even if it will later be exported. Such diesel fuel that meets ULSD standards would not need to be segregated and may be redesignated for export by a distributor. On the other hand, diesel fuel that does not meet the ULSD standards would need to be designated for export and segregated from the point of production until the diesel fuel was exported, as currently required under part 80. We are also not proposing to require segregation of fuel additives and regulated blendstocks designated for export. However, some regulated parties have suggested applying the segregation requirement to those products, and we are seeking comment on whether to impose such a requirement as well as the impacts of imposing such a requirement.

Under part 80, gasoline manufacturers are required to segregate gasoline designated for export. In this action, we are not proposing to change this

[82] API Recommended Practice 1595 and Energy Institute & Joint Inspection Group Standard 1530.

[83] The explanation for the analysis we performed to determine the equivalency of the California fuel standards can be found in the technical memorandum, ''The California Fuel Equivalency Memorandum,'' available in the docket for this action.

[84] The California reformulated gasoline and diesel fuel standards are at least as stringent as the standards under this part, therefore, these fuels should be allowed to be used throughout the country. Cal. Code Regs. tit. 13, §§ 2281–2282 (2019).

segregation requirement for gasoline exports. The only modification from part 80 is that these provisions, instead of being included in each gasoline program subpart, will be consolidated into a single subpart for exports under part 1090.

C. Hardships

Under part 80, various subparts include separate provisions for receiving an exemption from that subpart's fuel quality standards due to unforeseeable hardship. We are proposing to consolidate these exemptions into one general hardship provision for unforeseeable circumstances (*e.g.,* a natural disaster or refinery fire) that a refinery cannot avoid with prudent planning (excluding financial and supply chain hardship). The proposed reorganization is intended to make the hardship provision easier to find and does not change either the opportunity for a hardship or the regulated party's burden to demonstrate that its circumstances satisfy the requirements for applicable hardship exemptions. This change would not affect the RFS program, however, given that we are retaining the program in part 80. Accordingly, any exemptions available under that program would similarly remain unaffected.

VII. Averaging, Banking, and Trading Provisions

A. Overview

We are transferring the part 80 averaging, banking, and trading (ABT) provisions for compliance with the sulfur and benzene average standards for gasoline to part 1090.[85] We are proposing modifications that will facilitate consolidation of these various ABT regulatory provisions in part 80 into a single set of ABT provisions in part 1090. We are not transferring part 80 regulations that established separate ABT provisions for small refiners and small volume refineries given that they expired at the end of 2019. We have used ABT provisions to as a means to both meet our environmental objectives and provide regulated parties with the ability to comply with our fuel standards in the most efficient and lowest cost manner. This section also includes changes to how gasoline manufacturers could account for oxygenate added to gasoline downstream of fuel manufacturing facilities in compliance calculations. This section further describes a new proposed mechanism that would allow downstream parties that recertify batches of gasoline to use different types and amounts of oxygenate downstream of a manufacturing facility.

B. Compliance on Average

We are proposing some minor changes to the format of the average compliance calculations to align the sulfur and benzene compliance calculations more closely to accommodate consolidating annual compliance reporting into a single reporting format. Under part 80, compliance with the benzene and sulfur average standards is demonstrated in separate forms and use a slightly different nomenclature. The proposed changes to the compliance calculations would not affect how gasoline manufacturers currently comply with the average standards or their stringency; however, the proposed equations appear slightly different compared to the similar equations in part 80. We are also proposing to add deficits incurred on an annual basis due to the recertification of BOBs downstream to use different types and amounts of oxygenates. This proposed change is discussed in detail in section VII.G.

As previously noted, all part 80 regulations that had separate ABT provisions for small refiners and small volume refineries have expired or will by the time this proposed rule is implemented. The last such provisions are those related to the Tier 3 gasoline sulfur program, which will expire on December 31, 2019, resulting in small refiners and small volume refineries being required to be in compliance with the same part 80 fuel quality standards as other refiners. Since the proposed streamlined fuel quality regulations would take effect January 1, 2021, part 1090 does not include separate ABT provisions for small refiners and small volume refineries. If in the future we propose new fuel standards, we would likely consider flexibilities for small refiners and small volume refineries as part of that future action.

C. Deficit Carryforward

Under the Tier 3 sulfur and MSAT2 gasoline programs, we allow gasoline manufacturers to carryforward deficits, whereby an individual fuel manufacturing facility that does not meet either the sulfur or benzene standard in each compliance period may carry a credit deficit forward into the next compliance period. Under this deficit carryforward allowance, the manufacturer for the facility must make up the credit deficit and come into compliance with the applicable standard(s) in the next compliance period. We are proposing to consolidate the deficit carryforward provisions and we have proposed language that differs from the part 80 deficit carryforward provisions because the proposed language accommodates the consolidation of the gasoline sulfur and benzene deficit carryforward provisions into a single carryforward provision.

D. Credit Generation, Use, and Transfer

We are also transferring the part 80 credit generation, use, and transfer provisions for gasoline manufacturers to part 1090. We are proposing minor changes to the language largely to ensure consistency between the sulfur and benzene credit trading programs.

We are not proposing any changes to the lifespan of generated credits (*i.e.,* credits generated under part 1090 would have the same lifespan as afforded them under part 80). Additionally, credits generated under part 80 would still be usable to comply with average standards under part 1090. To facilitate the use of part 80 credits under part 1090, we are including language to make it clear that credits generated under part 80 would still be valid for compliance under part 1090 for the specified life of the credits under part 80. For example, for credits generated for the 2020 compliance period, gasoline manufacturers could use those credits through the 2025 compliance period.

E. Invalid Credits

We are transferring the part 80 provisions for treatment of invalid credits to part 1090 without any modifications. Since the establishment of the sulfur and benzene ABT programs, we migrated tracking of credit transactions into EMTS. During the rule development process, we received feedback from stakeholders suggesting that the process for remediating invalid credits was onerous due to the administrative process associated with modifying credits in EMTS. Stakeholders also suggested that we rearrange the compliance deadlines to have annual compliance reports due after annual audits have occurred. Some stakeholders suggested that since the annual audit process identifies several issues after annual compliance reports have been submitted (*i.e.,* after credits have been traded and retired for compliance), this switch would then allow for fewer resubmissions of reports and fewer remedial actions for invalid credits. Responsible parties would not need to amend reports since they would have been able to correct the original compliance reports based on an audit. We are not proposing to change the compliance deadlines. We believe

[85] We do not have ABT provisions for diesel fuel, so this section is only applicable to gasoline.

changing the compliance deadlines would disrupt a relatively well functioning compliance program and we believe other actions proposed as part of the streamlined fuel quality regulations would reduce the frequency of resubmissions and remedial actions. For example, we believe by allowing less precision in the rounding of gallons, responsible parties would have fewer remedial actions if audits identify that a party was off by a single gallon on their annual reports. We also believe that by streamlining the regulatory and reporting requirements, compliance demonstrations would be less prone to the types of errors that often require resubmissions. We also note that companies always have the option of performing their own audits internally. However, we seek comment on whether we should rearrange the compliance deadlines as a means to reduce resubmissions and remedial actions.

F. Downstream Oxygenate Accounting

We are proposing a single method for gasoline manufacturers to account for oxygenate added downstream of a fuel manufacturing facility. Oxygenate accounting provides the flexibility for fuel manufacturers to ensure that average standards are met. Under part 80, we have provided several mechanisms, depending on the gasoline program, for refiners and importers to account for oxygenate added downstream. Under the current part 80 RFG provisions for oxygenate blending and accounting, refiners and importers create a hand blend and test the hand blend for reported parameters and include these values in their compliance calculations to demonstrate compliance with sulfur and benzene average standards and the RFG performance standards. The refiner or importer then specifies the type(s) and amount(s) of oxygenates on PTDs to be added by the oxygenate blender, who must then follow the blending instructions by the refiner or importer. Further, refiners and importers must contract with an independent surveyor to verify that an oxygenate is added downstream at levels reported to EPA in batch reports.

Due to the fungible nature of most CG and CBOB, it is difficult for many CG/CBOB refiners or importers to account for oxygenate that is added downstream. Under part 80, CG/CBOB refiners and importers can only account for oxygenate if the refiner or importer can establish that the oxygenate was in fact added to the CG or CBOB. The CG/CBOB refiner or importer can establish that the oxygenate was blended by either: (1) Blending the oxygenate themselves; or (2) having a contract with an oxygenate blender specifying procedures the oxygenate blender will follow to add the amount of oxygenate claimed by the CG/CBOB refiner or importer and the refiner or importer has an oversight program to ensure that the oxygenate blending takes place. Under Tier 3, CG/CBOB refiners and importers may assume 10 percent ethanol containing 5 ppm sulfur in compliance calculations to account for oxygenate added downstream. Further, part 80 does not contain any allowance provisions to assume dilution of benzene from oxygenate added downstream. Based on information gleaned during the rule development process, it appears the average sulfur levels for DFE are lower (2–3 ppm) than the assumed value of 5 ppm allowed under Tier 3. This regulatory disparate treatment of CG/CBOB compared to RFG/RBOB has created a scenario where it is more difficult for CG/CBOB refiners and importers to account for the benefits of the addition of downstream oxygenates.

In part 1090, we are proposing to require gasoline manufacturers to use ''hand blends'' when accounting for oxygenate added downstream. We are also proposing to require that oxygenate blenders follow instructions for the type(s) and amount(s) of oxygenated from the BOB manufacturer. The proposed requirements for gasoline manufacturers and oxygenate blenders largely mirror the requirements for oxygenate blending and accounting found in the RFG program.

The main differences between the proposed hand blend approach and the current RFG program is that the accompanying in-use survey would be national in scope (instead of just a survey of RFG areas), and the BOB manufacturer would need to participate in the proposed national sampling oversight program. The accompanying in-use survey requirements are discussed in more detail in Section X. Additionally, since we are broadening the scope of the oxygenate accounting process from RBOB to all BOB, we are also proposing that gasoline manufacturers prepare samples using the hand blend procedures in ASTM D7717 and that commercially available oxygenate (*e.g.,* denatured fuel ethanol) be used to make hand blends. The oxygenate used should reflect the anticipated sulfur and benzene levels of the oxygenate that will ultimately be blended with the BOB. All other proposed requirements would be the same as currently specified for the RFG program.

During the rule development process, we received feedback from some stakeholders requesting that we allow multiple different options for gasoline manufacturers to account for oxygenate added downstream. These stakeholders argued that the use of assumptions in compliance calculations, as currently allowed under Tier 3 for sulfur, could be easier for some manufacturers to adopt. As discussed earlier, we currently allow for many different methods for accounting for oxygenate added downstream. While this has allowed some gasoline manufacturers (primarily manufacturers of RFG) to benefit from this ability, it has practically precluded other gasoline manufacturers (primarily manufacturers of CG) from enjoying the same flexibility, creating an unlevel playing field. We believe that providing a single method of accounting for oxygenate added downstream ensures a level playing field for all gasoline manufacturers and allows us to better assure that appropriate levels of oxygenate are accounted for through in-use verification in the downstream survey. Additionally, setting assumptions for manufacturers to use in compliance calculations would require information on what those assumptions should be for all regulated parameters (*i.e.,* benzene, sulfur, and RVP). The validity of such assumptions could change over time as new oxygenates or, in the case of DFE, new sources of denaturant are established over time. Changing such assumptions would require EPA to amend its regulations, potentially resulting in an inadvertent change in in-use fuel quality. On the other hand, by utilizing the proposed hand blend approach, we would allow gasoline manufacturers to adjust hand blends to adapt to market changes almost immediately (*e.g.,* if there was an increased demand for E0 or E15). This would ensure that what is reported is ultimately reflective of what is happening in the market, thereby maintaining the stringency of the fuel quality standards over time. However, we seek comment on allowing parties to use assumptions and if so, appropriate assumed values for oxygenates added downstream. In particular, we seek specific data supporting the use of assumed values.

Also, during the rule development process, some stakeholders highlighted that allowing CG manufacturers that are not currently accounting for oxygenate added downstream may result in a change in in-use fuel quality. These stakeholders pointed out that if CG manufacturers are not currently taking advantage of oxygenate accounting due to the difficulty of ensuring that

oxygenate is added downstream, these manufacturers would be slightly over-complying with the required sulfur and benzene average standards. We expect any such effects to be minimal, and we discuss these potential effects in more detail in Section XIV.[86]

G. Downstream Oxygenate Recertification

Under the part 80 RFG program, oxygenate blenders must add the type(s) and amount(s) of oxygenate(s) to RBOB as specified by refiners under 40 CFR 80.69. Refiners must specify blending instructions for all RBOB, most of which is to be made into E10. An oxygenate blender that recertifies a batch of RBOB under part 80 is a gasoline refiner and must comply with all the applicable requirements for a gasoline refiner. These requirements include registration under part 79 as a fuel manufacturer, registering under part 80 as a refiner, complying with sulfur and benzene average standards, and batch sampling and testing. As a result of these requirements and the relatively low volume of E0 needed, oxygenate blenders do not typically opt to assume the role of a gasoline refiner, reducing the availability of E0 in RFG areas. Similarly, the RFG regulations under part 80 practically preclude the use of isobutanol in RBOBs since the regulations require that oxygenate blenders add the type and amount of oxygenate specified by the RFG refiner or importer (which is predominately E10). Under part 80, parties may recertify the batch of RFG; however, the high cost associated with recertifying batches of RBOB downstream essentially precludes oxygenate blenders from blending isobutanol in RFG areas since the batch sizes are relatively small (typically the volume of a single tanker truck).

These restrictions, currently limited to RFG areas, could be compounded by the proposed downstream oxygenate provisions discussed in Section VII.F. Consequently, we are proposing a provision in part 1090 that would allow parties downstream of gasoline manufacturing facilities to more easily recertify BOBs for different types and amounts of oxygenates. Specifically, we are proposing a downstream certification mechanism to allow for oxygenate blenders to recertify batches of BOB for different types and amounts of oxygenates as the market demands to make sure that consumers can still have E0, E15, or isobutanol-blended gasoline available as needed. In other words, under part 1090, oxygenate blenders must follow the blending instructions on PTDs by gasoline manufacturers unless they recertify the batch for a different type and/or amount of oxygenate.

We are proposing to require that parties that wish to recertify BOBs must determine the number of sulfur and benzene credits lost by any lack of downstream oxygenate dilution in cases where the party added less oxygenate than was specified by the gasoline manufacturer. For example, if a party takes a premium BOB intended for blending with ethanol at 10 volume percent and wishes to use it as E0 for recreational vehicles, this party would need to make up for the lost dilution of the sulfur and benzene in the national fuel pool. We have included additional compliance calculations that such parties would need to use to determine the number of sulfur and benzene credits needed. In this calculation, we are proposing default assumed values for the amount of sulfur and benzene from the BOB. We are proposing default values of 11 ppm sulfur and 0.68 volume percent benzene. These proposed values are reflective of the national sulfur and benzene average values adjusted for the absence of denatured fuel ethanol added at 10 volume percent ethanol.[87] The goal of these proposed values is to avoid requiring additional sampling and testing from the recertifying party. We believe that due to the small batch volume for recertified product, typically the size of a tanker truck, the amount of credits needed for any given batch of recertified gasoline would be low and small changes from actual benzene and sulfur content would be in the noise of the proposed compliance calculation and washed out in the marketplace. However, we seek comment on whether different default values would be appropriate.

In cases where a party adds the same volume of oxygenate or more, these credit makeup regulations would not apply, as more than enough sulfur and benzene dilution would have occurred. For example, adding 15 volume percent ethanol into a BOB intended for the addition of 10 volume percent ethanol or adding 12 volume percent isobutanol to a batch of BOB intended for the addition of 10 volume percent ethanol. All other applicable requirements under the CAA and parts 79, 80 and 1090 would apply to the recertified fuel. For example, the recertified gasoline would need to meet RVP requirements in the summer, meet per-gallon sulfur requirements, and be substantially similar under CAA section 211(f). Part 80 currently does not allow oxygenate blenders to generate credits in cases where additional oxygenate is added to RBOB or CBOB and part 1090 would not change this. The challenges associated with implementing and enforcing such a credit provision with so many entities on such small volumes has historically created considerable difficulties, and there does not appear to be any compelling reason here to change from the current regulations.

In order to ensure that parties that recertify BOBs downstream adhere to the proposed provisions for downstream oxygenate recertification, we are proposing that these parties would need to register with EPA, transact any needed sulfur and benzene credits, submit annual compliance reports, and keep records documenting the blending activities and reports submitted to EPA. In lieu of requiring the burden of sampling and testing each batch, we are also proposing that these parties simply undergo an annual attest engagement audit and submit an attest report similar to the report required for gasoline manufacturers. The proposed requirements would only apply to parties that incur a deficit by recertifying BOBs with less oxygenate than specified on the PTD. If a party is already registered with EPA and complies with sulfur and benzene averaging requirements, the party would include the total number of credits needed as a result of downstream oxygenate recertification in their annual compliance calculations as a deficit.

During the rule development process, we solicited feedback on whether parties that recertify BOBs downstream should undergo an annual audit to help ensure that the party complied with the proposed requirements correctly. We received feedback from stakeholders stating that while many of the parties that would elect to use this flexibility are already registered with EPA under part 80, these parties often do not have an annual attest engagement as they do not manufacture gasoline. Therefore, these stakeholders argued that having an attest engagement, which costs tens of thousands of dollars per year, for a small volume of fuel (one tanker truck of approximately 8,000 gallons) is unreasonably burdensome and would significantly increase the costs of recertified fuels. We agree with this feedback; however, we believe that parties that recertify a significant

[86] We discuss these effects in more detail in the technical memorandum, ''Estimated Effects of Proposed Downstream Oxygenate Accounting Provisions,'' available in the docket for this action.

[87] We took the national average values for sulfur (10 ppm) and benzene (0.62 volume percent) and multiplied them by 110 percent.

amount of gasoline for different types and amounts of oxygenates should undergo an annual audit as these parties could have a greater effect on the larger sulfur and benzene pools. Therefore, we are proposing that parties that recertify less than 200,000 total gallons of gasoline for different types and amounts of oxygenate during a compliance period would be exempt from the annual attest audit and report.[88] We believe this proposed flexibility would allow small blenders to avoid a substantial amount of compliance costs associated with recertification of batches of gasoline for different types and amounts of oxygenates while ensuring integrity in the sulfur and benzene credit markets. We seek comment on whether this allowance is appropriate.

Also, during the rule development process we received feedback asking for alternatives to the proposed downstream oxygenate recertification approach. Stakeholders suggested potentially developing a factor that would go into a gasoline manufacturer's compliance calculations that estimated the nationwide level of oxygenate blended into gasoline. While we believe this measure could effectively capture the amount of oxygenate added downstream, it creates level-playing field concerns by effectively increasing the standard for gasoline manufacturers that certify 100 percent of their batches with oxygenates and decreasing the standards for parties that certify less than 100 percent. Additionally, we believe that setting the factor creates challenges. For example, if we set a level consistent with today's oxygenate blending levels and the market changes the amount of oxygenate added to the fuel pool in the future, we would have to undertake a future rulemaking to accommodate the new amount of oxygenate blended into gasoline. If we put in place an administrative process to adjust the factor on a periodic basis (*e.g.,* annually), we believe it would be challenging to continually monitor and track the appropriate number without imposing significant additional reporting and tracking burdens on the part of industry. Failure to provide a new reporting and tracking mechanism would result in delays in establishing the factor on a periodic basis providing uncertainty for gasoline manufacturers in determining sulfur and benzene average standards. We believe the proposed approach provides the desired marketplace flexibility, puts in place appropriate and manageable measures to ensure environmental performance, and allows for flexibility both now and into the future without the need for additional regulatory action. However, we seek comment on other approaches to allow parties to recertify batches of BOB for different types and amounts of oxygenates downstream.

Finally, during the rule development process, we received feedback asking for an allowance to carry forward a deficit related to downstream oxygenate recertification. Stakeholders suggested that it would take time for the sulfur and benzene credit markets and regulated parties to adjust to this proposed flexibility. They suggested that allowing a limited time deficit carry-forward would allow for this proposed flexibility to be implemented more smoothly. We believe that the amount of credits needed to satisfy deficits incurred related to downstream oxygenate recertification is relatively small and that allowing parties to carry-forward deficits related to this proposed provision would result in some parties failing to satisfy those deficits. Therefore, we are not proposing to allow deficit carry-forwards for deficits created by downstream oxygenate recertification. However, we seek comment on whether providing such a deficit carry-forward is needed to help implement the proposed downstream oxygenate recertification provisions. Comments on this subject should include a reasonable period of time for consideration.

VIII. Registration, Reporting, Product Transfer Document, and Recordkeeping Requirements

A. Overview

We are mostly transferring the existing part 80 registration, reporting, PTD, and recordkeeping provisions that are distributed among various subparts in part 80 to part 1090. We also intend to reconcile, simplify, and logically organize those provisions. The resulting registration, reporting, product transfer document (PTD), and recordkeeping requirements proposed for part 1090 are like those already in place under part 80. Where possible we have sought to reduce the impacts upon regulated parties and reduce the burden associated with maintaining and submitting information. In certain cases, we have proposed regulations to simplify or better align reporting requirements with current industry practice, which is particularly true of the batch reporting requirements described in greater detail below.

Information submitted under part 1090 may be claimed as confidential business information (CBI) by the submitter, including certain information submitted via registration and reporting systems. EPA will protect such information from public release in accordance with the provisions of 40 CFR part 2 and in a manner consistent with EPA rules and guidelines related to CBI. Our public release of EPA enforcement-related determinations and EPA actions, together with basic information regarding the party or parties involved and the parameter(s) or credits affected, does not involve the release of information that is entitled to treatment as CBI. Such information may include the company name and company identification number, the facility name and facility identification number, the total quantity of fuel and parameter, and the time period when the violation occurred. Enforcement-related determinations and actions within the scope of this release of information include notices of violation, administrative complaints, civil complaints, criminal information, and criminal indictments. Although we are not proposing a comprehensive CBI determination at this time, we may undertake that activity in a future rulemaking.

B. Registration

1. Purpose of Registration

Registration is necessary to: (1) Identify which parties engage in regulated activities under our regulations; (2) allow regulated parties access to systems to submit information required under our fuel quality regulations; and (3) provide regulated parties with company and compliance-level identification numbers for producing PTDs and other records. This action would make modest changes to the existing registration system including modernizing certain terminology and making updates that make registration easier to understand and implement.

2. Who Must Register

The proposed registration requirements are designed to update terminology to better reflect current roles and activities in the fuel production and distribution system. We are proposing registration requirements for certain third parties, such as independent auditors. These are explained in greater detail below. The following parties would have to register

[88] We estimated this value based on the 1st percentile of credit transaction sizes for benzene credits in 2018. Our analysis for calculating the 200,000 gallon number is included in the technical memorandum, ''Estimated Effects of Proposed Downstream Oxygenate Accounting Provisions,'' available in the docket for this action.

with EPA prior to engaging in any activity under part 1090:

- Gasoline manufacturers
- Diesel fuel and ECA marine manufacturers
- Oxygenate blenders
- Oxygenate producers
- Certified butane blenders
- Certified pentane producers
- Certified pentane blenders
- Transmix processors
- Certified ethanol denaturant producers
- Distributors, carriers and resellers who are part of a 500 ppm LM diesel chain and who are part of a compliance plan proposed under 40 CFR 1090.515(c)
- Independent surveyors
- Auditors
- Third parties who require access to EPA's registration and reporting systems, including those who submit reports on behalf of any party regulated under part 1090

Nearly all parties who would be subject to registration under part 1090 are already registered under part 80. We are not requiring parties who are already registered under part 80 to go through the effort to re-register their company or their facilities under part 1090. We are proposing to include specific provisions in part 1090 that would ensure such parties do not need to re-register. For example, although we do not currently register parties under part 80 as ''gasoline manufacturers,'' parties who are currently registered as ''refiners'' would be understood to fall under this new term and would not have to re-register. We do not believe that this action will result in a significant number of new registrants, and existing registrants would only need to make the type of routine registration updates they already are required to make (*e.g.,* to add or delete activities they engage in or to change an address).

We are also proposing to remove an existing registration requirement under part 80. Although independent laboratories are required to register under part 80, we are proposing to remove this registration requirement and are not transferring this requirement from part 80 to part 1090. As a result, independent laboratories would no longer be required to register unless they submit information directly on behalf of another party, such as a gasoline manufacturer. In such cases, they would need to update their registration to reflect that they are submitting reports on behalf of a regulated party and would have to associate with the company or companies for which they will submit reports. Association is a step within the existing registration system and is designed to ensure that the company for which the reports are submitted by the ''agent'' agrees to that arrangement. Association is designed to be a simple step that would still prevent an unauthorized party from submitting reports on another's behalf without their consent or knowledge.[89]

We are also proposing new registration requirements for independent surveyors and independent auditors under part 1090. These parties are not subject to registration requirements under part 80 but either submit survey plans and periodic reports to EPA under various provisions or perform attest engagements for regulated parties under part 80. We thus believe that requiring them to register would allow them to submit reports directly to EPA and thereby further streamline the process of getting the information to EPA.

Independent surveyors perform the compliance surveys and the proposed voluntary sampling oversight program (discussed in more detail in Section X). At present, there is only one known independent surveyor, performing four types of surveys under part 80. As previously noted, independent surveyors already submit survey reports to EPA, in a variety of ways. As discussed in Section VIII.C.8, we are proposing to have them register so that they may submit reports via EPA's reporting systems. Although this would create a small, new class of registrants (currently only one new submitter), we believe the burden of registering is outweighed by the simplicity and reliability of having surveyors utilizing the electronic reporting system to submit their information. This proposed change would allow us to more quickly publicly post in-use survey results.

As also previously noted, independent auditors already perform attest engagements on behalf of parties who are required to demonstrate compliance via reporting. Under part 80, the regulated party (*e.g.,* a gasoline manufacturer) is required to hire an auditor to perform the attest engagement, and the auditor gives the attest engagement to the party who then must submit it to EPA. In order to streamline the reporting process, we are proposing to require auditors to submit the attest engagement directly to EPA in a manner that ensures that the party for whom it was prepared is aware of the submission to EPA. To implement this change, auditors would register and associate with the party to submit reports directly to EPA. Association will ensure that the regulated party knows and agrees that the auditor is submitting their report.

3. What Is Included in Registration

Similar to existing provisions in part 80, registration under part 1090 would entail submitting general information about the company and its compliance-level activities (*e.g.,* facilities), including the address, activities engaged in, name of a responsible corporate officer (RCO), contact information, and location of records. Parties who submit reports to EPA must complete the steps required to set up an account with EPA's Central Data Exchange (CDX) and/or with OTAQ Registration (OTAQReg). Most regulated parties affected by this action have already registered and have already set up the necessary accounts.

4. Deadlines for Registration

We are proposing that registration must occur prior to a party engaging in any activity that requires registration, but we are not specifying a firm deadline for registration as we have in the past. Under part 80, new registrants had to register 60 days prior to engaging in activity. This timeframe remains a useful guideline, however, as we must be allowed an appropriate amount of time to process and activate registration-related requests. We are retaining the requirements from part 80 that updates to existing registration must occur within 30 days of the event requiring the change. We do not expect many new registrants and existing registrants would continue to be registered under part 1090. However, we do anticipate registering up to 100 attest auditors, one surveyor, and 50 third parties. We have docketed a detailed ICR supporting statement that describes the recordkeeping and reporting (including registration) burden in terms of number of parties, hours, and dollars.

Company and compliance-level (*e.g.,* facility) identification numbers already in use will remain valid under part 1090.

5. Proposed Approach to Changes in Ownership

In part 1090 we have sought to address some on-going issues and concerns regarding registration updates. For example, we have received feedback over the years from registrants that changes in ownership should be addressed more clearly in the registration section. Consequently, we

[89] During the rule development process, we received feedback suggesting that we should maintain the registration requirement and the itinerant RFG independent laboratory testing program; this issue is discussed in more detail in Section X.B.

are proposing provisions to clarify how a company may initiate a change in ownership for registration purposes. The proposed provisions on updating registrations for ownership change largely codify existing guidance provided to companies under part 80.

Proposed provisions in part 1090 clarify that companies would have to notify EPA of a change in ownership and, in cases requiring registration of a new company, complete registration prior to engaging in any activity requiring registration under part 1090. In the case of a change in ownership requiring an update to an existing registration, the company would need to complete the registration update within 30 days of the change. For any party that is a fuel or fuel additive manufacturer, the new owner would need to be in full compliance with any applicable part 79 registration requirements. Since part 1090 registration is needed in order to report and engage in credit transactions and comply with the fuel quality regulations, parties have great incentive to submit ownership change information to EPA as soon as it is available. We have received feedback from stakeholders who have told us that having a requirement that they submit ownership change information by a specific, advance deadline (*e.g.,* 60 days before the change in ownership occurs) is not workable due to how ownership changes are effectuated in the business world. Although we are not proposing a specific, advance deadline, we note that it typically takes some time for EPA to process a new registration and urge companies to attempt to submit materials as soon as possible and to consider that 60 days prior is a good guideline. Based on our experience with ownership changes under part 80, companies want EPA to activate registration changes for ownership changes in a timely manner to ensure that registrations are up-to-date and that the company can engage in credit generation, trading, and use as soon as practical. Often, these companies request a specific date for the ownership change to be reflected with respect to their registration. Because many ownership changes in the fuel quality programs are quite complicated and involve many facilities, in order for EPA to reasonably act on this type of registration update, we need adequate time to process registration changes.

We believe common ownership changes may include: Companies and/or facilities that are bought in their entirety by another party; companies and/or facilities whose majority owner changes; or a merger resulting in creation of a new company and/or facility. We are not proposing a specific list of documentation that parties may have to submit to support a change in ownership affecting their registration. What documentation, if any, is needed is highly situational. However, we do have experience with typical documentation submitted by parties that may be appropriate, and that may include: sale documentation or contract (portions may be claimed as CBI and redacted); Articles of Incorporation, Certificate of Incorporation, or Corporate Charter issued by a state; and/or other legal documents showing ownership (*e.g.,* deeds). Parties anticipating the need to update registration due to a change in ownership should contact EPA as soon as possible in order to discuss their unique situation.

6. Proposed Approach to Cancellation of Registration

We are proposing provisions regarding voluntary and involuntary cancellation of registration. Similar provisions exist for the RFS program in 40 CFR part 80, subpart M, and we believe they work well for both compliance and compliance assistance purposes; therefore, we are proposing to adopt them for part 1090.

Voluntary cancellation would be initiated by the registered party (*e.g.,* if the party's business changes and it no longer engages in an activity that requires registration).

Involuntary cancellation would be initiated by EPA, typically in cases where the party has failed to submit required reports or attest engagements, or for a prolonged period of inactivity. Specifically, involuntary cancellation may occur where:

- The party has not accessed its account or engaged in any registration or reporting activity within 24 months.
- The party has failed to comply with any registration requirements, such as updating needed information.
- The party has failed to submit any required notification or report within 30 days of the required submission date.
- The attest engagement has not been received within 30 days of the required submission date.
- The party fails to pay a penalty or to perform any requirements under the terms of a court order, administrative order, consent decree, or administrative settlement between the party and EPA.
- The party submits false or incomplete information.
- The party denies EPA access or prevents EPA from completing authorized activities under sections 114 or 208 of the CAA despite presenting a warrant or court order. This includes a failure to provide reasonable assistance.
- The party fails to keep or provide the records required by part 1090.
- The party otherwise circumvents the intent of the CAA or part 1090.

We would provide notification of our intention to cancel the party's registration and the registrant would have an opportunity to address any deficiencies identified in the notice (*e.g.,* to submit required reports) or to explain why no deficiency exists. If we do not receive missing reports within 14 days of notification, then the registration may be canceled without further notice. We believe it is important to have a procedure to keep registrations up-to-date and to ensure that parties perform activities required to maintain active registration.

We are proposing that in instances of willfulness or those in which public health, interest, or safety requires otherwise, EPA may deactivate the registration of the party without any notice to the party. In such cases, we will provide written notification to the RCO identifying the reason(s) EPA deactivated the registration of the party. We expect such situations to be extreme and rare and intend to follow the notice and response provisions described above in nearly all cases.

C. Reporting

1. Purpose of Reporting

We require reports from regulated parties for the following reasons: (1) To monitor compliance with standards necessary to protect human health and the environment; (2) to allow regulated parties to comply with average standards via the use of credits and credit trading systems; (3) to have accurate information to inform EPA decisions; and (4) to promote public transparency. Regulated parties submit various reports to EPA under both parts 79 and 80. Part 1090 updates and, in many cases simplifies, what must already be reported to EPA under part 80. As described further in this section, we are proposing to reduce the number of parameters to be tested and reported and, in some cases, to reduce the required frequency of reporting.

2. Who Must Report

The following parties would have to report under part 1090:

- Gasoline manufacturers
- Diesel manufacturers and ECA marine manufacturers
- Transmix Processors
- Oxygenate producers
- Certified butane blenders
- Certified pentane producers

- Certified pentane blenders
- Independent surveyors
- Auditors

As discussed earlier in this section, certain parties are required to register to receive company and compliance-level identification numbers for use on PTDs and for recordkeeping, although they would not have reporting requirements under part 1090. For example, parties involved in the manufacture and distribution of 500 ppm LM diesel fuel would register and receive company and compliance-level identification numbers to use on PTDs and records but would not submit reports under this part 1090.

3. What Is New With This Proposal

We are proposing to eliminate reporting of the following gasoline parameters that are currently collected under part 80 and no longer necessary under part 1090 to certify batches and demonstrate compliance with the RFG standards (discussed in more detail in Section V.A.2):

- Aromatics and the associated test method
- Olefins and the associated test method
- Methanol and the associated test method
- MTBE and the associated test method
- Ethanol and the associated test method
- ETBE and the associated test method
- TAME and the associated test method
- T-Butanol and the associated test method
- T50 and the associated test method
- T90 and the associated test method
- E200 and the associated test method
- E300 and the associated test method
- Toxics
- VOCs
- Exhaust Toxics Emission
- Other identifying information (*i.e.,* Batch Grade, lab waiver, Independent lab analysis requirement)

We are proposing to retain only four main parameters for gasoline reporting: Sulfur, benzene, RVP, and oxygenate type/content.[90] We believe the parameters we are proposing to eliminate from reporting, although once useful, are no longer needed in reports, as discussed in Section V.A.2. Removing these parameters would reduce compliance costs related to reporting, sampling, and testing, without sacrificing our goal of protecting human health and the environment. We are also proposing to simplify the annual, batch, and credit transactions reporting, which result in many fewer forms and data elements for respondents.

There are currently numerous reporting forms in use under part 80; we seek to simplify and reduce the number of forms under part 1090. Proposed reporting formats are available in the docket for this action and have also been included in the information collection request (ICR) described in Section XV.C.

4. Proposed Reporting Requirements for Gasoline Manufacturers

As previously discussed, we are transferring the current part 80 requirements for annual, batch, and credit transaction reporting for gasoline manufacturers to part 1090. We are proposing to: (1) Reduce the number of parameters and test methods to be reported under part 1090 as compared to part 80; and (2) simplify the method of reporting. The proposed reporting requirements for these parties includes the following:

- Annual compliance demonstration for sulfur, to include information about the total volume of gasoline produced or imported, the compliance sulfur value, summary information about sulfur credits owned, generated, retired, etc., and information about credit deficits. This information is like the information already required and submitted under part 80.
- Annual compliance demonstration for benzene, to include information about the total volume of gasoline produced or imported, the compliance benzene value, summary information benzene credits owned, generated, retired, etc., and information about credit deficits. This information is like the information already required and submitted under part 80.
- Batch reporting, including information about individual batches of gasoline, to include information about the date of production or import, the volume, the designation of the gasoline or BOB, the tested sulfur and benzene content of the batch, and the tested RVP for summer gasoline or BOB. The proposed regulations address reporting for a variety of gasoline products and reporting scenarios and explains reporting for specific scenarios, such as the reporting for blendstocks added by gasoline manufacturers to PCG by either the compliance by addition or compliance by subtraction method and reporting for blending of certified butane or pentane. We have prepared a technical memorandum and a detailed color-coded batch reporting summary table reflecting the information to be submitted for a variety of products. This information is available in the docket for this action and has been provided as an addendum to the ICR described in Section XV.C.
- Credit transaction reporting, including information about the generation, purchase, sale, retirement, etc. of sulfur and benzene credits. This information is like the information already required and submitted under part 80.
- Attest engagements. Under part 1090, there is a change to the method of submission of annual attest engagements. As discussed above, we are proposing to add independent auditors to the list of parties that can submit attest engagements, provided that they first register with EPA and are associated with a company. To ensure the party for whom the attest engagement is prepared is aware, we are proposing that the independent auditor and the company for whom they are preparing the report must associate within the registration system. The existing attest engagement requirements are sprinkled around part 80; this action would condense the existing requirements into a single subpart (subpart R). We are also proposing to align the submission of the attest engagements for the RFS program so that they would be submitted directly by the independent auditor and to include association, as well. We are aware that some regulated parties have expressed concern that they would not know if their attest engagement has been submitted by the auditor and would not be afforded time to review and respond to the auditor's findings. To address this concern, we are requesting comment from regulated parties on what information and required steps are needed prior to submission by the attest auditor. The attest engagement submission would require a description of the findings and the steps the regulated party will take to address remedial actions, but does not necessarily require the remedial action steps to all occur before submission. Attest engagements are discussed in detail in Section XII.B.

[90] For batches that are certified using the hand blend approach (discussed in more detail in Section VII.F), oxygenates typically would not be tested; however, gasoline manufacturers would report the type and amount of each oxygenate blended to make the hand blend. Manufacturers that certify batches of gasoline using a different approach would still need to test and report oxygenate content unless they know that the gasoline contains no oxygenate (*i.e.,* the gasoline is E0). Furthermore, in all cases, we would only require that gasoline manufacturers report the oxygenates added or tested for instead of reporting information for all potential oxygenates. We believe this would greatly simplify oxygenate reporting requirements compared to part 80.

5. Proposed Reporting Requirements for Gasoline Manufacturers That Recertify BOB for Different Type(s) and Amount(s) of Oxygenate

In order to implement the proposed optional provisions discussed in Section VII.G with respect to treatment of BOBs, we are proposing reporting requirements for gasoline manufacturers that recertify BOB for different types and amounts of oxygenate. When a person recertifies a BOB with less oxygenate than specified by the fuel manufacturer, they would be required to submit information about recertification activity on a batch level report and include any deficits incurred in their annual sulfur and benzene compliance report.[91] Credit transactions associated with re-certification of the BOB would also be reported. Similar to what is currently allowed under part 80 for certified butane and pentane blending, we are proposing to allow parties that recertify BOBs to include all volumes and deficits in a single reported batch of up to 30 days. This will help minimize the potential reporting burden associated with this requirement.

6. Proposed Reporting for Oxygenate Producers and Importers

We are proposing that oxygenate producers and importers must continue under part 1090 to submit batch reports providing information about the oxygenate they produce or import as already required under part 80. Reporting for oxygenate producers would be on a compliance-level (*e.g.,* facility) basis. The information to be submitted includes information about the oxygenate produced or imported, including the sulfur content of the batch and the test method used. For denatured ethanol, the report would specify whether the denaturant is certified ethanol denaturant or non-certified. The information contained in these reports does not differ from current part 80 reporting requirements, but the proposed regulation is designed to standardize the type and format of the information submitted.

7. Proposed Reporting for Certified Pentane Producers and Importers

We are proposing that certified pentane producers and importers submit batch reports that provide information about the certified pentane produced or imported, including the pentane, sulfur, and benzene content of each batch and the test methods used. The information contained in these reports does not differ from current part 80 reporting requirements, but the proposed regulation is designed to standardize the type and format of the information submitted.

8. Proposed Reporting by Diesel Manufacturers

We are proposing limited batch reporting for manufacturers of diesel fuel. Specifically, we are proposing that manufacturers of diesel fuel (excluding 500 LM from transmix) that test any batch found to exceed the applicable 15 ppm sulfur standard would report information about that batch. Batches that do not exceed the applicable 15 ppm sulfur standard would not be reported to EPA. The specific information proposed to be reported includes the company and facility identifier, the batch identifier, and the tested sulfur content in ppm, and test method used. Since diesel manufacturers are required to test their product for sulfur content and must retain information related to sampling and test results already, we believe the burden of reporting a relatively small number of batches found to exceed the applicable 15 ppm is small. We acknowledge that diesel sulfur batch reporting under 40 CFR part 80, subpart I, generally ended on September 1, 2014; however, the requirement to test and retain records related to sulfur content continues. We are proposing limited batch reporting because we believe it will assist us in our compliance oversight efforts and in ensuring that the human health and environmental benefits of the program are realized.

We also collect some information about diesel sulfur via the annual fuel manufacturer reports, required under part 79. The existing reports are limited in their contemporary value for several reasons. First, they require only information about highway diesel fuel and do not include NRLM diesel fuel. Second, they require information on a manufacturer level, rather than on a facility/refinery level and, therefore, are of limited use for compliance purposes. Third, the high/low/average sulfur values are collected as a volume percentage rather than in ppm, a throwback to the 1970s when diesel sulfur levels were not regulated and sulfur content was much higher. Our purpose in collecting this information at that time was to understand, on a high level, the general characteristics of fuel that may affect human health and the environment and to determine whether future regulation might be needed. The part 79 reports have historically collected the information to the extent known by the manufacturer. Although manufacturers of diesel fuel have been submitting the information, it is submitted in an inconsistent format. For example, we typically receive values expressed in ppm already, as the use of volume percent is no longer the preferred method.

We are proposing to transition diesel sulfur reporting from part 79 and move it entirely into part 1090 reporting forms. This transition includes reporting total volume and max/average sulfur results (using ppm as the unit of measure) by company ID and five-digit reporting ID (*i.e.,* facility ID).

9. Reports by Independent Surveyors

As previously discussed, we are proposing to remove the requirement for registration and submission of reports by independent laboratories and also proposing a requirement for registration and reporting by independent surveyors. The proposed registration requirement for independent surveyors are discussed in greater detail in Section X.A.2.d. For reporting purposes, an independent surveyor must submit plans, notifications, and quarterly survey reports to EPA electronically. The quarterly reports include information about retail outlets visited by the independent surveyor and the characteristics of the fuels samples and tested (*e.g.,* oxygenate type and amount, sulfur content, benzene content, etc.). Independent surveyors would also have an annual reporting requirement that addresses summary statistics and describes compliance rates and non-compliance issues. For the proposed national survey program, this type of information is already collected as part of the part 80 survey programs. Information collected under the proposed national sampling oversight program is like information already collected under the RFG independent laboratory testing program under part 80.

10. Deadlines for Reporting

We are proposing that the annual reports by independent surveyors must be submitted by March 31. We are retaining the existing deadlines for reports under part 80 for reports submitted under part 1090. Specifically:

- Annual compliance reports for sulfur and benzene would continue to be submitted by March 31 for the preceding compliance period (*e.g.,* reports covering the calendar year 2021 must be submitted to EPA by March 31, 2022).

[91] Parties that add more of the same type of oxygenate would not be expected to submit reports for those volumes. For example, under part 1090, if a party only blended 15 volume percent ethanol into a BOB that was specified for blending up to 10 volume percent ethanol, the blender would not submit reports.

• Batch reports would be submitted by March 31 for the preceding compliance period. This was previously the fourth quarter batch reporting due date. We are proposing to reduce the frequency of batch reporting that currently applies under part 80, going from quarterly to annually.

• Attest engagements would continue to be submitted by the independent auditor by June 1 for the preceding compliance period.

• Reports by independent surveyors would continue to be submitted quarterly on June 1 (covering January 1–March 31), September 1 (covering April 1–June 30), December 1 (covering July 1–September 30), and March 31 (covering October 1–December 31). Annual reports by independent surveyors must be submitted by March 31.

11. Proposed Reporting Forms

Proposed reporting formats are discussed in more detail in the technical memorandum covering batch reporting, available in the docket for this action, and in the ICR. The ICR includes actual proposed reporting instructions. Interested parties are urged to review these materials and provide feedback.

The information collected in the proposed reports should be familiar to existing registered and reporting parties. We have designed part 1090 and the proposed reports to address areas where reporting requirements were previously unclear or cumbersome and to reduce the existing reporting burden.

D. Product Transfer Documents (PTDs)

The general purpose and requirements for PTDs do not differ from the existing requirements in part 80. PTDs are documents generated in the normal course of business that provided a clear description of the product being transferred. Under part 1090, PTDs would still be required each time a person transfers title or custody to a product regulated under part 1090. The typical format of PTDs is not changed by this action—basic information including identification of the transferor/transferee, location of the transfer, volume and type of product, etc. remain familiar. As with existing part 80, commonly understood codes may be used by ''upstream parties'' and where a transfer is made to those other than truck carriers, retailers, or wholesale purchaser-consumers (WPCs). Transfers to truck carriers, retailers, or WPCs would require the specified, printed statement and product information rather than a code. As with existing part 80, PTDs would have to be kept by each transferor and transferee.

Part 1090 mostly consolidates the various PTD language requirements throughout part 80 into a single, consistent section to help bring uniformity to the PTD language across fuels, fuel additives, and regulated parties. This action would remove PTD language that is no longer needed and provide standard, updated language to address a variety of common products and situations. We are, however, proposing some minor modifications from the existing part 80 requirements.

We are proposing language to identify fuel covered by all known, specific exemptions (*e.g.,* R&D exemption, racing fuel exemption, etc.) in a more consistent manner. Part 80 only requires that exempt fuels be identified on PTDs as exempt and is inconsistent with its language requirements across the various part 80 fuel quality programs. We intend to make our PTD requirements more consistent so we are proposing a more prescriptive format for exempt fuels.

Under some programs in part 80, we have allowed parties to petition for alternative PTD language for some PTD requirements, but not for other PTD requirements. During the rule development process, several stakeholders highlighted that instances exist where our PTD requirements may conflict with other federal, state, or local PTD or identification requirements. In such cases, fuels, fuel additives, or regulated blendstocks could be identified with contradictory language that makes it difficult for parties in the fuel distribution system to comply with all applicable federal, state, and local requirements. To address these potential issues, we are also proposing to allow parties to seek approval for alternative PTD language for all proposed PTD language requirements. Based on experience implementing part 80, we do not anticipate that many parties will request alternative PTD language.

E. Recordkeeping

We are maintaining the record retention requirements in part 80. All parties that keep records under part 80 would continue to keep the same or similar records under part 1090. Records that must be maintained are those already familiar to regulated parties, including: Information that supports the registration and reports submitted to EPA, information related to waivers (such as R&D programs), copies of PTDs, sampling and test results and related laboratory documents, information about credit transactions for sulfur and benzene, and information related to compliance calculations. We anticipate that the number of records retained will decrease under part 1090, in large part because the number of sampled, tested, and reported parameters for gasoline and certain regulated blendstocks would decrease.

F. Rounding

The standards and compliance requirements under part 1090 require extensive use of numbers to quantify fuel parameters and fuel volumes, along with numerous occasions to calculate new quantities to properly document compliance. A rigorous compliance demonstration depends on properly managing precision and significant figures in recorded values and calculations. Part 80 addresses rounding and precision by simply instructing regulated parties to round test results to the nearest unit of significant digits specified in the applicable fuel standard as described in ASTM E29. We are proposing a much broader and consistent approach in part 1090. We codified a standard approach to rounding in 40 CFR 1065.20 that is consistent with ASTM E29. We are proposing to apply this rounding protocol to all recorded values under part 1090.

The action includes additional specifications for calculating and recording numerical values. First, we are proposing to specify that rounding intermediate values in a calculation is not appropriate. This principle is intended to preserve the accuracy and precision until the calculations reach a final result, at which point the final result can be rounded to the appropriate number of decimal places or significant figures. We recognize that intermediate values must sometimes be transcribed (such as from an analyzer to a spreadsheet), which cannot be done with infinite precision. We are therefore proposing that intermediate values should be recorded and used with full precision, except that rounding is permissible if the value retains at least six significant digits. This is not a proposal to require six significant digits for all recorded values. Rather, if an intermediate quantity with more than six significant digits needs to be transcribed, parties may use the specified rounding protocol to eliminate the additional digits. Also note that we generally allow for using measurement devices that incorporate proper internal rounding protocols to report test results.

Second, multiplying a value by a percentage must keep the precision of the original value. This is equivalent to considering the specified percentage to be infinitely precise. For example, calculating 1 percent or 1.0 percent of 1,234 would result in a value of 12.34.

This is relevant for calculating an averaging standard for benzene. Fuel volume is multiplied by exactly 0.62 percent, rather than using a value of 0.624 (which rounds down to 0.62) before multiplying by fuel volume.

G. Certification and Designation of Batches

The certification and designation of batches of fuels, fuel additives, and regulated blendstocks are crucial elements to ensuring that fuels, fuel additives, and regulated blendstocks meet our fuel quality standards and aid in the distribution of such products. Certification is the process where a manufacturer or producer demonstrates that their product meets EPA's standards. Designation is the identification of a batch (typically on PTDs) as meeting specific requirements for a category of fuel (*e.g.,* summer RFG), fuel additive (*e.g.,* diesel fuel additives), or regulated blendstocks (*e.g.,* certified butane or certified pentane). Parties throughout the fuel distribution system rely on designations to appropriately transport, store, dispense, and sell fuels. Part 80 generally has provisions for certification and designation of products separately for each program. Part 1090 consolidates these various certification and designation procedures into a single set of provisions.

Regarding certification, most of the certification procedures for fuels, fuel additives, and regulated blendstocks for part 80 are outlined in guidance. We are proposing in part 1090 to incorporate such guidance into the regulations and establishes a clear process to certify batches. The proposed regulations include the following four steps:

- Registration prior to the production of fuel, fuel additive, or regulated blendstock (if required).
- Sampling and testing the fuel, fuel additive, or regulated blendstock to demonstrate that the product meets applicable quality standards.
- Assignment of a batch identification number (if required).
- Designation of the batch as appropriate.

We believe these four steps are consistent with how parties currently certify products under part 80. These requirements satisfy CAA section 211(k)(4) describing certification procedures for RFG.

Regarding designation, for gasoline and gasoline-related additives and regulated blendstocks, we are proposing to substantially modify the designation requirements for these products. Most of these proposed changes reflect the removal of the Complex Model for use in the certification of batches of RFG and the harmonization of the RFG and CG programs. Many of the prior designations to segregate RFG and CG are no longer necessary, so we are proposing to remove those designations. Additionally, we are proposing more flexible redesignation provisions for distributors of gasoline. These proposed provisions largely reflect the proposed streamlining of the RFG program and the more fungible nature that would result.

Distributors of gasoline would be allowed to redesignate winter RFG/RBOB to winter CG/CBOB (and vice versa) and summer gasoline from a more stringent RVP standard to a less stringent RVP standard without recertification (*e.g.,* from summer RFG meeting the 7.4 psi RVP standard to 9.0 psi RVP summer CG). Any person that mixes summer gasoline with summer or winter gasoline that has a different RVP designation must either designate the resulting mixture as meeting the least stringent RVP designation of any batch in the blend or determine the RVP of the mixture and designate the new batch accurately to reflect the RVP of the gasoline as described under this section. When transitioning from winter to summer gasoline, parties are not required to test the RVP but must exercise good engineering judgement to assure that the gasoline meets the applicable RVP standard.

We are also making it clear that parties can redesignate California gasoline that meets CARB standards without recertification, as explained in more detail in Section VI.A. We believe these flexibilities will help maximize the fungibility of gasoline.

For diesel fuel, diesel additives, and diesel regulated blendstocks, we are largely proposing to maintain the part 80 designation requirements. We are, however, proposing two notable changes. First, we are proposing a more flexible designation scheme for distillate fuels certified to meet ULSD standards. The intent of the proposed regulations is to ensure that fuels that meet the ULSD standards could be designated as necessary to be used as home heating oil, motor vehicle, nonroad, locomotive, or marine diesel fuel (defined as MVNLRM diesel fuel in part 80), or IMO marine fuel. This change would allow parties to make sure that fuels are designated appropriately throughout the distribution system.[92] Second, similarly to gasoline, we are proposing to allow parties to redesignate California diesel fuel that meets the ULSD standards without recertification. We believe the proposed designation changes for diesel fuel would help maximize the fungibility of distillate fuels that meet the ULSD standards.

We seek comment on the proposed certification and designation provisions.

IX. Sampling, Testing, and Retention Requirements

Our fuel quality programs consists of performance standards and compliance provisions that require measurement of various fuel parameters. These measurements in turn rely on specified procedures contained in part 80. We are transferring these same test procedures from part 80 into part 1090. We are also reorganizing the testing provisions in part 1090 and proposing several clarifications to reflect current best practices. We are further consolidating test procedures for gasoline and diesel fuel in some cases. This section highlights the proposed changes relative to what currently applies under part 80.[93]

A. Overview and Scope of Testing

Part 80 requires gasoline manufacturers to measure 11 complex model parameters. This action would significantly reduce the number of parameters that gasoline manufacturers must measure for determining compliance with the fuel standards. Part 1090 would require fuel manufacturers to measure the sulfur and benzene content of every batch of gasoline and to measure the RVP of every batch of summer gasoline. Fuel manufacturers will also be required to sample and test for oxygenates in specific situations when EPA believes it could be difficult for the fuel manufacturer to assure compliance with oxygenate standards without sampling and testing the gasoline. For gasoline produced at a blending manufacturing facility or a transmix processing facility, we are retaining the part 80 requirement to test gasoline for distillation parameters. The distillation testing provides a distillation curve that shows how much of the gasoline has flashed off as the temperature of the sample is increased. This curve can provide some confirmation that the blended product has a distillation profile that is generally

[92] This action does not address how these fuels are accounted for inclusion in obligated parties' RVO calculations under the RFS program. We recently finalized changes to part 80 to account for the redesignation of distillate fuels meeting the ULSD standards (see 85 FR 7054–7057, February 6, 2020).

[93] The updated procedures are described in greater detail in the technical memorandum, ''Technical Issues Related to Streamlining Measurement Procedures for 40 CFR part 1090,'' available in the docket for this action.

consistent with gasoline meeting the substantially similar requirements of the CAA. The results of the distillation testing would not be required to be reported, but instead would be retained at the facility to provide additional data that can be reviewed in the event of complaints about potential compliance or performance issues. We understand that distillation parameters are effectively a condition of merchantability of gasoline in the U.S., so such testing is already being performed by fuel manufacturers.

Part 80 requires RFG refiners to obtain test results for all parameters required to determine compliance. Part 80 also requires CG refiners to measure sulfur content in gasoline and diesel fuel prior to introduction into commerce. Requiring measurement before shipping from the refinery provides assurance of compliance prior to the fuel being mixed and commingled in the fungible distribution system and potentially even consumed. Unlike many regulatory situations where it is possible to go back after the fact and correct the noncompliance, this is difficult if not impossible in most situations for fuel once it has left the fuel manufacturing facility. Consistent with part 80, we are proposing to require all gasoline manufacturers to obtain test results for sulfur and RVP (during the summer months) before shipping gasoline from the fuel manufacturing facility. Part 80 requires RFG refiners to obtain test results for benzene before shipping gasoline, but does not require CG refiners to obtain these results before shipping from the refinery. We are not proposing to require gasoline manufacturers to test for benzene before shipping gasoline from the fuel manufacturing facility, but we are seeking comment on whether this would be appropriate. Some fuel manufacturers have suggested that being able to test after shipping product from the fuel manufacturing facility would make the testing substantially less burdensome. Taking time to perform testing and verify results can cause delays in managing the flow of producing and shipping product. We are not revising fuel requirements that impose the obligation to test fuels before shipping from the fuel manufacturing facility. With the simplified test requirements of the streamlined program, we believe there is no justification to avoid the compliance-assurance advantage of individual batch measurements whenever that is possible. However, we seek comment on this and what provisions could be put in place in its absence to provide assurance that the fuel met the standards in the absence of testing. For example, we could require fuel manufacturers to keep records documenting their engineering assessment that supports a conclusion that the fuel meets applicable standards despite the absence of test results. Such an assessment would need to account for varying refinery processes, maintenance or other system changes, personnel changes, source and quality of any blending components, and any other relevant variables.

We are maintaining exceptions to testing under current waivers that do not require measurement of fuel properties prior to shipment. Currently 40 CFR 80.65, 80.581, and 80.1630 describe separate programs for in-line blending configurations to qualify for a waiver from the test-before-ship requirements as part of an approved process with annual quality audits. We are transferring these existing provisions that allow for the in-line blending waiver only for shipment configurations because they do not allow for conventional batch testing. For example, sending finished fuel directly into a pipeline or a marine vessel generally does not allow for conventional batch measurement, so we expect refiners to continue to rely on the in-line blending waiver for these shipping arrangements. Refiners are similarly prevented from timely batch measurements if they create fuel batches that are greater than they can contain in a single storage tank. We are therefore transferring these existing part 80 waiver provisions for in-line blending also to operations that involve these over-sized batches to part 1090. The transferred provisions, when effective, would mean that the restricted application of the in-line blending waiver does not prevent refiners from using automated in-line sampling procedures as described in ASTM D4177 for measuring fuel parameters for a given batch.

B. Handling and Testing Samples

1. Collecting and Preparing Samples for Testing

Accurate test results are dependent on the sample being representative of the fuel batch. We are transferring the sampling procedures and demonstrating homogeneity of fuel samples that are currently specified in 40 CFR 80.8. This provision generally specifies procedures for manual sampling as described in ASTM D4057 or automated in-line sampling as described in ASTM D4177. The additional procedures for sampling related to gasoline RVP as described in ASTM D5842 are also being transferred to part 1090.

Some of the current regulations in part 80 related to sample collection, however, do not adequately address sampling procedures because they do not provide the necessary specifications for testing. We have addressed some of those omissions through guidance documents published over the years.[94] We are also proposing to add numerous minor clarifications and adjustments to the regulatory text to reflect current best sampling practices.

2. Sample Preparation for BOB Testing

Section VII describes the proposed new approach for oxygenate accounting for gasoline that would allow parties that either produce or import BOB and instruct downstream blenders to add oxygenates to meet sampling requirements by blending oxygenates into a BOB sample to represent the final blended fuel—a ''hand blend.'' [95] This would involve preparing each fuel sample by adding oxygenates to the BOB sample in a way that corresponds to instructions to downstream blenders for the sampled batch of fuel.

Preparing the hand blend sample involves decisions about which samples to use for blending. For example, three tested BOB samples may be available to prepare the hand blend. Also, a single hand blend might represent different types and amounts of oxygenate, as reflected in the blending instructions for downstream parties. We are proposing to address these examples of discretion in the specified procedures by requiring that the hand blend represent a worst-case test condition. In the case of sulfur measurements from multiple samples to represent a batch of BOB, this requires further testing with the sample that has the highest sulfur measurement.

Winter gasoline would need to be blended with the lowest specified percentage of any oxygenate type given in the instructions for downstream blending. For example, if blending instructions specify an 8 percent isobutanol blend in addition to E10 and E15, the hand blend would need to be an 8 percent isobutanol blend. This reflects the fact that dilution is the primary effect of blending on fuel parameters other than RVP. A different

[94] See ''Consolidated List of Reformulated Gasoline and Anti-Dumping Questions and Answers: July 1, 1994 through November 10, 1997,'' EPA–420–R–03–009, July 2003.

[95] The regulations at 40 CFR 80.69 and 80.101 practically limits this practice to RBOB. As discussed in Section VII, we are proposing to make it more practical for all fuel manufacturers of BOB to account for the addition of oxygenate added downstream. Part 80 does not currently specify preparation procedures for hand blends.

approach is necessary to properly select the type and amount of oxygenate for hand blending in summer gasoline. Under this proposal, summer gasoline would need to be blended with the lowest specified percentage of ethanol given in the instructions for downstream blending (*i.e.,* blend for E10 if the instructions identify E10 and E15 for downstream blending, even if the blending instructions include an option to blend with a lower percentage of a different oxygenate).

3. Sample Retention

Part 80 currently describes sample-retention requirements in multiple provisions. Stakeholders have pointed out that there is ambiguity about whether the regulation requires sample retention for 30 or 90 days. We are proposing to require all fuel manufacturers to keep fuel samples used to demonstrate compliance with all applicable standards for 30 days, except for blending manufacturers.

A longer retention time applies for blending manufacturers since these manufacturers typically have less control over the quality of the blendstocks they use to produce gasoline, which can cause decreased fuel quality without robust controls. Crude refineries typically distribute fuels through a distribution network with multiple levels of control to ensure fuel quality (*e.g.,* through pipelines that have strict product specifications prior to injection) while blending manufacturers can make fuels on a more ad hoc basis (*e.g.,* in a tanker truck). We therefore believe it is appropriate to require a longer retention period to help trace potential issues with fuel quality. We are proposing a minimum retention period of 120 days for fuel samples that blending manufacturers use for testing to demonstrate compliance with gasoline or diesel fuel standards.

For testing BOB and hand blended samples of oxygenated gasoline as described in Section IX.C, the sample-retention requirements apply for both the BOB sample and the hand-blended sample used to demonstrate compliance. Gasoline manufacturers producing BOB have expressed a concern that space limitations would make it difficult to store both the BOB sample and the hand-blended sample used to demonstrate compliance. We are therefore proposing that gasoline manufacturers do not need to keep each hand-blended sample; they would instead need to keep a DFE sample to allow them to create new hand-blended samples corresponding to each BOB sample. With this approach, a single DFE sample might be available for blending with multiple BOB samples.

C. Measurement Procedures

Demonstrating compliance with fuel quality standards requires a wide range of measurement procedures. Our fuel quality regulations rely heavily on standardized test methods published by voluntary consensus standards bodies such as ASTM International. As described below, the proposed regulations in part 1090 reference certain measurement procedures, in most cases with provisions allowing for using alternative procedures, including updated versions of referenced procedures in some instances.

1. Procedures for Gasoline Surveys

Testing for gasoline surveys is intended to provide a consistent indication of in-use fuel parameters over time. Testing will generally be performed by a selected set of test labs to represent the range of fuels in distribution over time.

We are proposing to require that survey measurements rely on the referee procedures identified under PBMS, where applicable. The following procedures apply for additional parameters:

- ASTM D5769 for aromatic content
- ASTM D6550 for olefin content
- ASTM D86 for T50 and T90 distillation points

We request comment on the specified procedures for measuring the various fuel parameters for surveys.

2. Procedures To Determine Cetane Index for Diesel Fuel

Part 80 and the Clean Air Act establishes a cetane index standard at or above 40 for diesel fuel used with motor vehicles and nonroad equipment. (See 40 CFR 80.520(a)(2)). Part 80 also references ASTM D976 as the procedure for determining cetane index in diesel fuel. During the development of this action, industry stakeholders advocated for ASTM D4737 as a more robust method that relies on additional fuel parameters for calculating cetane index. In response to stakeholder request, we are proposing that either of the referenced ASTM procedures are acceptable for determining cetane index.

Both of the referenced ASTM procedures are valid for the full range of distillate fuels qualifying as diesel fuel. However, these procedures rely on fuel characteristics for distillate fuel and they are therefore not appropriate for biodiesel. The chemical make-up of pure biodiesel causes it to inherently have higher cetane values and no aromatic content. With no suitable measurement procedure for cetane index in biodiesel, and no concern that biodiesel will fail to meet the cetane index standard or have greater than 35 percent aromatics, we are proposing to exempt biodiesel from testing to verify compliance with the cetane index or aromatic content requirement for diesel fuel.

Additionally, EPA is aware of industry efforts aimed at developing new test methods for determining cetane index and similar parameters related to cetane number. We request comment on incorporating new measurement procedures into part 1090 as an alternative means of demonstrating compliance with the cetane index standard. In particular, we request comment on quantitative correlations between the new procedures with the existing procedures used to determine cetane index. Where appropriate, these comments should address whether such quantitative correlations depend on fuel formulations of properties that may be more or less prevalent than in the past.

3. Performance-Based Measurement System

EPA adopted the Performance-Based Measurement System (PBMS) that establishes objective criteria for qualifying laboratories and measurement procedures (see §§ 80.46 and 80.47). Our fuel quality regulations specify referee test methods for several fuel parameters and define precision and accuracy criteria so laboratories can demonstrate that they qualify their equipment for using the referee procedure, or for using alternative procedures. Precision and accuracy criteria apply for initial qualification, and for ongoing quality checks.

Part 80 includes a specified date for laboratories to omit initial qualification testing if they have been using the specified referee procedure for a given parameter. We are proposing to broaden this approach in part 1090 by allowing laboratories to omit initial qualification testing if they are using the specified referee test procedure. This approach treats all laboratories the same. Since the ongoing quality checks apply for laboratories using these procedures, the laboratories will still be demonstrating that they are properly performing these measurement procedures.

a. Scope

We have received questions on the applicability of PBMS requirements beyond the predominant scenario of testing fuel at a refinery. The PBMS provisions for measuring specified fuel parameters apply to all parties and at all

points in the fuel distribution system. PBMS provisions also apply for batch testing for compliance, and for quality audits such as what is required for in-line blending waivers, for test waivers for truck and rail imports, and for blending certified butane and pentane into PCG. Any other approach would be inconsistent with PBMS and would create an unlevel playing field for different market participants.

b. Referee Procedures

We are transferring the same referee procedures for part 1090 that currently apply under part 80, subject to the following proposed exceptions and clarifications.

First, we are proposing to change the designated referee procedure for measuring benzene in gasoline from ASTM D3606 to ASTM D5769. We believe ASTM D5769 is as a superior procedure because measurements involve little or no interference from ethanol blended into gasoline. In contrast, ASTM D3606 has interference effects from ethanol that require careful work to adjust for that interference. Since ASTM D3606 is the referee procedure for measuring benzene in gasoline under part 80, we are proposing to waive requirements to initially qualify testing with ASTM D3606 as an alternative procedure. We believe the ongoing PBMS quality demonstrations are sufficient to demonstrate proper precision and accuracy using ASTM D3606.

Second, we are proposing to remove measurement of aromatic content in diesel fuel from the PBMS protocol. We are not proposing to require aromatic testing for every batch of diesel fuel. As a result, we believe the PBMS protocols for referee procedures, qualifying alternative procedures, and ongoing quality testing are no longer appropriate. We are instead proposing to simply specify that ASTM D1319 and ASTM D5186 are acceptable procedures for measuring aromatic content in diesel fuel and allowing for alternative procedures that correlate with either of these specified procedures.

Part 80 specifies ASTM D6667 as the referee procedure for measuring sulfur in butane. We are proposing to specify the same referee procedure (and precision and accuracy criteria) for measuring sulfur in pentane.

We have also received questions on the applicability of PBMS to oxygenates used in gasoline. We have always intended for the PBMS requirements to apply for testing oxygenates in the same way that test requirements apply for testing gasoline. Accordingly, we are clarifying in part 1090 that oxygenates, including denatured fuel ethanol, are subject to PBMS requirements for all testing under part 1090 in the same way that these requirements apply for testing gasoline. This includes the protocol for qualifying alternative test procedures and the requirements for ongoing quality testing.

c. Updated Versions of Referenced Procedures

Part 80 currently references specific published versions of the various test procedures for measuring fuel parameters. These specific references do not automatically change with periodic updates to those procedures from the publishing organization, which makes it difficult for us to keep the regulations current as the industry continues to improve measurement procedures. To maintain the integrity of the PBMS protocol while allowing for the regulations to remain current with evolving industry practices, we are proposing that laboratories may use updated versions of referee procedures or qualified alternative procedures without our prior approval, as long as the updated version has published repeatability and/or reproducibility that is the same as or better than the version referenced in part 1090.

A similar approach applies for using an updated method of a referee procedure to qualify alternative procedures. Laboratories wanting to do this must first get our approval. We would expect to approve such requests based on a demonstration that the repeatability and reproducibility are the same as or better than the referenced procedure, but we are proposing to establish EPA's approval role to the extent the updated version of the referee procedure is used to qualify new alternative procedures. This interaction will also help us identify instances where we should consider updating the regulation to rely on the latest available procedures.

d. Criteria and Methods for Qualifying Procedures

The precision and accuracy criteria from part 80 are migrating to part 1090 with two exceptions. First, we are proposing to specify precision and accuracy criteria based on the most recently published repeatability values from ASTM D2622 for measuring sulfur in 500 ppm LM diesel fuel and ECA marine fuel. Second, we are proposing to specify precision and accuracy criteria for gasoline benzene based on the most recently published reproducibility values from ASTM D5769 instead of ASTM D3606. The published reproducibility for ASTM D5769 is slightly higher than for ASTM D3606, which means that it allows for a slightly more accommodating approach for qualifying alternative procedures.

We are proposing to transfer part 80 requirements for calculating precision and accuracy criteria for diesel sulfur based on calculated values for sulfur concentrations at fixed values to represent compliance at the standard. This would allow for a fixed criterion for testing all fuel samples. Selecting a test fuel with very low sulfur would not be meaningful, since it is not reasonable to compare such small quantities of measured sulfur to precision and accuracy criteria that are keyed to the standard. As a result, we are simply transferring the same specified minimum sulfur values for measuring sulfur in all the different types of diesel fuel. This becomes problematic for measuring sulfur in neat biodiesel, since it has inherently low sulfur concentrations. We would expect testing to qualify methods or to perform ongoing quality checks with neat biodiesel to include doping the fuel with enough diesel fuel to meet the minimum sulfur specification.

We are proposing to specify that precision and accuracy criteria for all fuel parameters other than sulfur are to be determined based on the actual value of the tested fuel. For example, for precision testing to qualify an alternative method, this would be based on an average value from the 20 tests (or more) used to evaluate precision.

We are also proposing that the between-methods-repeatability, R_{xy}, for qualifying alternative procedures for method-defined parameters using non-VCSB methods must be at or below 75 percent of the reproducibility of the designated referee procedure. This is an increase from the 70 percent value specified in 40 CFR 80.47. The increase in the specified value for the R_{xy} criterion is based on the observation that it may be mathematically impossible to achieve a 30 percent improvement over the repeatability of the designated referee procedure. We are not aware of anyone seeking to use a non-VCSB method for fuel-defined procedures, but we want to continue to allow this to be a viable option. We request comment on the appropriateness of the proposed value of 75 percent for the R_{xy} criterion.

e. Ongoing Testing for Statistical Quality Control

We are further transferring the statistical quality control procedures established under 40 CFR 80.47 to part 1090. However, by rewriting these

procedures in their own section, the proposed provisions may clarify some points that were previously subject to differing interpretations. We request comment on the proposed rewrite of the statistical quality control procedures.

X. Proposed Third-Party Survey Provisions

Third-party verification plays an important role in overseeing compliance with our fuel quality programs under the existing part 80. One key element to our existing third-party oversight regime are in-use retail level surveys. An advantage of retail survey programs is that they target fuel quality at the point the fuel is dispensed from a retail outlet. Under part 80, we have four in-use survey programs that primarily focus on RFG and RFG areas, ethanol content, E15 labeling, and ULSD sulfur levels, which are tracked nationally. For the most part, however, we have little or no other retail level information under part 80 for CG, which constitutes about 70 percent of the national gasoline fuel pool. We are proposing a national survey program in part 1090 that would consolidate the four programs into a single national survey in-use retail program, thereby reducing costs, while at the same time expanding the benefits of the survey program nationwide. When finalized, the part 1090 survey would build upon the existing in-use survey provisions, leveraging independent third-parties to a greater extent to ensure that compliant fuels are used in vehicles and engines in exchange for allowing fuel manufacturers greater flexibility to account for oxygenates added downstream in their annual compliance demonstrations,[96] and reducing the number of fuel parameters that fuel manufacturers need to be test and report.

Part 1090 includes two survey programs: a national survey program of retail outlets that offer gasoline and diesel to ensure that in-use standards are met, and a voluntary national sampling and testing oversight program that is intended to help ensure that gasoline manufacturers collect samples for testing in a consistent manner for purposes of compliance with applicable standards and thus, maintain the integrity of our fuel quality program. This section discusses both proposed programs in detail.

A. National Survey Program

As previously explained, we are proposing provisions for a nationwide survey of in-use gasoline and diesel fuel that is intended to ensure that gasoline and diesel fuel meet our applicable fuel quality standards when dispensed into gasoline- and diesel-fueled engines. We have used survey programs to great effect under the existing part 80 regulations. Table X.A–1 outlines the four survey programs currently in part 80 and describes the geographic scope, parties that participate in the survey program, and the estimated sample size.

TABLE X.A–1—EXISTING SURVEY PROGRAMS IN PART 80

Program	Regulation citation	Geographic scope	Who participates	Minimum sample
RFG Survey	§ 80.68	RFG Areas	RFG Refiners	4,500
RFG Ethanol Survey.	§ 80.69(a)(11)	RFG Areas	RFG Refiners	4,500
ULSD Survey	§ 80.613(e)	Nationwide, on-highway diesel stations.	Anyone	1,800
E15 Survey	§ 80.1502	Nationwide gasoline stations	E15 fuel and fuel additive manufacturers.	7,500

1. Background

We have historically used survey programs to provide flexibilities in fuel quality programs that we administer, which allows regulated parties to more efficiently meet our fuel quality standards. For example, we provided RFG refiners with the option of complying with RFG requirements on an average basis by demonstrating that RFG meets the applicable in-use oxygen content and NO_X, toxics, and summertime VOC performance at retail stations. By being able to rely on an in-use survey at the retail level to verify overall compliance, the regulations thus allow RFG refiners considerable flexibility in their day-to-day operations to produce fuel at the lowest cost. The norm for over 20 years has thus been that RFG refiners and importers produce a sub-octane, oxygenate-free RBOB that is distributed throughout the distribution system to which ethanol is added at downstream terminals. The retail survey then allows for verification that the RFG standards are met in-use. Since most RFG areas are supplied by multiple refiners, we allowed RFG refiners and importers to consolidate resources to establish a survey to demonstrate that RFG standards were met for RFG areas on average.

Additionally, in order to discourage misfueling of vehicles and engines, we have historically imposed pump labeling requirements at the retail level. In order to provide oversight of the thousands of retail stations, we also currently have provisions for a retail outlet survey to ensure that fuel dispensers are labeled appropriately (*e.g.,* E15 programs). A statistically representative sample of retail outlet fuel dispensers gathered through a survey helps inform responsible parties and EPA whether labeling requirements are being met without having to impose direct costs on the retail outlet to demonstrate compliance.

The focus of much of our current compliance oversight has been on parties that manufacture fuels at crude refineries with provisions that then attempt to ensure that the fuel quality as measured at the crude refinery is maintained all the way to retail. What happens at the crude refinery has historically been and continues to be the greatest factor as to whether a fuel is ultimately compliant. However, as the transportation fuel market has continued to evolve and parties at all locations downstream of refineries (*e.g.,* pipeline, terminal, retail) are now increasingly engaged in the process of producing the finished fuel (*i.e.,* adding ethanol or gasoline blendstocks into PCG, or adding biodiesel into diesel fuel), it has likewise become more important to not only receive information from the manufacturers of gasoline and diesel fuel at the start of the process, but also from the end of the process—at retail level—to ensure fuel quality standards are met. In the past this was mostly necessary just for RFG to ensure that the oxygenate was in fact

[96] See Section VII.F.

added to the refinery-certified RBOB downstream and the RFG standards were met. However, now that essentially all gasoline has ethanol added downstream to a refinery-produced and/or certified CBOB and many downstream parties are taking actions that can impact fuel quality, all in-use gasoline could benefit from a retail survey. Without it we would not propose the changes discussed in Section VII.F to allow refiners and importers to account for the downstream addition of ethanol in their compliance calculations. Consequently, we are proposing to extend the retail survey that has been applicable for over 20 years in RFG areas nationwide to all gasoline. The proposed national in-use gasoline survey would provide EPA with the data necessary to ensure that in-use gasoline is in fact blended with ethanol as claimed by the gasoline manufacturer, meets our gasoline standards, and continues to meet RFG and anti-dumping statutory requirements. An in-use survey would also enable EPA to provide compliance flexibility to CG refiners and importers similar to RFG refiners and importers.

There are no associated overall increased costs or compliance burden for the proposed expansion of the scope of the survey to all CG. As discussed in Section V.A.2.c, we are proposing a substantial reduction in sampling and testing requirements on gasoline refiners and importers at the refinery/import facility by removing the requirement for the certification of gasoline using the Complex Model. In its place, we are proposing requirements for refiners and importers to test for just sulfur, benzene, RVP in the summer, and oxygenates.

2. Proposed National Survey Program

a. Consolidation and Scope

We are proposing to consolidate the existing four in-use survey programs outlined in Table X.A–1 into a single national survey program. We believe the expanded scope of gasoline samples tested nationwide would help us ensure fuel quality oversight and compliance with our applicable fuel quality standards. This would also allow for providing compliance flexibility for CG refiners and importers to account for oxygenate (as discussed in Section VII.F). As previously explained, the ULSD and E15 survey programs are national surveys of retail stations but only test for sulfur in diesel fuel and ethanol content and RVP in the summer. On the other hand, the RFG survey and RFG ethanol survey are limited to RFG areas but test for the full suite of Complex Model fuel parameters. We believe there is technical support for allowing a survey program to collect a sample that satisfies multiple survey requirements (*i.e.,* as long as retail stations are identified using sound selection procedures, there is no reason an independent surveyor could not obtain both a gasoline and a diesel fuel sample to satisfy all applicable survey program requirements).

The main benefit to stakeholders of consolidation of the current four survey programs into a single program is a substantial reduction in sample size. Currently, the four survey programs require industry participants to contract for over 18,000 fuel samples collected nationwide (see Table X.A–1 above). As further discussed in Section X.A.2.c, we are proposing that the required sample size of our fuels survey programs could be reduced to less than 7,000 retail outlets sampled through consolidation. Since the largest expense in retail surveying is the costs to collect and ship a sample from a retail station, reducing the sample size from more than 18,000 to less than 7,000 would substantially decrease the costs of the program.

The main benefit to EPA is the expanded scope of testing for regulated fuel parameters to all fuel nationwide. Under the existing program, the RFG survey programs test approximately 30 percent of the national gasoline pool for the entire set of Complex Model fuel parameters, while in the nationwide E15 survey, only ethanol content year-round and RVP for E15 samples in the summer are tested.

In addition to consolidating the four survey programs into a single, nationwide program, we are proposing that all gasoline samples would be tested for sulfur, benzene, RVP (in the summer), and oxygenates. A statistically determined subset of the national gasoline sample would be tested for the rest of the Complex Model fuel parameters to allow us to verify that gasoline continues to meet CAA section 211(k) requirements. The survey would continue to ensure E15 pump labeling compliance at retail stations. For diesel, the survey would still test diesel samples for sulfur. We seek comment on the proposed consolidation of the four part 80 survey programs and the proposed expanded scope of the national survey program.

b. Survey Participation

We are not proposing any revisions to the existing survey for fuel and fuel additive manufacturers that make E15 or ethanol for use in making E15, which is the only one of the current surveys that is mandatory. Other gasoline manufacturers would need to participate in the national survey program if they wanted to account for oxygenate added downstream. Under part 80, the RFG regulations impose a similar survey requirement on RFG refiners and importers that account for oxygenate in compliance calculations (see 40 CFR 80.69) and since we are proposing to allow this flexibility for manufacturers of CG, we are proposing to impose a similar survey requirement. We believe that monitoring in-use sulfur, benzene, and oxygenate content is necessary to allow this flexibility for all gasoline manufacturers because without in-use verification from a national survey, there would be no oversight on whether gasoline manufacturers claimed credit for oxygenate that was ultimately not blended.

Under part 1090, parties that participate in the survey would have an affirmative defense for downstream violations of our applicable fuel quality standards. Under part 80, we have provided an affirmative defense for upstream parties that participate in survey programs to ensure downstream compliance for the ULSD survey. We are extending this affirmative defense for any party that participates in the national survey program to help establish a defense against downstream diesel sulfur, gasoline sulfur, gasoline RVP, and E15 misfueling violations in part 1090. We believe that parties that are part of the ULSD distribution system that participate in the part 80 ULSD survey program would continue to participate in the national survey program as well as other parties in the gasoline distribution system that wish to use the survey to help establish affirmative defenses against downstream violations.

Under the E15 partial waivers and E15 substantially similar determination, fuel and fuel additive manufacturers that make E15 or ethanol for use in making E15 must participate in a compliance survey that ensures that E15 pump dispensers are labeled appropriately.[97] The E15 partial waiver conditions provide fuel and fuel additive manufacturers two options to satisfy the compliance survey condition: (1) A geographically-focused survey; or (2) a national survey. Under part 1090, we are proposing that participation in the national survey program would satisfy the national survey option for purposes of compliance with the E15 waiver conditions. The E15 waiver conditions would allow E15 fuel and

[97] See 75 FR 68094 (November 4, 2010), 76 FR 4662 (January 26, 2011), and 84 FR 26980 (June 10, 2019).

fuel additive manufacturers to continue using a geographically-focused option instead if they so desired, and part 1090 includes provisions to facilitate such a program. However, we expect that fuel and fuel additive manufacturers would elect to participate in the national survey program due to significant amount of cost savings associated with participating in it.

c. Sample Sizes

We are proposing that the national survey program collect, at a minimum, gasoline samples from 5,000 gasoline retail outlets and 2,000 diesel retail outlets. Since most retail outlets offer both gasoline and diesel fuel, we believe that the total number of retail outlets sampled would be closer to 5,000 retail outlets rather than 7,000 outlets. This proposed total would be substantially lower than the current regulatory program, which requires sampling for approximately 17,000 retail outlets. We selected the number of retail outlets for gasoline and diesel based on the recent sample size determinations of the existing part 80 survey programs and we are proposing the same sample size determination methodology that is used for the existing part 80 survey programs. This results in approximately 5,000 retail outlets since the existing survey program for E15 misfueling mitigation is national in scope. Since we are consolidating the four existing programs into a national program, the statistical rigor of the sample selection methodology is unchanged and would result in the same sample size. What is different for this proposed program compared to the E15 survey program is the types of fuel samples the independent surveyor would collect at retail outlets and parameters that are tested for those fuel samples once collected (discussed more in Section X.A.2.d).

For the subset of gasoline samples that would continue to be tested for the full suite of Complex Model fuel parameters, we are proposing that the sample size would be determined using a standard calculation to estimate national fuel parameters. We expect that around 1,200 gasoline samples would be analyzed for the full suite of Complex Model fuel parameters using this methodology. We seek comment on the proposed sample size and sample size determination methodology.

d. Requirements for Independent Surveyors

We are retaining and transferring certain existing requirements for independent surveyors in part 80 to part 1090. These include the requirement that an independent surveyor would need to conduct the national survey program and meet similar independence requirements from parties that hire the surveyor to conduct the program. The independent surveyor would not be allowed to have financial interest in companies that hire the independent surveyor to conduct a survey, nor would companies be allowed to have an interest in the independent surveyor's organization. Like the part 80 survey programs, the surveyor would need to submit an annual plan for surveys conducted under part 1090. The plan would identify how the independent surveyor intends to meet the proposed regulatory requirements and would be subject to EPA approval prior to conducting the survey. Additionally, the independent surveyor would need to submit annually to EPA proof that the national survey program has been fully funded for the next compliance period by December 15.

As part of our effort to modernize the fuel quality programs, we are proposing to require that independent surveyors register with EPA and submit periodic reports electronically to EPA, which is not currently required under the part 80 survey programs. This would help EPA more quickly provide information collected as part of the national survey program and promote greater transparency in the fuel quality program. The proposed independent surveyor reporting requirements are similar to those currently specified in part 80, and the independent surveyor would need to keep records in a similar manner. We seek comment on the requirements outlined for independent surveyors conducting the national survey program under part 1090.

B. National Sampling and Testing Oversight Program

The RFG regulations in part 80 currently require that each refiner have an independent laboratory sample and test batches of RFG unless the RFG refiner has an in-line blending waiver. Refiners have the choice of having an independent lab sample and test 100 percent of their batches or 10 percent of their batches randomly selected. We also require that every 33rd batch of RFG collected by an independent lab be sent to EPA for analysis.[98] As part of consolidating the compliance provisions across the various gasoline and diesel fuel to create a single fuel quality program, we considered how best to ensure proper EPA oversight of the sampling and testing for fuels compliance.

During the rule development process, we received feedback that due to guidance set forth by EPA in the past on how to select the 10 percent of batches,[99] refiners needed to arrange for an independent laboratory to sample 100 percent of RFG batches made by a refinery and select the 10 percent random sample from among all those RFG batch samples. Since arranging to have an independent laboratory collect a sample is the most expensive part of the process, parties that provided feedback to us argued that this requirement is unnecessarily burdensome.

At the same time, we are proposing to no longer require the use of the Complex Model and remove various restrictions on the production and use of RFG. These proposed actions would diminish the need for the independent lab testing requirement as currently outlined in the part 80 RFG regulations. However, we believe that continuing to ensure that appropriate sampling and testing is conducted for fuels compliance demonstration is an important element of any streamlined fuel quality program.

Consequently, in lieu of the existing RFG requirements, we are proposing provisions for a voluntary national sampling oversight program designed to ensure that samples are collected in a consistent manner by gasoline manufacturers. The purpose of this proposed program is to help ensure that fuel manufacturers are sampling and testing in a manner consistent with required procedures, as discussed in more detail in Section IX.

As part of the proposed voluntary national sampling oversight program, we are also proposing to require that the independent surveyor review appropriate PBMS qualification and statistical quality control (SQC) data for the samples collected and tested as part of the proposed sampling oversight program. We believe that this would help ensure that labs that test gasoline for compliance under our fuel quality programs are complying with EPA quality control provisions for labs.

During the rule development process, we discussed whether a review of all PBMS qualification and SQC data as part of the annual attest audit would be appropriate.[100] In response, stakeholders suggested that auditors, many of whom lack the technical

[98] See ''Consolidated List of Reformulated Gasoline and Anti-Dumping Questions and Answers: July 1, 1994 through November 10, 1997,'' EPA–420–R–03–009, July 2003.

[99] Id.

[100] See EPA–420–D–19–001, available in the docket for this action.

expertise to review lab quality control data, would be unable to perform such auditing functions for each lab on an annual basis, especially before the June 1 annual deadline to complete the attest audit process. These stakeholders suggested that in many cases there would be too much SQC data across an entire compliance period for auditors to reasonably review. Due to the expertise needed to review lab PBMS and SQC information and the amount of information needed to review, we believe a limited review by the independent survey as part of the proposed voluntary national sampling oversight program is appropriate. Independent surveyors must demonstrate technical competency to EPA as part of the annual plan approval process and should be familiar with EPA quality control procedures. Additionally, we are proposing a basic record review requirement as part of the attest engagement process, discussed in more detail in Section XII.B. Combined, we believe these two proposed requirements would help ensure that labs are meeting EPA's PBMS and SQC requirements.

During the rule development process, we also received feedback arguing that a voluntary national sampling oversight program would not be necessary due to SQC measures imposed on labs that test fuel samples in the Tier 3 gasoline sulfur rule. We disagree with the view that Tier 3 SQC provisions serve the same function as the national sampling oversight program. The SQC provisions place certain control measures on the actual testing by the labs of gasoline and diesel fuel samples to help ensure valid measurements. However, the SQC provisions do not address whether the sample was collected appropriately. Inappropriate sampling can affect the validity of test results regardless of whether the SQC provisions show the lab is testing appropriately. Additionally, EPA enforcement personnel have identified several issues with sampling during past audits of fuel testing laboratories that we believe can be reduced by a national sampling oversight program.

Like the national survey program described in Section X.A, we believe there is an opportunity to reduce the overall cost of sampling oversight while expanding the scope from just RFG to all gasoline nationwide. Taken together, we are proposing to require an estimated 300–400 samples would be collected as part of this proposed national sampling oversight program annually. This compares to the several thousand samples currently collected from RFG refiners each year. These samples would be spread across all gasoline manufacturers instead of just RFG refiners. We believe this is a substantial reduction in associated burden with independent sampling while still providing the necessary oversight.

We are proposing to require gasoline manufacturers that elect to account for oxygenate added downstream to participate in the proposed national sampling oversight program. We believe this requirement would help ensure that fuel manufacturers are sampling, testing, and reporting results of gasoline that is representative of gasoline (*i.e.,* BOB) leaving the refinery gate. We are also proposing to exempt refineries that have in-line blending waivers from the national sampling oversight program since these refineries already have an annual audit requirement by an independent auditor.

Gasoline manufacturers that participate in the program would need to arrange for a sample to be overseen by an independent surveyor for each season (winter and summer). This would mean that, as long as a gasoline manufacturer has product available for testing, the gasoline manufacturer would have at least two samples collected per year. We are also proposing that an additional number of random samples be collected to ensure an effective deterrent against complacency for parties that have samples collected early in a season. For example, if we only required sampling once per season and a gasoline manufacturer had a winter sample surveyed in January of a compliance period, that gasoline manufacturer would not be surveyed in the winter for the rest of the compliance period. Additional random sampling would help ensure that gasoline manufacturers are following appropriate sampling and testing procedures year-round, even if sampled early in the season.

During the rule development process, we received feedback stating that having an independent surveyor collect a sample without advanced notice would pose a safety hazard and encounter logistical challenges that would inhibit the independent surveyor's ability to collect a sample. For example, refineries and import facilities would often not have product available for sampling, which would create an issue for an independent surveyor showing up at random to collect at a refinery. We believe that an independent surveyor should provide the minimal amount of advanced notice as practical to ensure that product is available for sampling and that the independent surveyor could observe whether samples are collected in accordance with specified sampling procedures. We also believe that since each gasoline manufacturing facility is different, the independent surveyor would need to tailor the advanced notification procedures for each facility. Specifying a procedure for every gasoline manufacturing facility would not be practical given the breadth of specific situations, so we are proposing that the independent surveyor would need to address advanced notification in its annual plan. We seek comment on ways to minimize advanced notification for the national sampling oversight program.

We also received feedback from stakeholders that suggested that replacing the RFG independent laboratory testing program with the proposed voluntary national sampling oversight program would allow for parties to more easily arrange for favorable test results that demonstrated a fuel met EPA fuel quality standards. These stakeholders suggested that having a requirement that RFG refiners specify a registered independent laboratory for testing would make it more difficult for RFG refiners to arrange for multiple laboratories to test separate samples from a single batch in search of a favorable test result. These stakeholders suggested that EPA propose to expand the RFG independent laboratory requirement to include CG refiners in addition to RFG refiners under part 1090. They suggested that we require that all third-party laboratories register and that gasoline refiners be limited to using a specified, registered third-party laboratory. While we believe that such a proposal would greatly increase the burden associated with third-party laboratory testing, which would largely fall on smaller gasoline refiners as they typically do not have their own testing laboratories, we do believe it could be useful to limit the multiple testing of a single batch by multiple laboratories to help ensure a level playing and better ensure fuel quality. Therefore, we seek comment on whether we should require that all third-party laboratories register and that refiners be limited to using a specified, registered third-party laboratory.

Historically, EPA's National Vehicle and Fuel Emissions Laboratory (NVFEL) has played a role in the development and quality control of analytical test methods used to determine compliance with our fuel quality standards. Under part 80, as part of the RFG program, NVFEL receives several hundred oversight samples from RFG refiners and independent laboratories. NVFEL analyzes these samples and compares the results to results from RFG refiners

and independent labs.[101] Under part 1090, we would no longer collect these oversight samples from RFG refiners and independent labs. However, as part of the national sampling oversight program, we are proposing that the independent surveyor would send a random selection of samples collected as part of the proposed oversight program to NVFEL for comparison to the results obtained from the independent surveyor and fuel manufacturer's lab. This would allow our lab to continue to serve as a reference installation and maintain our oversight of the national sampling oversight program.

Like the proposed national survey program, we are proposing that an independent surveyor would conduct the national sampling oversight program. We envision that these parties would function similar to the way that independent surveyors operate under the existing part 80 program. Therefore, we are proposing a similar independence and plan approval process as those used for independent surveyors under part 80 and the proposed national survey program. The only difference would be a change in the reported elements as samples are collected from gasoline manufacturing facilities instead of retail stations. We seek comment on whether the approach outlined for independent surveyors is appropriate for the national sampling oversight program.

We seek comment on all aspects regarding the proposed national sampling oversight program.

XI. Import of Fuels, Fuel Additives, and Blendstocks

We are transferring most of the current provisions in part 80 that address the importation and exportation of fuels, fuel additives, and blendstocks to part 1090 (subpart P). As described in this section, importers would continue to be subject to the same requirements as refiners, while exporters would continue to be subject to certain fuel designation and recordkeeping provisions. Overall, we are proposing few changes to how imported and exported fuel products are treated relative to the current provisions of part 80, although we are proposing to significantly change the regulatory text. Many of the proposed provisions are merely codification of existing implementation policies summarized in a 2003 question and answer (Q&A) document (''2003 Q&A'').[102]

A. Importation

With few exceptions, we are proposing requirements for importers that largely mirror what we currently require under part 80. However, we are proposing some updates to provisions for imports. First, under part 1090, importers that import fuel at multiple import facilities within a single PADD would need to aggregate the facilities for purposes of complying with the benzene maximum average standard. For compliance with other average standards, importers would continue to comply at the company level. Batches of imported fuel that are subject to certification requirements must be certified separately for U.S. Customs Service purposes at each U.S. port of entry.[103]

Second, under part 80, we currently have guidance that allows gasoline classified as ''American Goods Returned'' to the United States by the U.S. Customs Service to not count as imported gasoline.[104] We are proposing language consistent with that guidance in part 1090, provided all the following conditions are met:

- The gasoline was produced at a fuel manufacturing facility located within the U.S. and has not been mixed with gasoline produced at a fuel manufacturing facility located outside the U.S.
- The gasoline must be included in compliance calculations by the producing manufacturer.
- All the gasoline that was exported must ultimately be classified as American Goods Returned to the United States and none may be used in a foreign country.
- No gasoline classified as American Goods Returned to the United States may be combined with any gasoline produced at a foreign refinery prior to being imported into the U.S.

We are not making any significant changes to the definition of an importer, which we define as ''a person who imports gasoline, gasoline blendstocks or components, or diesel fuel from a foreign country into the United States (including the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands).'' The importer under part 1090 would generally be the importer of record under the Bureau of Customs and Border Protection regulations. This would typically be the entity that owns the fuel, fuel additive, or regulated blendstock when the import vessel arrives at the U.S. port of entry, or the entity that owns the fuel, fuel additive, or regulated blendstock after it has been discharged by the import vessel into a shore tank. We seek comment on these proposed updates to the import provisions under part 1090, and whether we should make changes to the definition of an importer.

B. Special Provisions for Importation by Rail or Truck

We are proposing reduced compliance options for meeting testing requirements when importing fuels by either rail or truck. These provisions would allow importers to meet the sampling and testing requirements based on test results from the supplier instead of testing each batch after the fuel was imported under certain conditions.

First, the importer would need to get documentation of test results from the supplier for each batch of fuel. Testing for a given batch would need to occur after the most recent delivery into the supplier's storage tank and before transferring product to the railcar or truck.

Second, the importer would need to conduct testing to verify test results from each supplier, by collecting samples either once every 30 days or every 50 rail or truckloads from a given supplier, whichever is most frequent. The proposed provisions would treat importation of gasoline and diesel fuel separately but apply to rail and truckloads together if the importer imported product from a given supplier by rail and truck.

C. Special Provisions for Importation by Marine Vessel

We are proposing provisions that specifically address importation of fuels by marine vessels. These provisions are generally the same as those addressed in the 2003 Q&A. Under part 1090, separate certification would be required at each import facility, unless the fuel is transported by the same vessel making multiple stops but does not pick up additional fuel. Consistent with the current part 80 requirements, we are proposing not to allow importers who import by marine vessels to rely on testing from a foreign source.

[101] See ''Consolidated List of Reformulated Gasoline and Anti-Dumping Questions and Answers: July 1, 1994 through November 10, 1997,'' EPA–420–R–03–009, July 2003.

[102] See Section IX.C, ''Consolidated List of Reformulated Gasoline and Anti-Dumping Questions and Answers: July 1, 1994 through November 10, 1997,'' EPA–420–R–03–009, July 2003.

[103] See 19 CFR part 151, subpart C.

[104] See ''Consolidated List of Reformulated Gasoline and Anti-Dumping Questions and Answers: July 1, 1994 through November 10, 1997,'' EPA–420–R–03–009, July 2003.

Additionally, testing may not be based on samples collected after the fuel is off-loaded, unless certain conditions are met that are designed to make sure the imported gasoline meets all per-gallon standards and that compliance reports accurately reflect the sulfur and benzene content of the imported fuel.

Under these proposed provisions, when finalized, different ship compartments would be considered different batches of fuel. However, we are proposing the following exceptions. First, importers would be allowed to treat the fuel in different compartments of a ship as a single batch if they demonstrate that the fuel is homogeneous across the compartments as proposed for all composite samples. As is the case under part 80, importers would need to demonstrate that results for homogeneity testing fell within the specified repeatability range for the test method used(s) used to determine homogeneity. Under the updated homogeneity testing procedures in part 1090, this would result in a decrease in the amount of analytical testing needed to establish homogeneity for combining marine vessel compartments compared to part 80. This decrease in testing is mostly a result of part 80 requiring that importers establish homogeneity for all Complex Model parameters, which could be as many as 11 fuel parameters. Under part 1090, importers would only need to establish homogeneity for two fuel parameters. This change would result in a substantial decrease in testing burden.

Second, we would also accept the analysis of samples collected from different ship compartments that are combined into a single volume-weighted composite sample if the compartments are off-loaded into a single shore tank, or each individual vessel compartment is shown, through sampling and testing, to meet all applicable standards.

D. Gasoline and Diesel Fuel Treated as Blendstocks

We are largely transferring current provisions for Gasoline treated as Blendstocks (GTAB) in part 80 to part 1090. We are also proposing to substantially reduce the number of parameters that are tested and reported to EPA. Our primary concern with GTAB has been to ensure that off-spec gasoline imported into the U.S. are properly blended to produce gasoline that meets applicable fuel quality standards. When initially established under the RFG and Anti-dumping programs, the GTAB provisions focused on the entire set of parameters needed to run the Complex Model. Since compliance with our fuel quality standards is based on sampling and testing the finished fuel and part 1090 would no longer require certification of batches of gasoline using the Complex Model, we believe that the testing and reporting of fuel parameters for GTAB is no longer necessary. However, volumes for batches of GTAB would continue to need to be reported. Other proposed provisions related to GTAB are consistent with current part 80 requirements and published guidance.

We are also proposing to replace the existing part 80 requirements for diesel treated as blendstock (DTAB) with a simplified procedure. Under part 80, most of the DTAB provisions are designed to account for the DTAB in compliance calculations that have not been used since 2010. The part 80 provisions require importers to include DTAB in compliance calculations that are no longer applicable, to keep DTAB segregated from other diesel fuel, and limit the importer's ability to transfer title of DTAB. Under part 1090, importers would be able to import diesel fuel that does not meet applicable EPA standards if the importer offloads the imported diesel fuel into one or more shore tanks containing diesel and then samples and tests the blended fuel to confirm that it meets all applicable per-gallon standards before introduction into commerce. We believe this process greatly simplifies the certification process for DTAB and seek comment on this approach.

XII. Compliance and Enforcement Provisions and Attest Engagements

A. Compliance and Enforcement Provisions

We are also transferring compliance and enforcement provisions, such as liability, penalty, and prohibited acts and affirmative defense provisions that are currently in part 80 to part 1090. We are however, revising existing regulatory text by providing them in an easier to understand format.[105] We are proposing regulatory text that consolidates and eliminates multiple prohibited acts statements in part 80 and replacing them with a simple statement that ''[a]ny person who violates any requirement in this part is liable for the violation.'' We solicit comment as to whether this proposed statement will address the universe of regulatory provisions in part 1090.

We are also seeking comment on the appropriate default value that would be applicable to sampling and testing requirements violations for fuel content standards. The existing requirements for regulated parties to accurately sample and test fuels are one of the lynchpins of our fuel quality regulations. If regulated parties fail to properly sample and test fuel, it makes is difficult for EPA and the public to know if the fuel meets the applicable standards. Unlike in the case of our vehicle and engine regulations where the vehicles and engines still exist and can be tested by EPA to verify compliance, in the case of fuel, it is typically commingled with other fuel in the distribution system immediately upon production, and quickly consumed. The existing part 80 regulations provide that if a refiner or importer fails to comply with the gasoline sampling and testing requirements, the gasoline will be deemed to have a sulfur content of 970 ppm, a benzene content of 5 volume percent, and a summer RVP of 11 psi, unless the respective party or EPA demonstrates by reasonably specific showings, by direct or circumstantial evidence, different properties for the gasoline giving rise to the violations.[106] This creates an additional incentive for refiners and importers to properly sample and test gasoline and ensures that that they will not benefit by underreporting the sulfur, benzene, and/or RVP of gasoline that is not properly sampled or tested. However, during the rule development process, several stakeholders requested that we reconsider the default values that EPA uses for enforcement when a regulated party lacks a valid test result for a regulated fuel parameter.

We are not proposing any revisions to the default values currently found in part 80. We recognize, however, that the gasoline pool today has substantially lower levels of sulfur and benzene than at the time the default values were promulgated. For this reason, we seek comment on whether to establish lower default values for these parameters, and what an appropriate default value should be. We are also proposing default values for regulated parameters for fuels, fuel additives, and regulated blendstocks where we do not have existing default values in part 80 for parties that fail to meet the applicable sampling and testing requirements. Table XII.A–1 lists the proposed default values.

[105] See 40 CFR 80.5 (penalties for fuels violations); 80.23 (liability for lead violations); 80.28 (liability for volatility violations); 80.30 (liability for diesel violations); 80.79 (liability for violation of RFG prohibited acts); 80.80 (penalties for RFG/CG violations); 80.610–615 (violation provisions for diesel sulfur program); 80.1504–80.1508 (violation provisions for gasoline ethanol blends); and 80.1660–80.1666 (violation provisions liability for Tier III gasoline sulfur program).

[106] See 40 CFR 80.80.

TABLE XII.A–1—PROPOSED DEFAULT VALUES FOR FUEL, FUEL ADDITIVE, AND REGULATED BLENDSTOCK PARAMETERS

Product	Sulfur value (ppm)	Benzene value (volume percent)	RVP value (psi)
Gasoline	970	5	11
PCG (by subtraction)	0	0	n/a
Diesel Fuel	1,000	n/a	n/a
ECA Marine Fuel	5,000	n/a	n/a
Fuel Additives	970	n/a	n/a
Regulated Blendstocks	970	5	n/a

In general, for fuel additives and regulated blendstocks, we are proposing default values consistent with the existing values for gasoline, as we believe these products have similar potential for high sulfur levels that would be found in the production of gasoline. During the rule development process, some stakeholders pointed out the use of default values by blender manufacturers who use PCG by subtraction could result in the inappropriate generation of sulfur and benzene credits. Since the main purpose of these default values is to provide incentives for parties to obtain valid test results, our proposal to assume zero sulfur and benzene content from the PCG in a PCG by subtraction scenario would attribute all sulfur and benzene to the added blendstock and provide incentives for a blending manufacturer to appropriately sample and test the PCG.

For diesel fuel, we are proposing a default 1,000 ppm sulfur value, as this level of sulfur content is consistent with the distillate ECA marine fuel specification. For ECA marine fuel, we are proposing a default 5,000 ppm sulfur value, as this level of sulfur content is consistent with global marine fuel standards to meet the 2020 MARPOL Annex VI marine fuel sulfur specification. For both diesel fuel and ECA marine fuel, we expect that the next higher sulfur standard provides a logical default value and would provide incentives for diesel fuel and ECA marine fuel manufacturers to obtain valid test results.

We seek comment on the newly proposed default values. When providing comments related to the proposed default values, commenters should provide a thorough rationale (including relevant data and information) for suggested default values to help EPA consider alternative default values.

We are not proposing any other significant revisions to current compliance and enforcement provisions that are in part 80. As earlier explained, we are merely consolidating and simplifying these provisions in part 1090. We will treat comments on any other compliance and enforcement provisions beyond those discussed in this section as outside of the scope of this action.

B. Attest Engagements

Part 80 includes a requirement for gasoline refiners and importers to engage auditors to review information reported to EPA. These annual attest engagements allow EPA to more effectively ensure compliance with regulatory requirements.

We are transferring existing attest requirements in part 80 to a single subpart in part 1090 (subpart R). We are removing obsolete material, updating the language for improved clarity, and making some minor adjustments and clarifications to improve the quality and consistency of reported information.

For instance, we are proposing to add a requirement for auditors to review the refiner's or importer's calculations showing that they comply with the sulfur and benzene average standards. We note that the EPA's Office of Inspector General made certain findings regarding compliance with these standards and recommendation as part of their review of the auditing requirements under part 80.[107] One recommendation was to modify the attest engagement regulations to require that attest auditors verify compliance calculations for gasoline manufacturers to help ensure that the average benzene standard was met. We believe the proposed attest engagement provisions are consistent with this recommendation and would provide better oversight of the gasoline sulfur and benzene average standards.

We are also proposing to codify the existing attest requirements spelled out in the RFG Q&A document.[108] We are proposing these requirements for both CG and RFG. The most significant proposal would be the requirement for auditors to review PBMS qualification and SQC records related to the sampling and testing requirements for gasoline on an annual basis. We are proposing to require a relatively straight-forward review by auditors of whether labs used to test gasoline for compliance have records demonstrating that methods have been qualified under the PBMS qualification requirements and that the lab is maintaining SQC records. It is worth noting that we are not proposing to require auditors to interpret this information as auditors may lack the appropriate technical expertise to interpret lab data for conformance with PBMS and SQC requirements. Instead, as discussed in Section X.B, we are proposing that the independent surveyor review this type of information under the voluntary sampling oversight program. We do not believe that this simple review will greatly increase the burden associated with the annual attest audits. We believe this lab record review would help ensure that labs used for testing fuels for compliance are doing so in a manner consistent with EPA's quality control requirements helping to ensure a level playing field and program integrity. We seek comment on this proposed lab record review requirement and other aspects of the streamlined attest engagement requirements. We are also seeking as to whether there are other requirements that would be implemented for purposes of providing adequate annual attest audits.

C. RVP Test Enforcement Tolerance

Currently, the agency recognizes and allows a 0.3 psi downstream enforcement test tolerance over applicable RVP standards for RVP test results.[109] This test tolerance was based on RVP testing variability and the reproducibility of the test methods. Under this approach, we rely on test

[107] See "Improved Data and EPA Oversight Are Needed to Assure Compliance With the Standards for Benzene Content in Gasoline," Report No. 17–P–0249, June 2017.

[108] See "Consolidated List of Reformulated Gasoline and Anti-Dumping Questions and Answers: July 1, 1994 through November 10, 1997," EPA–420–R–03–009, July 2003.

[109] See 55 FR 23695 (June 11, 1990), 59 FR 7764 (February 16, 1994), and "Consolidated List of Reformulated Gasoline and Anti-Dumping Questions and Answers: July 1, 1994 through November 10, 1997," EPA–420–R–03–009, July 2003.

results from locations downstream of refineries or import facilities to bring enforcement actions against downstream parties only if the downstream test results are more than 0.3 psi than the applicable standard. Although any sample that is over the standard is a violation, we generally do not bring enforcement actions against a downstream party if the sample it collects is over the standard but within the 0.3 psi enforcement test tolerance, as long as there is no reason to believe that the downstream party caused the gasoline to exceed the standard. Gasoline manufacturers may not use the tolerance to effectively raise the applicable standard. If the refiner's or importer's test results show the gasoline exceeds the RVP standard, then the gasoline is in violation regardless of whether or not the RVP test result is within the tolerance.

At this time, we intend to continue this same RVP enforcement test tolerance policy to enforce the gasoline volatility standards in part 1090. Under part 1090, the 0.3-psi RVP tolerance would apply to both summer CG and summer RFG. However, as before, we may change this enforcement policy at any time, including adopting new tolerances as data on test methods are developed, as technology changes, or as further information becomes available concerning the precision of RVP test methods.

XIII. Other Requirements and Provisions

A. Requirements for Independent Parties

We are proposing requirements for third parties performing actions authorized under part 1090 regarding their independence from the regulated parties who engage them and their technical qualifications. These proposed requirements would be consistent with part 80 independence and technical competency requirements for independent third-parties. We believe the proposed requirements would preserve and strengthen the integrity of our independent third-party verification programs.

We have always had concerns about the potential for conflicts of interest between the independent third-parties that monitor compliance on behalf of EPA and the regulated entities who engage them and are proposing the same independence requirements for third-parties as currently used in part 80. In addition, since proposing the original independence requirements for third-parties under the RFG and Anti-dumping programs in the 1990s, we have seen that third-parties often employ contractors or subcontractors to fulfill third-party oversight requirements. These contractors or subcontractors should also be free from conflicts of interest from regulated parties for whom services are performed. Therefore, we are proposing to clarify that independence requirements apply not only for the third parties and their employees, but also for any contractors and subcontractors.

Similar to part 80 provisions, we are proposing to impose restrictions on both employment history and financial interest. We are proposing that independent third parties would be required to ensure that their employees, contractors, and subcontractors had not worked for the regulated party that hired that third party for any amount of time over the previous three years. While the financial independence requirements imposed on the independent third party's employees, who are directly involved in overseeing the regulated parties, prohibiting them from owning or otherwise having any financial interest in that regulated party are generally not changing, we are proposing to apply these existing independence requirements at the contactor and subcontractor levels. There would also be a limitation imposed on the independent third party's firm or organization as to the proportion of revenue it can generate from any single regulated party. We believe this furthers our goal of independent third-party oversight and increases the trustworthiness of the program's results. We seek comment on these independence requirements and their impacts on the independent third parties, as well as the anticipated effectiveness of these provisions to increase reliability in our third-party oversight program.

Part 1090 also proposed to include requirements on the technical qualifications of the independent third parties. We have employed similar requirements under part 80 and have used these requirements in other cases where technical competency is important to conduct regulated activities for a regulated party; however, we do not currently require this demonstration for in-use surveys.[110] These provisions will ensure that program oversight is being conducted by parties with the requisite technical capabilities. We are proposing to require that the independent surveyors, which are regulated further under subpart N, employ personnel with expertise in the areas of petroleum marketing, sampling and testing fuels at retail stations, and survey design. Technical competency requirements for attest engagement auditors and independent laboratories that qualify alternative test procedures under PBMS would be unchanged in part 1090.

We request comment on these technical and experience requirements and their impacts on the third party oversight program.

B. Labeling

Part 1090 includes provisions that apply specifically to retailers and WPCs, consolidating the various provisions formerly scattered throughout part 80 (including the whole set of fuel pump labeling requirements) into one subpart (subpart O) with only minor changes (including removing several obsolete provisions from part 80). We are further proposing to streamline the description of the E15 label by replacing descriptive paragraphs with a graphic example of the E15 pump label. We believe these changes would make the regulations easier to identify and follow for retailers and WPCs.

We are proposing minor modifications to the existing label language. For heating oil, we are proposing to remove the label language identifying that heating oil contains greater than 500 ppm sulfur.[111] Most heating oil sold today meets state 15 ppm sulfur standards, and we believe that it is misleading and inappropriate to require that heating oil dispensers label their product as having greater than 500 ppm sulfur. To minimize burden on retailers, we are proposing that retailers could use existing labels to satisfy the part 1090 labeling requirements and that retailers would need to affix a heating oil label compliant with the part 1090 label requirements when the existing part 80 label needs replacement.

During the rule development process, we received feedback from stakeholders suggesting that the ECA marine fuel labels were no longer necessary due to the way that ECA marine fuel is sold and dispensed for use in Category 3 marine vessels. Another option would be to limit labeling to situations where ECA marine fuel is co-dispensed with other fuels since the purpose of the ECA marine fuel label is to help avoid the misfueling of diesel engines that require the use of ULSD with ECA marine fuel. This would only be an issue where such diesel engines could reasonably be misfueled (*i.e.,* in situations where both ECA marine fuel or ULSD are co-

[110] See 40 CFR 80.92 and 80.1469.

[111] See 40 CFR 80.573.

dispensed). While we are proposing to maintain the ECA marine fuel labels currently required under part 80, we seek comment on whether maintaining these labels is necessary or whether we could limit the use of the label to only situations where ECA marine fuel is co-dispensed with other fuels.

We also seek comment on the structure of proposed fuel pump labeling regulations, and on the various modifications to label content described in this section.

C. Refueling Hardware Requirements for Dispensing Facilities and Motor Vehicles

As described in the preceding section, part 1090 includes a subpart devoted to requirements for retailers and WPCs. This subpart also describes requirements related to refueling hardware.

The proposed nozzle requirements for refueling motor vehicles are aligned with the requirements adopted under part 80. There is one noteworthy adjustment. We are proposing to identify nozzle specifications only in millimeters. The parallel metric and English units in part 80 are nearly identical, but this nevertheless creates two separate sets of requirements, which is contrary to the objective of standardizing hardware. The specifications in part 80 also include a level of precision that is greater than is needed to properly identify a standard configuration. The single set of specifications, including rounding, is consistent with the specifications in part 80, so the updated nozzle specifications should not cause any existing hardware to be noncompliant, and any existing blueprints for producing nozzles would not need to be modified.

Similar nozzle requirements apply for dispensing gasoline into marine vessels. We are similarly proposing a singular set of nozzle-geometry specifications in millimeters in a way that is aligned with the specifications as originally adopted. We are also proposing to finish the allowed phase-in of these nozzle-geometry specifications. As originally adopted, the nozzle requirements applied as of January 1, 2009, to new installations and to new nozzles used to repair or replace damaged dispensing equipment. Based on industry feedback, the market has now transitioned, so there is no need for our regulations to continue to allow non-standard nozzles. If there are any remaining nozzles for marine refueling that do not meet specifications, we are proposing to require that they be replaced with a nozzle that meets the standardized configuration. The requirement would apply January 1, 2021, when part 1090 becomes effective. We request comment on the timing of this proposed requirement, and on the extent of modification that is required for all installations to meet the nozzle-geometry requirements.

Part 80 additionally specifies a standardized geometry for filler necks in light-duty and heavy-duty motor vehicles to correspond with the nozzle geometry specifications. We are proposing to move these vehicle-based requirements to 40 CFR parts 86 and 1037, which describe standards and other requirements for light-duty and heavy-duty motor vehicles.

D. Previously Certified Gasoline (PCG)

We are proposing to largely maintain the existing part 80 provisions for how blending manufacturers may make new batches of gasoline from PCG and blendstocks.[112] In the Tier 3 rule, we finalized changes to improve the consistency of the PCG provisions across part 80;[113] however, we maintained separate PCG provisions for each part 80 gasoline program. In part 1090 we are proposing to consolidate these provisions into a single set of PCG provision. The proposed PCG provisions maintain both options used in part 80: (1) PCG by subtraction and (2) PCG by addition.[114] Other proposed changes are minor and designed to improve clarity and consistency of the PCG provisions in part 1090. Other provisions related to blending certified butane or certified pentane are discussed in Section V.A.3. We seek comment on the proposed consolidation of the PCG provisions.

E. Transmix and Pipeline Interface Provisions

In part 1090 we are consolidating and simplifying the flexibilities provided to fuel manufacturers that use transmix to produce gasoline and diesel fuel. We are also proposing changes to align the requirements applicable to these parties to the requirements applicable to fuel manufactures under part 1090.[115] Some of the part 80 regulations characterize the requirements for transmix processors and transmix blenders as alternative compliance mechanisms. For instance, the gasoline sulfur regulations state that ''[t]ransmix processors and transmix blenders may comply with the following sampling and testing requirements and standards instead of the sampling and testing requirements and standards otherwise applicable to a refiner under this subpart O.'' [116] The part 1090 regulations set forth specific requirements for transmix processors and transmix blenders because we believe that virtually all transmix processors and blenders are using the alternative approaches set forth in part 80, and because we believe that it would be overly complex for transmix processors and blenders to comply with the requirements that apply to other fuel manufacturers. We seek comment on whether transmix processors and blenders should have the option to comply with the requirements that apply to other fuel manufacturers. Any comment on this issue should provide specific recommendations regarding how to structure the program to assure compliance with all per-gallon standards, accurately account for the sulfur and benzene content of the fuel, and avoid double counting. These proposed changes to the transmix rules are discussed in the following sections.

1. Clarifying and Consolidating the Definitions of Transmix and Pipeline Interface

Part 80 currently provides flexibilities for transmix due to the unique way in which transmix is reprocessed into useable products and the need to expeditiously clear transmix volumes from the fuel distribution system to keep product flowing to markets. Transmix has traditionally been processed at small facilities that cannot support the installation of fuel desulfurization equipment. For example, pipelines are permitted to blend limited volumes of transmix into fuels subject to EPA standards provided that such blending does not impact compliance with the standards. Part 80 also provides that 500 ppm diesel fuel from transmix processors can be sold for use in older locomotive and marine

[112] The purpose of allowing parties to make new batches using PCG is to allow flexibility for parties to make new fuels to accommodate the market demands while ensuring that the fuel quality standards are met. The provisions are designed to ensure that gasoline per-gallon standards are met in the new batch and that the blending manufacturer does not increase the average sulfur and benzene levels in the national gasoline pool.

[113] See 79 FR 23575–23576 (April 28, 2014).

[114] In PCG by subtraction, a blending manufacturer determines the regulated fuel parameters of the PCG and the new batch to quantify the sulfur and benzene levels of added blendstocks for making the new fuel. In PCG by addition, a blending manufacturer directly measures the parameters of added blendstocks to quantify the sulfur and benzene levels. In both cases, the new fuel has to meet per-gallon specifications for gasoline and blending manufacturers would need to sample and test for sulfur year-round and for RVP in the summer.

[115] Refiners that produce gasoline and diesel fuel by processing crude oil may not use the alternative provisions and are subject to all requirements that apply to a fuel manufacturer.

[116] See 40 CFR 80.1607.

engines that do not require the use of 15 ppm diesel fuel. Other diesel fuel producers are required to meet 15 ppm sulfur standard for all LM diesel fuel they produce. Transmix processors that produce 500 ppm LM diesel fuel are required to submit a compliance plan that demonstrates that the 500 ppm LM diesel fuel will not be used in engines that require the use of 15 ppm diesel fuel.

Products are commonly shipped by pipeline adjacent to each without any physical barrier between the products. Pipeline interface is defined as the volume of petroleum product generated in a pipeline between two adjacent volumes of non-identical petroleum product that consists of a mixture of the two adjacent products.[117] The pipeline interface ''cut'' refers to the point between the two adjacent pipeline batches where physical separations are reintroduced at the end of shipment by pipeline. Depending on the quality requirements of the adjacent products, pipeline interface can often be cut in one or both of the adjacent products. When one of the adjacent products has unique quality specifications, it is sometime necessary to cut all of the interface into the product with the less stringent specifications. In situations where the pipeline interface cannot meet the specifications for either of the adjacent batches, it is called transmix and must be segregated for further processing before being sold as a fuel. This is typically the case when batches of gasoline and diesel fuel must be shipped by pipeline adjacent to one another.

Provisions related to the treatment of transmix are currently located in various sections in part 80.[118] To improve clarity, we are consolidating most of the special provisions related to the treatment of transmix into a single subpart in part 1090 (subpart F). We are also incorporating the definitions of transmix and pipeline interface into the definitions section of part 1090. These definitions are currently imbedded in part 80 in a regulatory section that pertains to the treatment of interface and transmix.[119]

2. Blending Transmix Into Previously Certified Gasoline

In part 1090 we are proposing a minor change to the requirements that apply to parties that blend transmix into PCG.[120] When the quality assurance program required of a transmix blender indicates that the gasoline does not comply with EPA standards, blenders that use a computer controlled in-line blending system are temporarily required under part 80 to conduct more frequent sampling and testing. We are proposing that no more than one sample per day may be used to demonstrate compliance with this increased testing requirement. We believe that this is consistent with common industry practice to spread out the required samples at the proposed one per day frequency, so adoption of this proposed change would not result in an increased burden to industry. The existing part 80 regulations would allow unscrupulous parties to circumvent the intended purpose of the regulations by pulling all of the required samples at one time. This proposed change in part 1090 would ensure that the required increase in sampling and testing frequency fulfills the intended purpose of verifying that the issue that caused the violation has been resolved.

3. Gasoline Produced From Transmix Gasoline Product

Transmix gasoline product (TGP) is the distillation fraction produced by a transmix processor that is in the gasoline boiling range. Parties that produce gasoline from TGP are currently provided with streamlined provisions in part 80 to demonstrate compliance with the requirements that apply to fuel manufacturers. These current provisions are complicated by the additional fuel parameter specifications for RFG beyond those for CG. The proposed elimination of these additional requirements for RFG (discussed in Section V.A.2.c) makes these complications unnecessary since the only difference between RFG and CG would be the applicable volatility standard. Therefore, in the streamlined provisions in part 1090 we are proposing to eliminate the current differences for producing RFG versus CG from TGP and replace it with provisions consistent with the proposed streamlined provisions for gasoline.[121] Under the proposed approach, the only difference between the streamlined provisions producing RFG versus CG from TGP would pertain to the volatility standard that would apply. Under this approach, parties that use these streamlined provisions would exclude the volume of TGP and PCG used to produce gasoline from their annual compliance calculations to demonstrate compliance with the sulfur and benzene average standards under all circumstances. Parties that use only TGP or TGP and PCG to produce gasoline would be deemed in compliance with the sulfur and benzene average standards, provided they are in compliance with the proposed streamlined provisions. Parties that made gasoline with TGP and other blendstocks would use PCG procedures to account for the sulfur and benzene levels of the added blendstocks for demonstrating compliance with annual average sulfur and benzene standards. In all cases, as is the case today under part 80, parties that make gasoline using TGP would need to meet per-gallon sulfur and RVP (in the summer) standards for the resultant gasoline and make sure that the gasoline they produce meets the substantially similar requirements of the CAA.

To provide additional flexibility, we are proposing that parties who use these streamlined provisions and could demonstrate that the feedstocks they use to produce gasoline contain no oxygenate would not be required to test the gasoline they produce for oxygenate content.

4. 500 ppm LM Diesel Fuel Produced From Transmix

To improve clarity and remove restrictions that are not cost effective, we are proposing minor modifications to the regulatory provisions that allow transmix processors to produce 500 ppm LM diesel fuel for use in locomotive and marine engines that do not require the use of ULSD.

The current regulations in part 80 require facilities that handle 500 ppm LM diesel fuel to segregate it from fuel having other designations (*e.g.,* ULSD) all the way from the producer through to the ultimate consumer.[122] Locomotive refueling facilities stated that the supply of 500 ppm LM diesel fuel is sometimes not consistent enough to ensure an adequate supply in their 500 ppm LM storage tanks that are dedicated to supplying 500 ppm LM diesel fuel. To facilitate the efficient refueling of their locomotives that may use 500 ppm LM diesel fuel, they requested that EPA allow ULSD to be introduced to their 500 ppm LM storage tanks provided that the resultant mixture of 500 ppm LM and ULSD is treated as 500 ppm LM. We agreed that

[117] See 40 CFR 80.84(a)(1). We are proposing to maintain the current definition of pipeline interface.

[118] See 40 CFR 80.84, 80.213, 80.513, 80.840, and 80.1607.

[119] Current 40 CFR 80.84.

[120] Industry minimum flash point specifications in ASTM D975 prevent the blending of transmix into diesel fuel. Hence, there is not a need for regulatory provisions regarding blending transmix into previously certified diesel fuel.

[121] For example, compliance with the anti-dumping requirements of part 80 would no longer be required.

[122] See 40 CFR 80.513(h)(3).

providing this flexibility would be consistent with the intent of the 500 ppm LM diesel fuel segregation requirements under part 80 to ensure that the 500 ppm LM diesel fuel is not inappropriately swelled by the introduction of greater than15 ppm diesel fuel that was not produced from transmix. Accordingly, we issued guidance [123] to retail and WPCs of 500 ppm diesel fuel that ULSD may be introduced to their 500 ppm LM storage tanks provided that resultant mixture of 500 ppm LM diesel fuel and ULSD is treated as 500 ppm LM diesel fuel. We are proposing to codify this guidance in part 1090. There is thus no impact of this regulatory change, but it will improve the clarity and understanding of our regulations.

Part 80 currently requires that the volume of 500 ppm LM diesel fuel may increase by no more than 2 volume percent while in the custody of any party in the distribution system. We are proposing to remove this requirement because we believe that the other existing safeguards are sufficient to prevent an inappropriate increase in the volume of 500 ppm LM diesel fuel during distribution due to the introduction of other high sulfur distillate streams. For example, pipeline operators may only ship 500 ppm LM diesel fuel by pipeline if the fuel does not come into physical contact in the pipeline with batches of other distillate fuel that have a sulfur content greater than 15 ppm. Other parties in the distribution system are required to segregate 500 ppm LM diesel fuel from other fuels except for the allowance discussed above to introduce ULSD into retail and WPC storage tanks. All parties in the distribution system must maintain records to demonstrate that an increase in 500 ppm LM diesel fuel while in their custody was due to normal interface cutting practices, thermal expansion, and/or the addition of ULSD to retail or WPC storage tanks.

Stakeholders have also requested that regulatory language be added to clarify that ULSD may be used as a blendstock with transmix distillate product (TDP) to produce 500 ppm LM diesel fuel. They also requested that we clarify that 500 ppm LM diesel fuel may be redesignated as IMO marine fuel, heating, oil, or blendstock. We are proposing that these practices are acceptable under part 1090. We are proposing that parties that redesignate 500 ppm LM diesel fuel as IMO marine fuel would be required to maintain records from the producer of the 500 ppm LM diesel fuel (*i.e.,* PTDs accompanying the fuel) to demonstrate compliance with the 500 ppm maximum sulfur standard.

5. Streamlining the Requirements for Pipeline Interface That Is not Transmix

The current requirements for RFG include specifications for additional fuel quality parameters beyond those required for CG. These additional requirements for RFG necessitated unique requirements related to the treatment of the interface between RFG and CG. For example, part 80 currently requires that interface containing RFG and CG must be designated as CG.[124] The proposed changes to RFG discussed in Section V.A.2 would eliminate concerns over maintaining average RFG emission performance and limit the fuel property distinction between CG and RFG to just RVP and then only during the summer months. Therefore, we are proposing to similarly streamline the provisions regarding interface cuts between RFG and CG. We are proposing that pipeline operators may cut pipeline interface from batches of RFG and CG that are shipped adjacent to each other by pipeline into either or both these gasoline batches, with fewer limitations. During the winter months there would be no restrictions remaining. Only during the summer season are we proposing that pipeline operators could not cut pipeline interface from two batches of gasoline subject to different RVP standards that are shipped adjacent to each other by pipeline into the gasoline batch that is subject to the more stringent RVP standard. For example, pipeline operators could not cut pipeline interface from a batch of RFG shipped adjacent to a batch of CG into the batch of RFG. We believe these reduced restrictions would allow greater flexibility and efficiency in the distribution of gasoline.

F. Gasoline Deposit Control

1. Overview

Section 211(l) of the CAA requires EPA to establish specifications for additives to prevent the accumulation of deposits in engines and fuel supply systems and that all gasoline contain such additives. In response to this requirement, EPA's gasoline deposit control (''detergent'') program was finalized in July 1996 and became effective in July 1997.[125] The detergent program requires that all gasoline, including the gasoline blend component of E85, contain a detergent that satisfies EPA deposit control requirements before being distributed from a petroleum terminal. Terminal operators are required to prepare and keep volumetric accounting reconciliation (VAR) records to demonstrate that a sufficient volume of detergent was added to the gasoline they distribute for each accounting period.[126]

Based on a review of emissions test data on circa 1990 vehicles and information on the levels of detergent use absent a federal detergency requirement, we estimated that the detergent program would result in roughly a 1 percent reduction in hydrocarbon and carbon monoxide emissions, a 2 percent reduction in NO_X emissions, and a 0.06 percent improvement in fuel economy on average from the gasoline vehicle fleet at the time.[127] Given the considerable changes to vehicle technology and to gasoline composition since 1990 that may affect both deposit formation and its impact on emissions, and given the lack of emissions test data on the effects of deposits on emissions from modern vehicles, we are unable to quantify the emissions benefits of different levels of deposit control stringency under the detergent program today. During the rule development process, some stakeholders stated that the existing federal detergents program could affect gasoline direct injection engines in a different manner than circa 1990 vehicles. We have also been informed that there may be situations where the presence of a detergent may not provide any benefit and may actually exacerbate deposit formation. Given the paucity of data on the current effects of the detergent program in the modern vehicle fleet, we seek comment on information on the effects of the federal detergent program on controlling deposits in modern vehicles and the impact on vehicle emission performance.

At the same time, there is considerable cost and effort associated with continuing to implement the detergent program. Consequently, we are proposing to streamline the program to the extent possible to minimize its cost. Specifically, we are proposing to: (1) Eliminate the redundant requirement that a detergent that is demonstrated to control intake valve deposits also be

[123] See Question 14.4, ''Questions and Answers on the Clean Diesel Fuel Rules,'' EPA–420–B–06–010, July 2006.

[124] See 40 CFR 80.84(b)(1).

[125] See 61 FR 35310 (July 5, 1996).

[126] Under part 80, this period can be up to 30 days. Part 1090 would not change this period.

[127] Regulatory Impact Analysis and Regulatory Flexibility Analysis for the Detergent Certification Program, June 1996. Regulatory Impact Analysis and Regulatory Flexibility Analysis for the Interim Detergent Registration Program and Expected Detergent Certification Program, August 1995.

tested to demonstrate the ability to control fuel injector deposits; (2) ease the adoption of updated deposit control test procedures when they become available; (3) simplify the process for registration and certification of detergents and the demonstration of compliance by detergent blenders; (4) remove expired and unused provisions; and (5) remove the requirement that the gasoline portion of E85 must contain a certified detergent. The following sections detail the changes we are proposing.

CAA section 211(l) includes a requirement that gasoline must ''contain additives to prevent the accumulation of deposits in engines or fuel supply systems.'' Our regulations maintain this requirement, but we are proposing to modify or eliminate certain testing requirements and simplify the registration and certification process and compliance demonstrations. CAA section 211(l) also requires that EPA promulgate regulations with specifications for detergents. While this action modifies those specifications, it maintains the requirement that gasoline contain detergents and maintains specifications for detergents, updating them to accommodate new circumstances discussed in this section. These proposed changes to the detergent program continue to be compliant with CAA section 211(l).

2. Eliminating the Port Fuel Injector Deposit Control Testing Requirement

We are proposing to eliminate the requirement that detergents be tested to demonstrate the ability to control port fuel injector deposits. This would substantially decrease the burden of introducing new detergents while maintaining the benefits of the detergent program.

We currently require separate tests to demonstrate the ability of a detergent to control port fuel injector deposits and intake valve deposits. Input from stakeholders during the rule development process supports the conclusion that detergents that are capable of controlling intake valve deposits are inherently capable of controlling port fuel injector deposits.[128] This conclusion is also supported by the elimination of a port fuel injector testing requirement in the industry-based Top Tier detergency program. The Top Tier program was established by industry based on the premise that a superior level of deposit control was needed for today's vehicles than that provided by EPA requirements. Further support is evidenced by the lack of industry activity to have a separate test for port fuel injector deposits. The port fuel injector deposit control test required by EPA is based on the ASTM D5598 fuel injector deposit control test procedure that uses a 1985–1987 Chrysler 2.2L vehicle.[129] The fuel injector technology used in these antiquated test vehicles is no longer representative of technology used in the current vehicle fleet. Current industry efforts are focused on developing an updated intake valve deposit (IVD) control test procedure and the evaluation of deposit control in gasoline direct injection engines that represent an increasing share of the new vehicle fleet.

3. Amending the Intake Valve Deposit Control Test Procedures

Like the port fuel injector test procedure, the intake valve test procedure in our regulations is likewise antiquated and of questionable relevance to the in-use fleet today. New detergents are currently tested using the EPA ASTM D5500 BMW-based deposit control test procedure (''EPA ASTM D5500 procedure'') procedure, which uses a 1985 BMW 318i vehicle. This vehicle was accepted as representative of technology in the vehicle fleet when the detergent program was finalized in 1996. However, this 34-year-old vehicle is no longer representative of the technology used in modern vehicles.[130] It is also increasingly difficult for emissions laboratories to perform the EPA ASTM D5500 procedure due to the deterioration of the aged test vehicles and the lack of replacement parts. Consequently, CRC is currently developing an updated deposit control test procedure.[131]

In addition, the test fuel specified by EPA for use in the ASTM D5500 procedure is no longer representative of current gasoline. The composition of the requisite test fuel is specified to assure a 65th percentile concentration of gasoline parameters that affect deposit formation based on 1990 gasoline survey data.[132] The composition of gasoline in the U.S. has changed significantly since 1990 due to EPA fuel quality requirements and changes in refinery operations due to the widespread use of E10. These changes to gasoline composition have resulted in current in-use gasoline having a different deposit-forming tendency compared to the 1990 gasoline on which the test fuel specifications are based. The Tier 2 gasoline sulfur program, finalized in 2000, reduced the sulfur content of gasoline by up to 90 percent.[133] The Tier 3 gasoline sulfur program, finalized in 2014, required a further reduction in gasoline sulfur levels to a 10 ppm average from a 30 ppm average under the Tier 2 program.[134] Parties that formulate detergent test fuels stated that the more stringent gasoline sulfur requirements were making it impossible to make the sufficiently stringent test fuels using only normal refinery blendstocks or finished gasoline. As a result, we issued guidance that a sulfur doping compound could be used to meet the minimum test fuel sulfur specification for test purposes, even though such fuels no longer exist in-use.[135]

Consequently, we no longer have confidence that the current EPA ASTM D5500 procedure can be used to assess deposits in today's vehicle fleet and therefore that the detergent additives tested using it provide any of the real world emission benefits quantified in 1996 when the detergent regulations were finalized. As a result, we are proposing to streamline our intake valve deposit control requirements. Specifically, we are proposing that new detergent deposit control testing would be conducted using California's deposit control program or the Top Tier program.[136] Data from California's program is currently accepted to satisfy EPA requirements only for gasoline that meets California's gasoline program.[137] As discussed in Section XIII.F.4, we are proposing to expand the applicability of detergents in EPA's gasoline detergent program based on the ability of

[128] Coordinating Research Council (CRC) Annual Report, September 2018. The CRC Gasoline Engine Deposit Task Group, CRC Project No. CM–136, consists of members of the auto, oil, and additive industries. The objectives of this group include developing test procedures to evaluate fuel and fuel additive contributions to intake valve deposits, and injector deposits in port fuel injection and direct injection engines.

[129] The detergent program requires demonstration of no more than 5 percent flow restriction on any one port fuel injector when tested in accordance with ASTM D5598–94.

[130] CRC Gasoline Engine Deposit Task Group, CRC Project No. CM–136, CRC Annual Report, September 2018.

[131] Id.

[132] 65th percentile concentrations are specified for sulfur, aromatics, T90 distillation, and olefins. Under the national generic detergent certification option, 10 volume percent ethanol must be blended into a base fuel meeting 65th percentile concentrations for sulfur, aromatics, T90 distillation, and olefins.

[133] See 65 FR 6698 (February 10, 2000).

[134] See 82 FR 23414 (April 28, 2014).

[135] The approved sulfur doping compound is di-tertiary di-butyl sulfide.

[136] See Title 13, California Code of Regulations, Section 2257.

[137] We are also proposing to incorporate by reference the most recent version of the ASTM D5500 procedure.

California's program to satisfy EPA requirements for all gasoline. Data used to comply with the Top Tier program is currently accepted for EPA detergent certification in lieu of data using the EPA ASTM D5500 procedure. Data used to satisfy the requirements of the Top Tier program would continue to be accepted to satisfy EPA deposit control requirements.[138] However, the data from the EPA ASTM D5500 procedure would no longer be accepted for new detergents. Existing detergent certifications based on the EPA ASTM D5500 procedure would continue to remain valid indefinitely. As discussed in Section XIII.F.5, stakeholders could petition EPA to adopt updated deposit control test procedures for new detergents.[139] We seek comment on this proposal or whether we should continue to accept data from the EPA ASTM D5500 procedure for new detergents.[140]

Eliminating the separate EPA ASTM D5500 procedure for new detergent deposit control testing combined with the proposed expanded applicability of California-based detergent certifications, would substantially streamline the detergent program. Additive manufacturers would no longer need to be concerned with the difficulties associated with performing a separate EPA ASTM D5500 procedure.

We acknowledge that similar concerns exist regarding the representativeness of the California detergent program's ASTM D5500 procedure (''California ASTM D5500 procedure''). However, we are proposing to continue to accept valid detergent certification under California's program as demonstration of compliance with our requirements because we believe that the more stringent intake valve standard and more representative test fuel specifications for the California ASTM D5500 procedure sufficiently mitigates concerns about the representativeness of the test vehicle.

We also acknowledge that even the Top Tier test procedures are not new. The ASTM D6201 procedure adopted by the Top Tier program in 2004 and it is accepted that the technology in the 25-year-old engine used in the ASTM D6201 procedure is also no longer representative of the majority of the vehicle population.[141] Hence, the updated deposit control test procedure currently under development by CRC would also likely replace to the ASTM D6201 procedure. Some industry representatives stated that the fading relevance of the ASTM D6201 procedure suggests that EPA should defer taking action on retiring the ASTM D5500 procedure until an updated procedure is developed that would replace both the ASTM D6201 and D5500 procedures. Although, we agree that it is appropriate to consider retiring the ASTM D6201 procedure as soon as a replacement procedure is available, we believe that heightened issues regarding the ASTM D5500 procedure no longer allow EPA to rely on it. Issues regarding the continued viability of the ASTM D5500 procedure are more pronounced than those of the ASTM D6201 procedure both because the technology used in the ASTM D5500 procedure is 9 years older and because it requires vehicle mileage accumulation on a test rack whereas the ASTM D6201 procedure is an engine dynamometer laboratory procedure. A number of parts necessary to maintain the vehicle used in the ASTM D5500 procedure are no longer available, forcing the use of substitute parts.[142] The approximately 100-hour ASTM D6201 procedure conducted under controlled laboratory conditions is inherently less variable than the nearly month-long ASTM D5500 road-based procedure, thereby providing improved confidence in the repeatability of the results. Therefore, we believe that it is appropriate to continue to accept data from the ASTM D6201 procedure in the interim while a replacement test is under development, while also disallowing new detergent deposit control testing using the EPA ASTM D5500 procedure.

During the rule development process, some stakeholders stated that disallowing new detergent deposit control testing using the EPA ASTM D5500 procedure in favor of the Top Tier ASTM D6201 procedure or the California ASTM D5500 procedure would represent an increase in stringency in the detergent program that must be supported by an analysis of costs versus benefits. These parties stated that the concentration of detergent required to satisfy the requirements of the California ASTM D5500 procedure and Top Tier ASTM D6201 procedure is somewhat higher and significantly higher, respectively, than required under the EPA ASTM D5500 procedure.[143] We acknowledge that Top Tier, and perhaps the California procedure, could result in higher detergent treat rates. However, we are not proposing to eliminate the use of additives based on the EPA ASTM D5500 procedure. Additive packages can continue to be used at their existing treat rates indefinitely. It is only the use of new additives that would potentially be impacted, and for which we receive only several applications a year. Even then, as discussed in Section XIII.F.5, we are proposing an administrative process whereby industry could petition EPA to adopt updated deposit control test procedures when they become available, provided that such procedures are as least as protective as the currently accepted procedures. This demonstration could be made compared to any of the currently accepted procedures, including the EPA ASTM D5500 procedure.

Furthermore, we have no data to evaluate that there are any emissions benefits for the current vehicle fleet resulting from satisfying any of the current deposit control test procedures discussed in this section. The more modern nature of the California ASTM D5500 procedure and the Top Tier ASTM D6201 procedure should provide greater confidence that compliance with these procedures is providing an emissions benefit, whereas we lack confidence that compliance with the EPA ASTM D5500 procedure is providing any meaningful emissions benefit.

4. Expanding the Applicability of Detergent Certifications Based on Compliance With the California Deposit Control Regulations

Under the current regulations, a detergent certification based on compliance with the California's deposit control regulations may be used to demonstrate compliance with EPA's deposit control requirements only for gasoline that meets the California's compositional requirements and where the detergent is added in a terminal located in the California. This limitation was based on concerns that detergents certified using test fuels representative of California gasoline might not be capable of controlling deposits in

[138] We are also proposing to update the detergent deposit control testing provisions that are based on the Top Tier program to reflect current Top Tier test fuel composition specifications.

[139] The proposed procedures to adopt potential changes to detergent deposit control test procedures as they arise in the future are discussed in Section XIII.F.5. See Section XIII.F.4 regarding the geographic applicability of California detergent certifications.

[140] This approach is not reflected in the proposed regulatory text but would only require minor changes to allow.

[141] Id.

[142] Parts availability is also beginning to be problematic for the engine used in the ASTM D6201 procedure, although difficulties in maintaining the vehicle used in the ASTM D5500 procedure are much more pronounced.

[143] The California ASTM D5500 procedure differs from the EPA procedure in that it has a more stringent IVD standard (50 versus 100 mg of IVD per valve), while requiring a test fuel that has less deposit forming severity than the test fuel required under the EPA procedure.

gasoline that does not meet California requirements. When our detergent program was finalized in 1996, the composition of gasoline that complies with California standards differed substantially from gasoline that met our requirements.[144] Through subsequent rulemakings, expansion of E10 nationwide, and other market changes, the composition of gasoline made for use outside of California is much closer to that required by California. Therefore, we believe that detergents certified under California's requirements should be capable of controlling deposits in gasoline that meets EPA's standards. Further support for this assessment is that California requires that a detergent limit the accumulation of intake valve deposits to less than 50 mg per valve whereas our program allows the accumulation of up to 100 mg per valve using the ASTM D5500 procedure. Consequently, we are proposing that a detergent certified under California's program could be used to meet our deposit control requirements in all gasoline.

5. Easing the Adoption of Future Updates to Deposit Control Test Procedures

We are co-proposing two approaches regarding the process of updating deposit control test procedures for the future and how regulated parties would reference the specifications for these procedures. The primary approach would be through an administrative process, and the alternative approach would be through a traditional rulemaking process. Under the primary approach, deposit control test procedures accepted by EPA would be specified in a publicly available document that could be updated as EPA accepts new procedures. The use of this streamlined process would greatly facilitate keeping the requirements consistent with current industry practice. For example, the current need for a notice-and-comment rulemaking to amend test procedures specified in the CFR has caused the detergent program to lag far behind in reflecting current industry practice regarding the test fuels used for the ASTM D6201 procedure. Such noncontroversial changes could be made much more been readily through a streamlined process.

Under this approach, stakeholders could petition EPA to adopt changes to the deposit control test procedures previously accepted by EPA (*e.g.,* when an update to an existing test procedure is incorporated into an existing test method). We would then conduct outreach with stakeholders to assess whether there is sufficiently broad support for the proposed change. If we determine that this is the case and the suggested change met applicable requirements, we would publish on our web page and by direct communications with stakeholders that we have accepted the change. We would periodically update the detergent regulations in the CFR to reflect accepted alternatives.

Under the alternative approach, a notice-and-comment rulemaking would always be required to make changes to the deposit control test procedures and the detergent regulations in the CFR would need to be amended before such changes could take effect. Based on historical experience, this process would make it more difficult to remain current with the changing vehicle and fuel marketplace.

6. Removing Expired and Unused Provisions

The detergent program in part 80 includes provisions to allow a detergent to be certified for use in different gasoline pools using test fuels that have specifications representative of the deposit-forming characteristics of these discrete pools. Under the ''national-generic'' certification option, a detergent can be certified for use in all gasoline containing any approved oxygenate. Other options allow a detergent to be certified for use only within one of the five Petroleum Administration for Defense Districts (PADDs), in regular or premium gasoline, in oxygenated or nonoxygenated gasoline, in gasoline containing a specific oxygenate other than ethanol, or in a segregated gasoline pool defined by the certification applicant. California has separate detergency requirements for gasoline sold in California. We accept detergent certifications under the California program in lieu of meeting our requirements. All applications for detergent certification to date other than those based on the California program have been under the national-generic option.

We are proposing to remove expired and unused provisions in the detergent program to make the detergent regulations more accessible and understandable and eliminate the ongoing costs of maintaining these provisions. Despite the lack of utility of these provisions, there is a cost to both EPA and industry of maintaining an understanding of them as well as the cost of continuing to print them in the CFR. We are proposing to remove regulatory provisions associated with the interim detergent program that were superseded by the detergent program in 1996.[145] We are also proposing to remove the unused options to certify a detergent for a discrete gasoline pool under the PADD-specific, regular versus premium grade, non-oxygenated gasoline, oxygenate-specific, and fuel-specific certification options.[146] We believe that it is reasonable to conclude that these options do not provide a meaningful flexibility to industry given that they have remained unused since the detergent program's inception in 1996. Under part 1090, the detergent program would allow all detergents to be used in all gasoline containing any approved oxygenate, as is the case today under the national-generic detergent certification option. Detergent certifications under California's program would also remain valid.[147]

7. Streamlining the Detergent Registration Process

Detergent manufacturers are currently required under part 80 to submit detergent certification test data and detergent composition information for evaluation and approval by EPA prior to the detergent being used to comply with our deposit control requirements. To speed up the introduction of new detergents and to reduce the burden of detergent certification, we are proposing that detergent manufacturers could begin marketing a detergent once the manufacturer is satisfied that they have met EPA testing requirements without the need for a prior submission of the data to EPA and approval by EPA. Under this approach, detergent manufacturers would be required to submit data that demonstrates compliance with the deposit control testing requirements upon request by EPA.

Composition information is required for all additives that are registered for use in gasoline under our Fuel and Fuel Additive Program in part 79. We are proposing that the additional composition information that is required for detergents to be evaluated for deposit control efficacy under part 80, including the lowest additive concentration (LAC) established by detergent deposit control testing, would be required to be submitted as part of a detergent's part 79 additive registration rather than requiring a separate submission under part 80. Combining all the detergent composition information that must be submitted to EPA under part 79 would reduce the

[144] See 61 FR 35326–27 (July 5, 1996).

[145] See 40 CFR 80.141 through 80.156.

[146] See 40 CFR 80.163.

[147] See Section XIII.F.4 regarding the proposed expansion to the applicability of California-based detergent certifications.

burden of a separate submission under part 80.

8. Simplifying the Detergent Volumetric Accounting Reconciliation Requirements

Detergent blenders must maintain periodic VAR records to demonstrate that they added a volume of detergent to the gasoline they distribute at least as great as the LAC associated with the certification for the detergent that is used. The current VAR provisions require that detergent blenders compile a separate record for each monthly VAR period in a standard format. Detergent blenders stated that the necessary VAR records are kept in electronic form as standard business practice, but that compiling such information into a standard format as required by EPA for each VAR period represents a significant burden. To reduce the burden, they requested that EPA be more flexible regarding the format of these records. We agree that the goals of the VAR program can be achieved while providing the requested flexibility. Removing the requirement that a VAR report be prepared for each accounting period would also eliminate the burden on industry of requesting and on EPA of issuing a waiver from this requirement during emergency situations to ensure the availability of gasoline. Therefore, we are proposing to require that detergent blenders keep the necessary records to demonstrate compliance with detergent LAC requirements for each blending facility in whatever form that is their common practice. The same one calendar month or lesser accounting period would still apply.

9. Removing the Requirement That the Gasoline Portion of E85 Contain Detergent

The current deposit control regulations require that the gasoline portion of E85 must contain a detergent additive at a concentration at least as great as that used during detergent certification testing (referred to as the lowest additive concentration or LAC).[148] The addition of ethanol to gasoline, with detergent at the LAC, to produce E85 results in a detergent concentration that is lower than the LAC due to the increased dilution from the additional ethanol. We proposed to remove this requirement in the 2016 Renewables Enhancement and Growth Support (REGS) rule.[149]

In the REGS rule, we noted that we are not aware of data on the deposit control needs of flex-fuel vehicles (FFVs) that operate on E85. We also related input from stakeholders that as additive concentration diminishes due to dilution with ethanol in making E85, there is a point where the presence of a detergent ceases to be beneficial and can contribute to deposit formation. We also noted that certain detergents are not completely soluble in high ethanol content blends. Comments on the REGS rule were supportive of removing the requirement that the gasoline portion of E85 contain detergents. During the rule development process for this action, stakeholders indicated that they were also supportive of this change. Therefore, we are proposing to remove the current requirement that the gasoline portion of E85 contain detergents.

This action is allowable under the CAA as CAA section 211(l) only refers to deposit control additives for gasoline. E85 is not gasoline because only fuels composed of at least 50 volume percent clear gasoline are included in the gasoline family under part 79 and E85 contains at least 51 volume percent ethanol.[150]

G. In-Line Blending

We are proposing to continue to allow the use of EPA-approved in-line blending waivers. These in-line blending waiver provisions allow refiners to use a procedure to certify batches using in-line blending equipment instead of the more typical batch certification procedures. Under part 80, we have two different sets of requirements for in-line blending for RFG and CG. However, we are proposing to consolidate these two sets of requirements into a single set of requirements for in-line blending in part 1090. For RFG refiners, the in-line blending requirements would remain largely unchanged except that RFG refiners' in-line blending waivers would not have to cover parameters we are proposing to no longer require for the certification of batches of gasoline (discussed in more detail in Section V.A.2). RFG refiners would still need to arrange for an annual audit to ensure that the terms of the in-line blending waiver are being implemented appropriately. For CG refiners, we are proposing to allow in-line blending waivers to cover all regulated gasoline parameters instead of just sulfur. CG refiners would also have to undergo the same annual audit procedure for RFG refiners that currently exists under part 80. We believe that the flexibility to cover additional parameters for CG refiners through the in-line blending waiver would far exceed any costs associated with the additional audit.

Due to the substantial proposed changes in part 1090 to the existing requirements for in-line blending waivers, we are proposing to require that all refiners with an existing in-line blending waiver would need to resubmit their in-line blending waiver requests. We believe this is necessary to ensure that in-line blending waivers appropriately cover the proposed changes to the in-line blending requirements. Due to the time it would take for refiners to prepare new submissions and for us to review and approve those submissions, we are proposing to allow refiners to operate under their existing part 80 in-line blending waiver until January 1, 2022, a full year after we are proposing to implement most other proposed part 1090 provisions. We believe this would provide an adequate amount of time for refiners to submit and receive new in-line blending waivers. We seek comment on whether we should require resubmissions and whether we are providing an adequate amount of time for refiners to do so.

H. Confidential Business Information

We are proposing regulations that would streamline our processing of claims that requests for exemptions or flexibilities should be withheld from public disclosure under Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. 552(b)(4), as CBI. If finalized, the rules would identify certain types of information collected by EPA under part 1090 that EPA will consider as not entitled to confidential treatment pursuant to Exemption 4 of the FOIA and which EPA will release without further notice.

Exemption 4 of the FOIA exempts from disclosure ''trade secrets and commercial or financial information obtained from a person [that is] privileged or confidential.'' [151] In order for information to meet the requirements of Exemption 4, EPA must find that the information is either: (1) A trade secret, or (2) commercial or financial information that is: (a) Obtained from a person, and (b) privileged or confidential. Information meeting these criteria is commonly referred to as CBI.[152]

In June 2019, the U.S. Supreme Court issued its decision in *Food Marketing*

[148] See 40 CFR 80.161(a)(3).

[149] See 81 FR 80828 (November 16, 2016).

[150] See 40 CFR 79.56(e)(1)(i) regarding the gasoline family definition. See ASTM D5798 regarding the ethanol content of E85.

[151] 5 U.S.C. 552(b)(4).

[152] We note that CAA section 114 explicitly excludes emissions data from treatment as confidential information.

Institute v. *Argus Leader Media,* 139 S. Ct. 2356, 2366 (2019) (*Argus Leader*). *Argus Leader* addressed the meaning of ''confidential'' within the context of FOIA Exemption 4. The Court held that ''[a]t least where commercial or financial information is both customarily and actually treated as private by its owner and provided to the government under an assurance of privacy, the information is 'confidential' within the meaning of Exemption 4.'' [153] The Court identified two conditions ''that might be required for information communicated to another to be considered confidential.'' [154] Under the first condition, ''information communicated to another remains confidential whenever it is customarily kept private, or at least closely held, by the person imparting it.'' (internal citations omitted). The second condition provides that ''information might be considered confidential only if the party receiving it provides some assurance that it will remain secret.'' (internal citations omitted). The Court found the first condition necessary for information to be considered confidential within the meaning of Exemption 4, but did not address whether the second condition must also be met.

Following issuance of the Court's opinion, the U.S. Department of Justice (DOJ) issued guidance concerning the confidentiality prong of Exemption 4, articulating ''the newly defined contours of Exemption 4'' post-*Argus Leader.*[155] Where the government provides an express or implied indication to the submitter prior to or at the time the information is submitted to the government that the government would publicly disclose the information, then the submitter cannot reasonably expect confidentiality of the information upon submission, and the information is not entitled to confidential treatment under Exemption 4.[156]

Here, EPA is providing an express indication that we may release certain basic information incorporated into EPA actions on petitions and submissions, as well as information contained in submissions to EPA under part 1090 without further notice, and that such information will not be entitled to confidential treatment under Exemption 4 of the FOIA. In particular, this decision applies to requests under the following processes: Testing and R&D exemptions under 40 CFR 1090.610, hardship exemptions under 40 CFR 1090.635, alternative quality assurance programs under 40 CFR 1090.505, alternative PTD language under 40 CFR 1090.1175, in-line blending waivers under 40 CFR 1090.1315, alternative measurement procedures under 40 CFR 1090.1365, survey plans under 40 CFR 1090.1400, and alternative labels under 40 CFR 1090.1500. Accordingly, such information may be released without further notice to the submitter and without following EPA's procedures set forth in 40 CFR part 2, subpart B. Thus, to expedite processing of information requests and increase transparency related to EPA determinations, we are proposing to clarify in the regulations that a clearly delineated set of basic information related to our decisions on exemptions, waivers, and alternative procedures under part 1090 will not be treated as confidential.

In this action, we are, by rulemaking, providing potential submitters notice of our intent to release particular information related to future submissions. We are proposing that upon receipt of submissions, we may release the following information: Submitter's name; the name and location of the facility for which relief is requested, if applicable; the general nature of the request; and the relevant time period for the request, if applicable. Additionally, once we have adjudicated submissions, we may release the following additional information: The extent to which EPA either granted or denied the request, and any relevant conditions. For information submitted under part 1090 claimed as confidential that is outside the categories described above, and not specified in the proposed regulations at 40 CFR 1090.15(b) or (c), EPA will evaluate such confidentiality claims in accordance with our regulations at 40 CFR part 2, subpart B.

We find that it is appropriate to release the information described above in the interest of transparency and to provide the public with information about entities seeking exemptions or requests for alternative compliance procedures under part 1090. This approach will also provide certainty to submitters regarding the release of information under part 1090. With this advance notice, each potential submitter will have the discretion to decide whether to make such a request with the understanding that EPA may release certain information about the request without further notice.

XIV. Costs and Benefits

A. Overview

In general, we expect that this action would reduce the cost of fuel distribution by improving fuel fungibility, reduce the costs for regulated parties to comply with our fuel quality regulations, and reduce the costs for EPA to implement those regulations. We do not expect a measurable effect on regulated emissions or air quality as this rule is not proposing to change the stringency of our fuel quality standards. This section lays out the general areas of potential cost savings for producing fuels that would result if the proposing streamlining rule was finalized. We outline in more detail these areas for savings in a technical memo to the docket.[157] We specifically solicit comment on quantifying cost savings associated with increased fungibility of fuels, as well as the tables provided and assumptions invoked in the technical memo.

B. Reduced Fuel Costs to Consumers From Improved Fuel Fungibility

A number of the provisions being proposed in part 1090 are expected to improve fuel fungibility. This would result in decreased costs associated with the distribution and sale of such fuels. Some examples of ways that this could result in potential cost savings is from the decreased need for separate tanks at terminals, the shipment of larger batches of fuels through pipelines with less interface downgrade, and fewer constraints on distribution and use of certain fuels in various markets (*e.g.,* winter RFG in CG areas). While we believe that these types of savings could be significant, especially when applied to the national gasoline and diesel fuel pools, these types of costs savings are difficult to quantify. We reached out to stakeholders to attempt to quantify potential costs savings and did not receive any information that would help us determine cost savings from increased fuel fungibility. Therefore, we seek comment on potential cost savings as from increased fuel fungibility directly for the proposed fuels regulatory streamlining provisions.

[153] *Argus Leader,* 139 S. Ct. at 2366.

[154] Id. at 2363.

[155] ''Exemption 4 After the Supreme Court's Ruling in Food Marketing Institute v. Argus Leader Media and Accompanying Step-by-Step Guide,'' Office of Information Policy, U.S. DOJ, (October 4, 2019), available at *https://www.justice.gov/oip/exemption-4-after-supreme-courts-ruling-food-marketing-institutev-argus-leader-media.*

[156] See id.; see also ''Step-by-Step Guide for Determining if Commercial or Financial Information Obtained from a Person is Confidential under Exemption 4 of the FOIA,'' Office of Information Policy, U.S. DOJ, (updated October 7, 2019), available at *https://www.justice.gov/oip/step-step-guide-determining-if-commercial-or-financial-information-obtained-person-confidential.*

[157] See ''Economic Analysis: Fuels Regulatory Streamlining Proposed Rule,'' available in the docket for this action.

C. Costs and Benefits for Regulated Parties

We anticipate that the proposed streamlined fuels provisions would significantly reduce the administrative burden for regulated parties to comply with our fuel quality standards. The opportunities to reduce such administrative burden have been discussed throughout this proposal. Some examples of areas where savings could result are the decrease in the number of fuel parameters needed to be tested to certify gasoline (discussed in Section V.A.2), the reduction in the number and frequency of reports submitted to EPA to demonstrate compliance with our gasoline requirements (discussed in Section VIII.C), and cost savings associated with consolidating the current four in-use survey programs into a single, national in-use survey program.

In general, estimates in administrative burden reduction are captured in the supporting statement for the proposed information collection request (ICR) required under the Paperwork Reduction Act (PRA) and discussed in more detail in Section XV.C.[158] As part of this action, we are proposing to replace the multiple existing ICRs for part 80 into a single ICR for all fuel programs that would now be included in part 1090. As part of that process, we are comparing the administrative burden from the existing ICRs to the estimated administrative burden in the proposed ICR. This results in a change of about $4.6 million less per year. Furthermore, we discuss additional areas of potential administrative savings for industry that may not be captured in ICRs in a technical memorandum.[159] We estimate that there are potential savings of about $28.3 million per year. Including the $4.6 million cost reductions estimated under the ICR, the total estimated savings in administrative costs to industry is $32.9 million per year. Table XIV.C–1 outlines the categories identified for savings, which are described in detail in a memorandum to the docket.[160]

TABLE XIV.C–1—ESTIMATED ANNUAL COST SAVINGS BY SAVINGS CATEGORY [1]

Savings category	Savings (in millions)
Eliminate Olefin, Aromatics and Distillation Testing	$5.4
Fewer Batch Reports	4.5
Less Retail Sampling	1.5
Eliminate Oxygenate Testing	2.5
Independent Labs	0.6
Oversight Testing	0.2
Barge Distribution Savings	13.8
Information Collection Request	4.6
Total Savings	32.9

[1] Cost savings in 2019 dollars.

In addition, there are other potential savings for all stakeholders that are more difficult to quantify. For example, an expected consequence of making the regulations clearer and less complex would be less time and effort for staff to understand our regulations and fewer inquiries to EPA or to hired consultants to untangle regulatory ambiguity.

Aspects of this action that are expected to increase costs are expected to be small and offset by a large margin by savings in provisions they replace. Since we are not proposing changes to the stringency of our standards, we do not expect fuel manufacturers to have to alter their production processes in order to comply with the proposed streamlined regulations. In prior fuels rulemakings, retooling petroleum refiners often serve as the most significant costs associated with changes in fuel standards. Similarly, other parties in the fuel distribution system should not be expected to have to make any costly adjustments to how they produce, distribute, and sell fuels, fuel additives, and regulated blendstocks. We do expect there may be some one-time costs associated with updating recordkeeping and reporting requirements associated with the proposed requirements. For example, parties would most likely need to change PTDs to reflect the proposed streamlined language. These costs are expected to be small and are reflected in the ICR supporting statement.[161]

Overall, we expect the savings from increased fungibility of fuels, the decrease in administrative costs, and other indirect cost savings resulting from the proposal to far exceed any one-time administrative costs needed to begin compliance with the proposed streamlined fuel quality regulations. These cost savings would be expected to be passed along to consumers in the form of lower fuel prices, given the highly competitive fuel marketplace. We discuss many of these areas, including a much more detailed analysis of the cost savings, in a technical memorandum[162] and the ICR supporting statement.[163] We also estimated the total new present value cost savings if the total savings are carried out over 30 years at a 3 percent and 7 percent discounted rate, which are presented in Table XIV.C–2.[164]

TABLE XIV.C–2—ESTIMATED NET PRESENT VALUE COST SAVINGS [1]

Three percent discount rate (in millions)	Seven percent discount rate (in millions)
$560	$380

[1] Cost savings in 2019 dollars.

We seek comment on the potential costs and benefits that would result from this action and whether there are other costs and benefits that we should consider.

D. Environmental Impacts

Since we are not proposing to make changes to the stringency of the existing fuel quality standards, we do not expect any measurable impact on regulated emissions or air quality. However, as discussed in more detail throughout the preamble, there are certain areas of this action where changes to compliance requirements could be viewed as marginally affecting in-use fuel quality. These marginal changes could then have a ripple effect on regulated emissions. In general, such changes would be very small, typically well below the levels that we have historically attempted to quantify in rulemakings where we establish fuel standards. Given the relative size of such changes, it would be difficult if not impossible to make an estimate with any level of confidence on the air quality effects that would result from this action. Despite this limitation, we have attempted to at least identify potential areas that could have an effect on in-use fuel quality.

First, we have heard concerns that the proposed RFG RVP maximum per-gallon of 7.4 psi, which is higher than the estimated RFG average RVP of 7.1–7.2 psi. might be perceived as a decrease

[158] The supporting statement for the proposed ICR and other supporting materials are available in the docket for this action.

[159] See ''Economic Analysis: Fuels Regulatory Streamlining Proposed Rule,'' available in the docket for this action.

[160] Id.

[161] The ICR supporting statement is available in the docket for this action.

[162] See ''Economic Analysis: Fuels Regulatory Streamlining Proposed Rule,'' available in the docket for this action.

[163] The ICR supporting statement is available in the docket for this action.

[164] These results are discussed in more detail in the technical memorandum, ''Economic Analysis: Fuels Regulatory Streamlining Proposed Rule,'' available in the docket for this action.

in in-use fuel quality. Section V discusses why we believe that based on historical information, the fuel system builds in compliance margins to assure that per-gallon RVP standards are met and result in RVP averages that are between 0.2–0.3 psi lower than the maximum per-gallon standard. We have also maintained limitations on the addition of certified butane and pentane to summer RFG to help ensure that an average RVP of 7.1–7.2 psi is realized in-use for summer RFG. Furthermore, by consolidating the three RFG VOC performance standards to the most stringent standard, there may be a slight reduction in the RVP of RFG supplied to areas with the less stringent VOC performance standards.

Second, we heard that by allowing manufacturers of CG to account for oxygenate added downstream, any current unintentional overcompliance with the gasoline average benzene and sulfur standards would be lost, resulting in a slight increase in the benzene and sulfur contents of the fuel pool. While this could result in a slight increase in the amount of benzene and sulfur in the national fuel pool,[165] we believe there are some other elements that could offset or eclipse these potential increases, making any real world quantification difficult. One is the downstream BOB recertification procedures that would require downstream parties that recertify BOBs for less oxygenate to make up for the unrealized dilution of sulfur and benzene through retiring credits (*e.g.,* if a party recertifies an E10 BOB as an E0 gasoline). This would pull sulfur and benzene out of the gasoline fuel pool and help offset some of the reduction in overcompliance. Additionally, we are not allowing the generation of credits from the over blending of oxygenates into BOB (*e.g.,* if a party recertifies an E10 BOB as E15). This would further dilute the amount of sulfur and benzene in the gasoline pool and help offset any perceived reduction in overcompliance.

During the rule development process, we also heard from stakeholders concerns that reducing the parameters needed to certify gasoline would make it easier for parties to blend dirtier gasoline and not comply with our fuel quality requirements. Other stakeholders suggested that the reduced reporting requirements would make it more difficult for EPA to oversee compliance with the fuel requirements. We believe the improved oversight, especially by third-party surveys, would address these concerns and, contrary to the concerns expressed, may improve the quality of fuel sold at retail. While fuel manufacturers would still be required to certify fuels for conformance with EPA fuel quality standards, the issue is that fuels are now blended with oxygenates, additives, and blendstocks at various points along the distribution chain before the fuels are used in vehicles and engines. Under the existing regulations, EPA monitors the quality of gasoline primarily at the refinery gate, not downstream at retail. The proposed national in-use survey program is designed to ensure that fuels continue to meet our standards when they are dispensed from retail stations and would help provide valuable information for EPA to oversee the fuel quality programs. In addition, the proposed voluntary national oversight program would ensure that manufacturers are sampling and testing in a manner consistent with our regulations to help ensure that parties are not biasing test results to make dirtier fuels. We also believe that by proposing to simplify and modernize our reporting requirements, we will be better able to oversee the fuel quality program as information is more readily available.

Taken together, we believe the proposed streamlining of the fuel quality programs would on balance ensure greater compliance with our regulatory requirements by making the requirements more intuitive to the regulated community to comply with. We also believe the increased oversight mechanisms proposed would allow us to better oversee compliance with the current fuel standards and take appropriate action when issues are identified. The net result of this could be a slight improvement in fuel quality across the national fuel pool; however, such an effect is difficult to quantify.

XV. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www.epa.gov/laws-regulations/laws-and-executive-orders.*

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review. Any changes made in response to OMB recommendations have been documented in the docket. EPA prepared an economic analysis of the potential costs and benefits associated with this action. This analysis, ''Economic Analysis: Fuels Regulatory Streamlining Proposed Rule,'' is available in the docket.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be an Executive Order 13771 deregulatory action. Details on the estimated cost savings of this proposed rule can be found in our analysis of the potential costs and benefits associated with this action in Section XIV.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned OMB ICR number 2060–NEW; EPA ICR number 2607.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The information collection activities under this proposed rule are similar to those under existing 40 CFR part 80 and include familiar requirements for respondents to register, report, sample, and test gasoline for four parameters (*i.e.,* sulfur, benzene, seasonal RVP and oxygenate/oxygen content in the cases of gasoline and sulfur in the case of diesel), keep records in the normal course of business (*e.g.,* PTDs and test results, as applicable), participate in surveys, conduct attest engagements, and apply pump labels. Many parties are already registered under part 80 and would not have to re-register under the proposed approach. The exact information collection requirements proposed are tied to the party's control over the quality and type of fuel—for example, a refiner of gasoline has great control over the quality and type of fuel and has proposed registration, reporting, sampling, testing, recordkeeping, survey, and attest engagement responsibilities; a party who owns a retail station has only limited, proposed information collection requirements involving the retention of customary business records (*e.g.,* PTDs) and affixing labels to certain pumps from which fuel is dispensed. The proposed information collection for part 1090 would not result in duplication of requirements under existing part 80, as this proposed regulation would replace nearly all non-RFS provisions under the existing part.

Respondents/affected entities: The respondents to this information collection are parties involved in the

[165] See ''Estimated Effects of Proposed Downstream Oxygenate Accounting Provisions,'' available in the docket for this action.

manufacture, blending, distribution, sale, or dispensing of regulated fuels and fuel blendstocks. These include refiners, importers, blenders, terminals and pipelines, truck facilities, fuel retailers, and wholesale purchaser-consumers.

Respondent's obligation to respond: Mandatory, under proposed 40 CFR part 1090.

Estimated number of respondents: 182,269.

Frequency of response: Annual and occasionally.

Total estimated burden: 522,368 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $ 56,744,171 (per year) including, $5,744,016 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on EPA's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs. These 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. EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule will not have a significant economic impact on a substantial number of small entities if the rule relieves regulatory burden, has no net burden, or otherwise has a positive economic effect on the small entities subject to the rule. This action proposes to consolidate EPA's existing fuel quality regulations into the new 40 CFR part 1090, and the proposed requirements on small entities are largely the same as those already included in the existing 40 CFR part 80 fuel quality regulations. While this action makes relatively minor corrections and modifications to those regulations, we do not anticipate that there will be any significant cost increases associated with these proposed changes—to the contrary, we anticipate cost decreases. We have therefore concluded that this action will have no net regulatory burden for all directly regulated small entities.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local or tribal governments. Requirements for the private sector do not exceed $100 million in any one year.

F. Executive Order 13132: Federalism

This action does not have federalism implications. It 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. However, to the extent that states have adopted fuel regulations based on EPA's regulatory provisions that we are proposing to change, states may need to make corresponding changes to their regulations to maintain their effectiveness.

Although Executive Order 13132 does not apply to this proposed rule, EPA did consult with representatives of various State and local governments in developing this rule. EPA has also consulted with representatives from the National Association of Clean Air Agencies (NACAA, representing state and local air pollution officials), Association of Air Pollution Control Agencies (AAPCA, representing state and local air pollution officials), and Northeast States for Coordinated Air Use Management (NESCAUM, the Clean Air Association of the Northeast States). In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and state and local governments, EPA specifically solicits comment on this proposed action from state and local officials.

G. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications as specified in Executive Order 13175. This proposed rule will be implemented at the Federal level and potentially affects transportation fuel refiners, blenders, marketers, distributors, importers, exporters, and renewable fuel producers and importers. Tribal governments would be affected only to the extent they produce, purchase, and use regulated fuels. Thus, Executive Order 13175 does not apply to this action.

H. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. This action proposes to consolidate EPA's existing fuel quality regulations into a new part, consistent with the CAA and authorities provided therein. There are no additional costs for sources in the energy supply, distribution, or use sectors. The proposed action would only be anticipated to improve fuel fungibility and therefore enhance fuel supply and distribution but in ways that are not readily quantifiable.

J. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This proposed action involves technical standards. We are proposing to update a number of regulations that already contain voluntary consensus standards (VCS), practices, and specifications to more recent versions of these standards. In accordance with the requirements of 1 CFR 51.5, we are proposing to incorporate by reference the use of test methods and standards from American Institute of Certified Public Accountants, American Society for Testing and Materials International

(ASTM International), National Institute of Standards and Technology (NIST), and The Institute of Internal Auditors. A detailed discussion of these test methods and standards can be found in Sections III.D.3, VII.F, VIII.F, IX, and XIII.F. The standards and test methods may be obtained through the American Institute of Certified Public Accountants website (*www.aicpa.org*) or by calling (888) 777–7077, ASTM International website (*www.astm.org*) or by calling ASTM at (610) 832–9585, the National Institute of Standards and Technology website (*www.nist.gov*) or by calling NIST at (301) 975–6478, and The Institute of Internal Auditors website (*www.theiia.org*) or by calling (407) 937–1111.

This rulemaking involves environmental monitoring or measurement. Consistent with EPA's Performance Based Measurement System (PBMS), for those fuel parameters that fall under PBMS, such as sulfur, benzene, Reid Vapor Pressure, and oxygenate content, we are proposing not to require the use of specific, prescribed analytic methods. Rather, we are proposing to allow the use of any method that meets the prescribed performance criteria. The PBMS approach is intended to be more flexible and cost-effective for the regulated community; it is also intended to encourage innovation in analytical technology and improved data quality. We are not precluding the use of any method, whether or not it constitutes a voluntary consensus standard, so long as it meets the performance criteria specified. We are also proposing the use of specific standard practices or test methods for situations when PBMS would not be applicable, such as gasoline detergency certification test methods or references to gasoline specification ASTM D4814 or ethanol specification ASTM D4806.

ASTM International routinely updates many of its reference documents. If ASTM International publishes an updated version of any of reference documents included in this proposal, we will consider referencing that updated version in the final rule.

TABLE XV.J–1—PROPOSED STANDARDS AND TEST METHODS TO BE INCORPORATED BY REFERENCE

Organization and standard or test method	Description
The Institute of Internal Auditors—International Standards for the Professional Practice of Internal Auditing (Standards), Revised October 2016.	Document describes standard practices for internal auditors to perform auditing services.
American Institute of Certified Public Accountants—Statements on Standards for Attestation Engagements (SSAE) No. 18, Attestation Standards: Clarification and Recodification, Revised April 2016.	Document describes standard practices for external auditors to perform attestation engagements using agreed-upon procedures.
American Institute of Certified Public Accountants—AICPA Code of Professional Conduct, September 1, 2018.	Document describes principles to establish a code of professional conduct for external auditors.
American Institute of Certified Public Accountants—Statements on Quality Control Standards, July 1, 2019.	Document describes an external auditor's CPA firm's responsibilities for its system of quality control for its accounting and auditing practices.
NIST Handbook 158, 2016 Edition, Field Sampling Procedures for Fuel and Motor Oil Quality Testing—A Handbook for Use by Fuel and Oil Quality Regulatory Officials, April 2016.	Document describes procedures for drawing fuel samples from blender pumps and other in-field installations for testing to measure fuel parameters.
ASTM D86–19, Standard Test Method for Distillation of Petroleum Products and Liquid Fuels at Atmospheric Pressure, approved December 1, 2019.	Test method describes how to perform distillation measurements for gasoline and other petroleum products.
ASTM D287–12b (Reapproved 2019), Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method), approved December 1, 2019.	Test method describes how to measure the density of fuels and other petroleum products, expressed in terms of API gravity.
ASTM D975–19c, Standard Specification for Diesel Fuel, approved December 15, 2019.	Specification describes the characteristic values for several parameters to be considered suitable as diesel fuel.
ASTM D976–06 (Reapproved 2016), Standard Test Method for Calculated Cetane Index of Distillate Fuels, approved April 1, 2016.	Test method describes how to calculate cetane index for a sample of diesel fuel and other distillate fuels.
ASTM D1298–12b (Reapproved 2017), Standard Test Method for Density, Relative Density, or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method, approved July 15, 2017.	Test method describes how to measure the density of fuels and other petroleum products, which can be expressed in terms of API gravity.
ASTM D1319–19, Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption, approved August 1, 2019.	Test method describes how to measure the aromatic content and other hydrocarbon types in diesel fuel and other petroleum products.
ASTM D2163–14 (Reapproved 2019), Standard Test Method for Determination of Hydrocarbons in Liquefied Petroleum (LP) Gases and Propane/Propene Mixtures by Gas Chromatography, approved May 1, 2019.	Test method describes how to determine the content of various types of hydrocarbons in light-end petroleum products, which is used for determining the purity of butane and propane.
ASTM D2622–16, Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-ray Fluorescence Spectrometry, approved January 1, 2016.	Test method describes how to measure the sulfur content in gasoline, diesel fuel, and other petroleum products.
ASTM D3120–08 (Reapproved 2019), Standard Test Method for Trace Quantities of Sulfur in Light Liquid Petroleum Hydrocarbons by Oxidative Microcoulometry, approved May 1, 2019.	Test method describes how to measure the sulfur content in diesel fuel and other petroleum products.
ASTM D3231–18, Standard Test Method for Phosphorus in Gasoline, approved April 1, 2018.	Test method describes how to measure the phosphorus content of gasoline.
ASTM D3237–17, Standard Test Method for Lead in Gasoline by Atomic Absorption Spectroscopy, approved June 1, 2017.	Test method describes how to measure the lead content of gasoline.
ASTM D3606–17, Standard Test Method for Determination of Benzene and Toluene in Spark Ignition Fuels by Gas Chromatography, approved December 1, 2017.	Test method describes how to measure the benzene content of gasoline and similar fuels.
ASTM D4052–18a, Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter, approved December 15, 2018.	Test method describes how to measure the density of fuel samples, which can be expressed in terms of API gravity.

TABLE XV.J–1—PROPOSED STANDARDS AND TEST METHODS TO BE INCORPORATED BY REFERENCE—Continued

Organization and standard or test method	Description
ASTM D4057–19, Standard Practice for Manual Sampling of Petroleum and Petroleum Products, approved July 1, 2019.	Document establishes proper procedures for drawing samples of fuel and other petroleum products from storage tanks and other containers using manual procedures.
ASTM D4177–16e1 Standard Practice for Automatic Sampling of Petroleum and Petroleum Products, approved October 1, 2016.	Document establishes proper procedures for using automated procedures to draw fuel samples for testing.
ASTM D4737–10 (Reapproved 2016), Standard Test Method for Calculated Cetane Index by Four Variable Equation, approved July 1, 2016.	Test method describes how to calculate cetane index for a sample of diesel fuel and other distillate fuels.
ASTM D4806–19a, Standard Specification for Denatured Fuel Ethanol for Blending with Gasolines for Use as Automotive Spark-Ignition Engine Fuel, approved September 15, 2019.	Specification describes the characteristic values for several parameters to be considered suitable as denatured fuel ethanol for blending with gasoline.
ASTM D4814–20, Standard Specification for Automotive Spark-Ignition Engine Fuel, approved February 1, 2020.	Specification describes the characteristic values for several parameters to be considered suitable as gasoline.
ASTM D5134–13 (Reapproved 2017), Standard Test Method for Detailed Analysis of Petroleum Naphthas through n-Nonane by Capillary Gas Chromatography, approved October 1, 2017.	Test method describes how to measure benzene in butane, pentane, and other light-end petroleum compounds.
ASTM D5186–19, Standard Test Method for Determination of the Aromatic Content and Polynuclear Aromatic Content of Diesel Fuels By Supercritical Fluid Chromatography, approved June 1, 2019.	Test method describes how to determine the aromatic content in diesel fuel.
ASTM D5191–19, Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method), approved January 1, 2019.	Test method describes how to determine the vapor pressure of gasoline and other petroleum products.
ASTM D5453–19a, Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Spark Ignition Engine Fuel, Diesel Engine Fuel, and Engine Oil by Ultraviolet Fluorescence, approved July 1, 2019.	Test method describes how to measure the sulfur content of neat ethanol and other petroleum products.
ASTM D5500–19 Standard Test Method for Vehicle Evaluation of Unleaded Automotive Spark-Ignition Engine Fuel for Intake Deposit Formation, approved November 1, 2019.	Test method describes a vehicle test procedure to evaluate intake valve deposit formation of gasoline.
ASTM D5599–18, Standard Test Method for Determination of Oxygenates in Gasoline by Gas Chromatography and Oxygen Selective Flame Ionization Detection, approved June 1, 2018.	Test method describes how to measure the oxygenate content of gasoline.
ASTM D5769–15, Standard Test Method for Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry, approved December 1, 2015.	Test method describes how to determine the benzene content and other types of hydrocarbons in gasoline.
ASTM D5842–19, Standard Practice for Sampling and Handling of Fuels for Volatility Measurement, approved November 1, 2019.	Document establishes proper procedures for drawing samples of gasoline and other fuels from storage tanks and other containers using manual procedures to prepare samples for measuring vapor pressure.
ASTM D5854–19a, Standard Practice for Mixing and Handling of Liquid Samples of Petroleum and Petroleum Products, approved May 1, 2019.	Document establishes proper procedures for handling, mixing, and conditioning procedures to prepare representative composite samples.
ASTM D6201–19a, Standard Test Method for Dynamometer Evaluation of Unleaded Spark-Ignition Engine Fuel for Intake Valve Deposit Formation, approved December 1, 2019.	Test method describes an engine test procedure to evaluate intake valve deposit formation of gasoline.
ASTM D6259–15 (Reapproved 2019), Standard Practice for Determination of a Pooled Limit of Quantitation for a Test Method, approved May 1, 2019.	Document establishes procedures to determine how to evaluate parameter measurements at very low levels, including a laboratory limit of quantitation that applies for a given facility.
ASTM D6299–19, Standard Practice for Applying Statistical Quality Assurance and Control Charting Techniques to Evaluate Analytical Measurement System Performance, approved November 1, 2019.	Document establishes procedures to evaluate measurement system performance relative to statistical criteria for ensuring reliable measurements.
ASTM D6550–15, Standard Test Method for Determination of Olefin Content of Gasolines by Supercritical-Fluid Chromatography, approved December 1, 2015.	Test method describes how to determine the olefin content of gasoline.
ASTM D6667–14 (Reapproved 2019), Standard Test Method for Determination of Total Volatile Sulfur in Gaseous Hydrocarbons and Liquefied Petroleum Gases by Ultraviolet Fluorescence, approved May 1, 2019.	Test method describes how to determine the sulfur content of butane, liquefied petroleum gases, and other gaseous hydrocarbons.
ASTM D6708–19a, Standard Practice for Statistical Assessment and Improvement of Expected Agreement Between Two Test Methods that Purport to Measure the Same Property of a Material, approved November 1, 2019.	Document establishes statistical criteria to evaluate whether an alternative test method provides results that are consistent with a reference procedure.
ASTM D6792–17, Standard Practice for Quality Management Systems in Petroleum Products, Liquid Fuels, and Lubricants Testing Laboratories, approved May 1, 2017.	Document establishes principles for ensuring quality for laboratories involved in parameter measurements for fuels and other petroleum products.
ASTM D7039–15a, Standard Test Method for Sulfur in Gasoline, Diesel Fuel, Jet Fuel, Kerosine, Biodiesel, Biodiesel Blends, and Gasoline-Ethanol Blends by Monochromatic Wavelength Dispersive X-ray Fluorescence Spectrometry, approved July 1, 2015.	Test method describes how to measure sulfur in gasoline and other petroleum products.
ASTM D7717–11 (Reapproved 2017), Standard Practice for Preparing Volumetric Blends of Denatured Fuel Ethanol and Gasoline Blendstocks for Laboratory Analysis, approved May 1, 2017.	Document establishes procedures for blending denatured fuel ethanol with gasoline to prepare a sample for testing.

K. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

EPA believes that this action does not have disproportionately high and adverse human health or environmental effects on minority populations, low income populations, and/or indigenous peoples, as specified in Executive Order 12898 (59 FR 7629, February 16, 1994). This proposed rule does not affect the level of protection provided to human health or the environment by applicable air quality standards. This action does not relax the control measures on sources regulated by EPA's fuel quality regulations and therefore will not cause emissions increases from these sources.

XVI. Statutory Authority

Statutory authority for this action comes from sections 202, 203–209, 211, 213, 216, and 301 of the Clean Air Act, 42 U.S.C. 7414, 7521, 7522–7525, 7541, 7542, 7543, 7545, 7547, 7550, and 7601. Additional support for the procedural and compliance related aspects of this proposed rule comes from sections 114, 208, and 301(a) of the Clean Air Act, 42 U.S.C. 7414, 7521, 7542, and 7601(a).

List of Subjects

40 CFR Part 79

Fuel additives, Gasoline, Motor vehicle pollution, Penalties, Reporting and recordkeeping requirements.

40 CFR Part 80

Environmental protection, Administrative practice and procedure, Air pollution control, Diesel fuel, Fuel additives, Gasoline, Imports, Oil imports, Petroleum, Renewable fuel.

40 CFR Part 86

Administrative practice and procedure, Confidential business information, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements.

40 CFR Part 1037

Administrative practice and procedure, Air pollution control, Confidential business information, Environmental protection, Labeling, Motor vehicle pollution, Reporting and recordkeeping requirements, Warranties.

40 CFR Part 1090

Environmental protection, Administrative practice and procedure, Air pollution control, Diesel fuel, Fuel additives, Gasoline, Imports, Incorporation by reference, Oil imports, Petroleum, Renewable fuel.

Andrew Wheeler,

Administrator.

For the reasons set forth in the preamble, EPA proposes to amend 40 CFR parts 79, 80, 86, 1037, and 1090 as follows:

PART 79—REGISTRATION OF FUEL AND FUEL ADDITIVES

■ 1. The authority citation for part 79 continues to read as follows:

Authority: 42 U.S.C. 7414, 7524, 7545, and 7601.

Subpart A—General Provisions

■ 2. Amend § 79.5 by revising paragraph (a)(1) to read as follows:

§ 79.5 Periodic reporting requirements.

(a) * * * (1) For each calendar year (January 1 through December 31) commencing after the date prescribed for any fuel in subpart D of this part, fuel manufacturers must submit to the Administrator a report for each registered fuel showing the range of concentration of each additive reported under § 79.11(a) and the volume of such fuel produced in the year. Reports must be submitted by March 31 for the preceding year, or part thereof, on forms supplied by the Administrator. If the date prescribed for a particular additive in subpart D of this part, or the later registration of an additive is between October 1 and December 31, no report will be required for the period to the end of that year.

* * * * *

Subpart C—Additive Registration Procedures

■ 3. Amend § 79.21 by:

■ a. Revising paragraphs (f) and (g); and

■ b. Adding paragraph (j).

The revisions and addition read as follows:

§ 79.21 Information and assurances to be provided by the additive manufacturer.

* * * * *

(f) Assurances that any change in information submitted pursuant to:

(1) Paragraphs (a), (b), (c), (d), and (j) of this section will be provided to the Administrator in writing within 30 days of such change; and

(2) Paragraph (e) of this section as provided in § 79.5(b).

(g)(1) Assurances that the additive manufacturer will not represent, directly or indirectly, in any notice, circular, letter, or other written communication or any written, oral, or pictorial notice or other announcement in any publication or by radio or television, that registration of the additive constitutes endorsement, certification, or approval by any agency of the United States, except as specified in paragraph (g)(2) of this section.

(2) In the case of an additive that has its purpose-in-use identified as a deposit control additive for use in gasoline pursuant to the requirements of paragraph (d) of this section, the additive manufacturer may publicly represent that the additive meets the EPA's gasoline deposit control requirements, provided that the additive manufacturer is in compliance with the requirements of 40 CFR 1090.240.

* * * * *

(j) If the purpose-in-use of the additive identified pursuant to the requirements of paragraph (d) of this section is a deposit control additive for use in gasoline, the manufacturer must submit the following in addition to the other information specified in this section:

(1) The lowest additive concentration (LAC) that is compliant with the gasoline deposit control requirements of 40 CFR 1090.240.

(2) The deposit control test method in 40 CFR 1090.1395 that the additive is compliant with.

(3) A complete listing of the additive's components and the weight or volume percent (as applicable) of each component.

(i) When possible, standard chemical nomenclature must be used or the chemical structure of the component must be given. Polymeric components may be reported as the product of other chemical reactants, provided that the supporting data specified in paragraph (j)(3) of this section is also reported.

(ii) Each detergent-active component of the package must be classified into one of the following designations:

(A) Polyalkyl amine.

(B) Polyether amine.

(C) Polyalkylsuccinimide.

(D) Polyalkylaminophenol.

(E) Detergent-active petroleum-based carrier oil.

(F) Detergent-active synthetic carrier oil.

(G) Other detergent-active component (identify category, if feasible).

(iii) *Composition variability.* (A) The composition of a detergent additive reported in a single additive registration (and the detergent additive product sold under a single additive registration) may not include the following:

(*1*) Detergent-active components that differ in identity from those contained in the detergent additive package at the time of deposit control testing.

(*2*) A range of concentrations for any detergent-active component such that, if the component were present in the detergent additive package at the lower bound of the reported range, the deposit control effectiveness of the additive package would be reduced as compared with the level of effectiveness demonstrated pursuant to the requirements of 40 CFR 1090.240. Subject to the foregoing constraint, a gasoline detergent additive sold under a particular additive registration may contain a higher concentration of the detergent-active component(s) than the concentration(s) of such component(s) reported in the registration for the additive.

(B) The identity or concentration of non-detergent-active components of the detergent additive package may vary under a single registration provided that such variability does not reduce the deposit control effectiveness of the additive package as compared with the level of effectiveness demonstrated pursuant to the requirements of 40 CFR 1090.240.

(C) Unless the additive manufacturer provides EPA with data to substantiate that a carrier oil does not act to enhance the detergent additive's ability to control deposits, any carrier oil contained in the detergent additive, whether petroleum-based or synthetic, must be treated as a detergent-active component in accordance with the requirements in paragraph (j)(3)(ii) of this section.

(D) Except as provided in paragraph (j)(3)(iii)(E) of this section, detergent additive packages that do not satisfy the requirements in paragraphs (j)(3)(iii)(A) through (C) must be separately registered. EPA may disqualify an additive for use in satisfying the requirements of this subpart if EPA determines that the variability included within a given detergent additive registration may reduce the deposit control effectiveness of the detergent package such that it may invalidate the lowest additive concentration reported in accordance with the requirements of paragraph (j)(1) of this section and 40 CFR 1090.240.

(E) A change in minimum concentration requirements resulting from a modification of detergent additive composition does not require a new detergent additive registration or a change in existing registration if the modification is affected by a detergent blender pursuant to the requirements of 40 CFR 1090.1240.

(4) For detergent-active polymers and detergent-active carrier oils that are reported as the product of other chemical reactants:

(i) Identification of the reactant materials and the manufacturer's acceptance criteria for determining that these materials are suitable for use in synthesizing detergent components. The manufacturer must maintain documentation, and submit it to EPA upon request, demonstrating that the acceptance criteria reported to EPA are the same criteria which the manufacturer specifies to the suppliers of the reactant materials.

(ii) A Gel Permeation Chromatograph (GPC), providing the molecular weight distribution of the polymer or detergent-active carrier oil components and the concentration of each chromatographic peak representing more than one percent of the total mass. For these results to be acceptable, the GPC test procedure must include equipment calibration with a polystyrene standard or other readily attainable and generally accepted calibration standard. The identity of the calibration standard must be provided, together with the GPC characterization of the standard.

(5) For non-detergent-active carrier oils, the following parameters:

(i) T10, T50, and T90 distillation points, and end boiling point, measured according to applicable test procedures cited in 40 CFR 1090.1350.

(ii) API gravity and viscosity.

(iii) Concentration of oxygen, sulfur, and nitrogen, if greater than or equal to 0.5 percent (by weight) of the carrier oil.

(6) Description of an FTIR-based method appropriate for identifying the detergent additive package and its detergent-active components (polymers, carrier oils, and others) both qualitatively and quantitatively, together with the actual infrared spectra of the detergent additive package and each detergent-active component obtained by this test method. The FTIR infrared spectra submitted in connection with the registration of a detergent additive package must reflect the results of a test conducted on a sample of the additive containing the detergent-active component(s) at a concentration no lower than the concentration(s) (or the lower bound of a range of concentration) reported in the registration pursuant to paragraph (j)(1) of this section.

(7) Specific physical parameters must be identified which the manufacturer considers adequate and appropriate, in combination with other information in this section, for identifying the detergent additive package and monitoring its production quality control.

(i) Such parameters must include (but need not be limited to) viscosity, density, and basic nitrogen content, unless the additive manufacturer specifically requests, and EPA approves, the substitution of other parameter(s) which the manufacturer considers to be more appropriate for a particular additive package. The request must be made in writing and must include an explanation of how the requested physical parameter(s) are helpful as indicator(s) of detergent production quality control. EPA will respond to such requests in writing; the additional parameters are not approved until the manufacturer receives EPA's written approval.

(ii) The manufacturer must identify a standardized measurement method, consistent with the chemical and physical nature of the detergent product, which will be used to measure each parameter. The documented ASTM repeatability for the method must also be cited. The manufacturer's target value for each parameter in the additive, and the expected range of production values for each parameter, must be specified.

(iii) The expected range of variability must differ from the target value by an amount no greater than five times the standard repeatability of the test procedure, or by no more than 10 percent of the target value, whichever is less. However, in the case of nitrogen analysis or other procedures for measuring concentrations of specific chemical compounds or elements, when the target value is less than 10 parts per million, a range of variability up to 50 percent of the target value will be considered acceptable.

(iv) If a manufacturer wishes to rely on measurement methods or production variability ranges which do not conform to the above limitations, then the manufacturer must receive prior written approval from EPA. A request for such allowance must be made in writing. It must fully justify the adequacy of the test procedure, explain why a broader range of variability is required, and provide evidence that the production detergent will perform adequately throughout the requested range of variability pursuant to the requirements of 40 CFR 1090.1395.

■ 4. Revise § 79.24 to read as follows:

§ 79.24 Termination of registration of additives.

(a) Registration may be terminated by the Administrator if the additive manufacturer requests such termination in writing.

(b) Registration for an additive for an additive that has its purpose-in-use identified as a deposit control additive for use in gasoline pursuant to the requirements of § 79.21(d) may be

terminated by the Administrator if the EPA determines that the detergent additive is not compliant with the gasoline deposit control requirements of 40 CFR 1090.240.

Subpart C—Additive Registration Procedures

■ 5. Amend § 79.32 by revising paragraph (c) to read as follows:

§ 79.32 Motor vehicle gasoline.

* * * * *

(c) Fuel manufacturers must submit the reports specified in 40 CFR part 1090, subpart J.

* * * * *

■ 6. Amend § 79.33 by revising paragraph (c) to read as follows:

§ 79.3 3 Motor vehicle diesel.

* * * * *

(c) Fuel manufacturers must submit the reports specified in 40 CFR part 1090, subpart J.

* * * * *

PART 80—REGISTRATION OF FUELS AND FUEL ADDITIVES

■ 7. The authority citation for part 80 continues to read as follows:

Authority: 42 U.S.C. 7414, 7521, 7542, 7545, and 7601(a).

Subpart A—General Provisions

■ 8. Revise § 80.1 to read as follows:

§ 80.1 Scope.

(a) This part prescribes regulations for the renewable fuel program under the Clean Air Act section 211(o) (42 U.S.C. 7545(o)).

(b) This part also prescribes regulations for the labeling of fuel dispensing systems for oxygenated gasoline at retail under the Clean Air Act section 211(m)(4) (42 U.S.C. 7545(m)(4)).

(c) Nothing in this part is intended to preempt the ability of state or local governments to control or prohibit any fuel or fuel additive for use in motor vehicles and motor vehicle engines which is not explicitly regulated by this part.

■ 9. Revise § 80.2 to read as follows:

§ 80.2 Definitions.

Definitions apply in this part as described in this section.

Administrator means the Administrator of the Environmental Protection Agency.

Carrier means any distributor who transports or stores or causes the transportation or storage of gasoline or diesel fuel without taking title to or otherwise having any ownership of the gasoline or diesel fuel, and without altering either the quality or quantity of the gasoline or diesel fuel.

Category 3 marine vessels, for the purposes of this part 80, are vessels that are propelled by engines meeting the definition of ''Category 3'' in 40 CFR 1042.901.

CBOB means gasoline blendstock that could become conventional gasoline solely upon the addition of oxygenate.

Control area means a geographic area in which only oxygenated gasoline under the oxygenated gasoline program may be sold or dispensed, with boundaries determined by Clean Air Act section 211(m).

Control period means the period during which oxygenated gasoline must be sold or dispensed in any control area, pursuant to Clean Air Act section 211(m)(2).

Conventional gasoline or CG means any gasoline that has been certified under § 1090.1100(b) and is not RFG.

Diesel fuel means any fuel sold in any State or Territory of the United States and suitable for use in diesel engines, and that is one of the following:

(1) A distillate fuel commonly or commercially known or sold as No. 1 diesel fuel or No. 2 diesel fuel;

(2) A non-distillate fuel other than residual fuel with comparable physical and chemical properties (*e.g.,* biodiesel fuel); or

(3) A mixture of fuels meeting the criteria of paragraphs (1) and (2) of this definition.

Distillate fuel means diesel fuel and other petroleum fuels that can be used in engines that are designed for diesel fuel. For example, jet fuel, heating oil, kerosene, No. 4 fuel, DMX, DMA, DMB, and DMC are distillate fuels; and natural gas, LPG, gasoline, and residual fuel are not distillate fuels. Blends containing residual fuel may be distillate fuels.

Distributor means any person who transports or stores or causes the transportation or storage of gasoline or diesel fuel at any point between any gasoline or diesel fuel refinery or importer's facility and any retail outlet or wholesale purchaser-consumer's facility.

ECA marine fuel is diesel, distillate, or residual fuel that meets the criteria of paragraph (1) of this definition, but not the criteria of paragraph (2) of this definition.

(1) All diesel, distillate, or residual fuel used, intended for use, or made available for use in Category 3 marine vessels while the vessels are operating within an Emission Control Area (ECA), or an ECA associated area, is ECA marine fuel, unless it meets the criteria of paragraph (ttt)(2) of this section.

(2) ECA marine fuel does not include any of the following fuel:

(i) Fuel used by exempted or excluded vessels (such as exempted steamships), or fuel used by vessels allowed by the U.S. government pursuant to MARPOL Annex VI Regulation 3 or Regulation 4 to exceed the fuel sulfur limits while operating in an ECA or an ECA associated area (see 33 U.S.C. 1903).

(ii) Fuel that conforms fully to the requirements of this part for MVNRLM diesel fuel (including being designated as MVNRLM).

(iii) Fuel used, or made available for use, in any diesel engines not installed on a Category 3 marine vessel.

Gasoline means any fuel sold in any State [1] for use in motor vehicles and motor vehicle engines, and commonly or commercially known or sold as gasoline.

Gasoline blendstock or component means any liquid compound that is blended with other liquid compounds to produce gasoline.

Gasoline blendstock for oxygenate blending or *BOB* has the meaning given in 40 CFR 1090.80.

Gasoline treated as blendstock or *GTAB* means imported gasoline that is excluded from an import facility's compliance calculations, but is treated as blendstock in a related refinery that includes the GTAB in its refinery compliance calculations.

Heating oil means any No. 1, No. 2, or non-petroleum diesel blend that is sold for use in furnaces, boilers, and similar applications and which is commonly or commercially known or sold as heating oil, fuel oil, and similar trade names, and that is not jet fuel, kerosene, or MVNRLM diesel fuel.

Importer means a person who imports gasoline, gasoline blendstocks or components, or diesel fuel from a foreign country into the United States (including the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands).

Jet fuel means any distillate fuel used, intended for use, or made available for use in aircraft.

Kerosene means any No. 1 distillate fuel commonly or commercially sold as kerosene.

Liquefied petroleum gas or *LPG* means a liquid hydrocarbon fuel that is stored under pressure and is composed primarily of species that are gases at atmospheric conditions (temperature = 25 °C and pressure = 1 atm), excluding natural gas.

[1] *State* means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa and the Commonwealth of the Northern Mariana Islands.

Locomotive engine means an engine used in a locomotive as defined under 40 CFR 92.2.

Marine engine has the meaning given under 40 CFR 1042.901.

MVNRLM diesel fuel means any diesel fuel or other distillate fuel that is used, intended for use, or made available for use in motor vehicles or motor vehicle engines, or as a fuel in any nonroad diesel engines, including locomotive and marine diesel engines, except the following: Distillate fuel with a T90 at or above 700 °F that is used only in Category 2 and 3 marine engines is not MVNRLM diesel fuel, and ECA marine fuel is not MVNRLM diesel fuel (note that fuel that conforms to the requirements of MVNRLM diesel fuel is excluded from the definition of ''ECA marine fuel'' in this section without regard to its actual use). Use the distillation test method specified in 40 CFR 1065.1010 to determine the T90 of the fuel.

(1) Any diesel fuel that is sold for use in stationary engines that are required to meet the requirements of 40 CFR 1090.300, when such provisions are applicable to nonroad engines, is considered MVNRLM diesel fuel.

(2) [Reserved]

Natural gas means a fuel whose primary constituent is methane.

Non-petroleum diesel means a diesel fuel that contains at least 80 percent mono-alkyl esters of long chain fatty acids derived from vegetable oils or animal fats.

Nonroad diesel engine means an engine that is designed to operate with diesel fuel that meets the definition of nonroad engine in 40 CFR 1068.30, including locomotive and marine diesel engines.

Oxygenate means any substance which, when added to gasoline, increases the oxygen content of that gasoline. Lawful use of any of the substances or any combination of these substances requires that they be ''substantially similar'' under section 211(f)(1) of the Clean Air Act, or be permitted under a waiver granted by the Administrator under the authority of section 211(f)(4) of the Clean Air Act.

Oxygenated gasoline means gasoline which contains a measurable amount of oxygenate.

Refiner means any person who owns, leases, operates, controls, or supervises a refinery.

Refinery means any facility, including but not limited to, a plant, tanker truck, or vessel where gasoline or diesel fuel is produced, including any facility at which blendstocks are combined to produce gasoline or diesel fuel, or at which blendstock is added to gasoline or diesel fuel.

Reformulated gasoline or RFG means any gasoline whose formulation has been certified under § 1090.1100(b), and which meets each of the standards and requirements prescribed under § 1090.245.

Reformulated gasoline blendstock for oxygenate blending, or RBOB means a petroleum product that, when blended with a specified type and percentage of oxygenate, meets the definition of reformulated gasoline, and to which the specified type and percentage of oxygenate is added other than by the refiner or importer of the RBOB at the refinery or import facility where the RBOB is produced or imported.

Residual fuel means a petroleum fuel that can only be used in diesel engines if it is preheated before injection. For example, No. 5 fuels, No. 6 fuels, and RM grade marine fuels are residual fuels. Note: Residual fuels do not necessarily require heating for storage or pumping.

Retail outlet means any establishment at which gasoline, diesel fuel, natural gas or liquefied petroleum gas is sold or offered for sale for use in motor vehicles or nonroad engines, including locomotive or marine engines.

Retailer means any person who owns, leases, operates, controls, or supervises a retail outlet.

Wholesale purchaser-consumer means any person that is an ultimate consumer of gasoline, diesel fuel, natural gas, or liquefied petroleum gas and which purchases or obtains gasoline, diesel fuel, natural gas or liquefied petroleum gas from a supplier for use in motor vehicles or nonroad engines, including locomotive or marine engines and, in the case of gasoline, diesel fuel, or liquefied petroleum gas, receives delivery of that product into a storage tank of at least 550-gallon capacity substantially under the control of that person.

§ 80.3 [Removed and reserved]

■ 10. Remove and reserve § 80.3.

§ 80.7 [Amended]

■ 11. In § 80.7 amend paragraph (c), by removing ''§ 80.22'' in second sentence and adding ''40 CFR 1090.1550'' in its place.

Subparts B, D, E, F, G, H, I, J, K, L, N, and O and Appendices A and B to Part 80 [Removed and reserved]

■ 12. Remove and reserve subparts B, D, E, F, G, H, I, J, K, L, N, and O and appendices A and B to Part 80.

Subpart M—Renewable Fuel Standard

■ 13. Amend § 80.1401 by:

■ a. Revising paragraph (2) in the definition of ''Fuel for use in an ocean-going vessel'';

■ b. Revising paragraph (1) in the definition of ''Heating oil''; and

■ c. Revising the definitions of ''Renewable gasoline'' and ''Renewable gasoline blendstock''.

The revisions read as follows:

§ 80.1401 Definitions.

* * * * *

Fuel for use in an ocean-going vessel * * *

(2) Emission Control Area (ECA) marine fuel, pursuant to § 80.2 and 40 CFR 1090.80 (whether burned in ocean waters, Great Lakes, or other internal waters); and

* * * * *

Heating oil * * *

(1) A fuel meeting the definition of heating oil set forth in § 80.2; or

* * * * *

Renewable gasoline means renewable fuel made from renewable biomass that is composed of only hydrocarbons and which meets the definition of gasoline in § 80.2.

Renewable gasoline blendstock means a blendstock made from renewable biomass that is composed of only hydrocarbons and which meets the definition of gasoline blendstock in § 80.2.

* * * * *

■ 14. Amend § 80.1407 by revising paragraph (f)(7) to read as follows:

§ 80.1407 How are the Renewable Volume Obligations calculated?

* * * * *

(f) * * *

(7) Transmix gasoline product (as defined in 40 CFR 1090.80) and transmix distillate product (as defined in 40 CFR 1090.80) produced by a transmix processor, and transmix blended into gasoline or diesel fuel by a transmix blender under 40 CFR 1090.505.

* * * * *

■ 15. Amend § 80.1416 by revising paragraph (b)(1)(i) to read as follows:

§ 80.1416 Petition process for evaluation of new renewable fuels pathways.

* * * * *

(b) * * *

(1) * * *

(i) The information specified under 40 CFR 1090.805.

* * * * *

■ 16. Amend § 80.1427 by revising paragraph (a)(2) introductory text and removing and reserving paragraph (a)(4) to read as follows:

§ 80.1427 How are RINs used to demonstrate compliance?

(a) * * *

(2) RINs that are valid for use in complying with each Renewable Volume Obligation are determined by their D codes.

* * * * *

■ 17. Amend § 80.1429 by:

■ a. Revising paragraph (b)(9) introductory text; and

■ b. Removing paragraphs (f) and (g).

The revision reads as follows:

§ 80.1429 Requirements for separating RINs from volumes of renewable fuel.

* * * * *

(b) * * *

(9) Except as provided in paragraphs (b)(2) through (b)(5) and (b)(8) of this section, parties whose non-export renewable volume obligations are solely related to either the importation of products listed in § 80.1407(c) or § 80.1407(e) or to the addition of blendstocks into a volume of finished gasoline, finished diesel fuel, or BOB, can only separate RINs from volumes of renewable fuel if the number of gallon-RINs separated in a calendar year is less than or equal to a limit set as follows:

* * * * *

§ 80.1441 [Amended]

■ 18. Amend § 80.1441 by removing paragraph (a)(6).

§ 80.1442 [Amended]

■ 19. Amend § 80.1442 by removing paragraphs (a)(3) and (b)(6).

■ 20. Amend § 80.1450 by:

■ a. Revising the first sentence in paragraph (a);

■ b. Revising the first sentence in paragraph (b) introductory text;

■ c. Revising the first sentence in paragraph (c);

■ d. Revising the last sentence in paragraph (d)(3)(iii);

■ e. Revising the first sentence in paragraph (e); and

■ f. Revising paragraph (g)(1).

The revisions read as follows:

§ 80.1450 What are the registration requirements under the RFS program?

(a) * * * Any obligated party described in § 80.1406, and any exporter of renewable fuel described in § 80.1430, must provide EPA with the information specified for registration under 40 CFR 1090.805, if such information has not already been provided under the provisions of this part. * * *

(b) * * * Any RIN-generating foreign or domestic producer of renewable fuel, any foreign renewable fuel producer that sells renewable fuel for RIN generation by a United States importer, or any foreign ethanol producer that produces ethanol used in renewable fuel for which RINs are generated by a United States importer, must provide EPA the information specified under 40 CFR 1090.805 if such information has not already been provided under the provisions of this part, and must receive EPA-issued company and facility identification numbers prior to the generation of any RINs for their fuel or for fuel made with their ethanol. * * *

* * * * *

(c) * * * Importers of renewable fuel must provide EPA the information specified under 40 CFR 1090.805, if such information has not already been provided under the provisions of this part and must receive an EPA-issued company identification number prior to generating or owning RINs. * * *

(d) * * *

(3) * * *

(iii) * * * The representative sample must be selected in accordance with the sample size guidelines set forth at 40 CFR 1090.1805.

(e) Any party who owns RINs, intends to own RINs, or intends to allow another party to separate RINs as per § 80.1440, but who is not covered by paragraph (a), (b), or (c) of this section, must provide EPA the information specified under 40 CFR 1090.805, if such information has not already been provided under the provisions of this part and must receive an EPA-issued company identification number prior to owning any RINs.

* * *

* * * * *

(g) * * *

(1) The information specified under 40 CFR 1090.805, if such information has not already been provided under the provisions of this part.

* * * * *

■ 21. Amend § 80.1454 by revising paragraph (h)(2)(i) to read as follows:

§ 80.1454 What are the recordkeeping requirements under the RFS program?

* * * * *

(h) * * *

(2) * * *

(i) Planned and conducted by an independent surveyor that meets the requirements in 40 CFR 1090.55.

* * * * *

■ 22. Amend § 80.1464 by:

■ a. Revising the first sentence of the introductory text;

■ b. Revising the first sentence in paragraph (a)(1)(iii); and

■ c. Revising paragraphs (a)(1)(iv)(D), (a)(2)(i), (b)(1)(iv), (b)(1)(v)(A), (b)(2)(i), and (c)(1)(i).

The revisions read as follows:

§ 80.1464 What are the attest engagement requirements under the RFS program?

The requirements regarding annual attest engagements in 40 CFR 1090.1800 also apply to any attest engagement procedures required under this subpart M. * * *

(a) * * *

(1) * * *

(iii) For obligated parties, compare the volumes of products listed in § 80.1407(c) and (e) reported to EPA in the report required under § 80.1451(a)(1) with the volumes, excluding any renewable fuel volumes, contained in the inventory reconciliation analysis under 40 CFR 1090.1810(b) and the volume of non-renewable diesel produced or imported. * * *

(iv) * * *

(D) Select sample batches in accordance with the guidelines in 40 CFR 1090.1805 from each separate category of renewable fuel exported and identified in § 80.1451(a); obtain invoices, bills of lading and other documentation for the representative samples; state whether any of these documents refer to the exported fuel as advanced biofuel or cellulosic biofuel; and report as a finding whether or not the exporter calculated an advanced biofuel or cellulosic biofuel RVO for these fuels pursuant to § 80.1430(b)(1) or § 80.1430(b)(3).

* * * * *

(2) * * *

(i) Obtain and read copies of a representative sample, selected in accordance with the guidelines in 40 CFR 1090.1805, of each RIN transaction type (RINs purchased, RINs sold, RINs retired, RINs separated, RINs reinstated) included in the RIN transaction reports required under § 80.1451(a)(2) for the compliance year.

* * * * *

(b) * * *

(1) * * *

(iv) Obtain product transfer documents for a representative sample, selected in accordance with the guidelines in 40 CFR 1090.1805, of renewable fuel batches produced or imported during the year being reviewed; verify that the product transfer documents contain the applicable information required under § 80.1453; verify the accuracy of the information contained in the product transfer documents; report as a finding any product transfer document that does not contain the applicable information required under § 80.1453.

(v)(A) Obtain documentation, as required under § 80.1451(b), (d), and (e) associated with feedstock purchases for a representative sample, selected in

accordance with the guidelines in 40 CFR 1090.1805, of renewable fuel batches produced or imported during the year being reviewed.

* * * * *

(2) * * *

(i) Obtain and read copies of a representative sample, selected in accordance with the guidelines in 40 CFR 1090.1805, of each transaction type (RINs purchased, RINs sold, RINs retired, RINs separated, RINs reinstated) included in the RIN transaction reports required under § 80.1451(b)(2) for the compliance year.

* * * * *

(c) * * *

(1) * * *

(i) Obtain and read copies of a representative sample, selected in accordance with the guidelines in 40 CFR 1090.1805, of each RIN transaction type (RINs purchased, RINs sold, RINs retired, RINs separated, RINs reinstated) included in the RIN transaction reports required under § 80.1451(c)(1) for the compliance year.

* * * * *

§ 80.1465 [Removed and reserved]

■ 23. Remove and reserve § 80.1465.

■ 24. Amend § 80.1466 by:

■ a. Revising paragraph (d)(3)(ii), paragraph (m)(3) introductory text, and paragraph (m)(4) introductory text;

■ b. Revising the second sentence in paragraph (m)(5); and

■ c. Revising paragraphs (m)(6)(ii) and (iii).

The revisions reads as follows:

§ 80.1466 What are the additional requirements under this subpart for RIN-generating foreign producers and importers of renewable fuels for which RINs have been generated by the foreign producer?

* * * * *

(d) * * *

(3) * * *

(ii) Be independent under the criteria specified in 40 CFR 1090.55; and

* * * * *

(m) * * *

(3) Select a sample from the list of vessels identified in paragraph (m)(2) of this section used to transport RFS–FRRF, in accordance with the guidelines in 40 CFR 1090.1805, and for each vessel selected perform all the following:

* * * * *

(4) Select a sample from the list of vessels identified in paragraph (m)(2) of this section used to transport RFS–FRRF, in accordance with the guidelines in 40 CFR 1090.1805, and for each vessel selected perform the following:

* * * * *

(5) * * * Select a sample from this listing in accordance with the guidelines in 40 CFR 1090.1805, and obtain a commercial document of general circulation that lists vessel arrivals and departures, and that includes the port and date of departure and the ports and dates where the renewable fuel was offloaded for the selected vessels. * * *

(6) * * *

(ii) Be licensed as a Certified Public Accountant in the United States and a citizen of the United States, or be approved in advance by EPA based on a demonstration of ability to perform the procedures required in 40 CFR 1090.1800, § 80.1464, and this paragraph (m); and

(iii) Sign a commitment that contains the provisions specified in paragraph (f) of this section with regard to activities and documents relevant to compliance with the requirements of 40 CFR 1090.1800, § 80.1464, and this paragraph (m).

* * * * *

■ 25. Amend § 80.1467 by revising paragraphs (h)(2) and (3) to read as follows:

§ 80.1467 What are the additional requirements under this subpart for a foreign RIN owner?

* * * * *

(h) * * *

(2) The attest auditor must be licensed as a Certified Public Accountant in the United States and a citizen of the United States, or be approved in advance by EPA based on a demonstration of ability to perform the procedures required in 40 CFR 1090.1800 and § 80.1464.

(3) The attest auditor must sign a commitment that contains the provisions specified in paragraph (c) of this section with regard to activities and documents relevant to compliance with the requirements of 40 CFR 1090.1800 and § 80.1464.

* * * * *

■ 26. Amend § 80.1469 by revising paragraph (c)(5) to read as follows:

§ 80.1469 Requirements for Quality Assurance Plans.

* * * * *

(c) * * *

(5) *Representative sampling.* Independent third-party auditors may use a representative sample of batches of renewable fuel in accordance with the procedures described in 40 CFR 1090.1805 for all components of this paragraph (c) except for paragraphs (c)(1)(ii), (c)(1)(iii), (c)(2)(ii), (c)(3)(vi), (c)(4)(ii), and (c)(4)(iii) of this section.

* * * * *

PART 86—CONTROL OF EMISSIONS FROM NEW AND IN-USE HIGHWAY VEHICLES AND ENGINES

■ 27. The authority citation for part 86 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

■ 28. Amend § 86.1810–17 by adding paragraph (j) to read as follows:

§ 86.1810–17 General requirements.

* * * * *

(j) Gasoline-fueled vehicles must have a refueling inlet that allows insertion of the refueling nozzle specified in 40 CFR 1090.1550(a), and does not allow insertion of a nozzle with an outside diameter at or above 24 mm.

PART 1037—CONTROL OF EMISSIONS FROM NEW HEAVY-DUTY MOTOR VEHICLES

■ 29. The authority citation for part 1037 continues to read as follows:

Authority: 42 U.S.C. 7401–7671q.

■ 30. Amend § 1037.115 by revising paragraph (c) to read as follows:

§ 1037.115 Other requirements.

* * * * *

(c) Gasoline-fueled vehicles must have a refueling inlet that allows insertion of the refueling nozzle specified in 40 CFR 1090.1550(a), and does not allow insertion of a nozzle with an outside diameter at or above 24 mm.

* * * * *

■ 31. Add part 1090 to read as follows:

PART 1090—REGULATION OF FUELS, FUEL ADDITIVES, AND REGULATED BLENDSTOCKS

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Sec.
1090.1 Applicability and relationship to other parts.
1090.5 Implementation dates.
1090.10 Contacting EPA.
1090.15 Confidential business information.
1090.20 Approval of submissions under this part.
1090.50 Rounding.
1090.55 Requirements for independent parties.
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1090.85 Explanatory terms.
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1090.115 Oxygenate blenders.
1090.120 Oxygenate producers.
1090.125 Certified butane producers.
1090.130 Certified butane blenders.

1090.135 Certified pentane producers.
1090.140 Certified pentane blenders.
1090.145 Transmix processors.
1090.150 Transmix blenders.
1090.155 Fuel additive manufacturers.
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1090.165 Retailers and WPCs.
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1090.230 Gasoline oxygenate standards.
1090.235 Ethanol denaturant standards.
1090.240 Gasoline deposit control standards.
1090.245 RFG standards.
1090.250 Anti-dumping standards.
1090.255 Gasoline additive standards.
1090.260 Gasoline substantially similar provisions.
1090.265 Requirements for E15.
1090.270 RFG covered areas.
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1090.505 Gasoline produced from blending transmix into PCG.
1090.510 Gasoline produced from TGP.
1090.515 ULSD produced from TDP.
1090.520 500 ppm LM diesel fuel produced from TDP.
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1090.635 Refinery extreme unforeseen hardship exemption.
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1090.1830 Alternative procedures for certified butane blenders.
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1090.1840 Additional procedures related to compliance with gasoline average standards.
1090.1845 Procedures related to meeting performance-based measurement and statistical quality control for test methods.
1090.1850 Procedures related to in-line blending waivers.

Authority: 42 U.S.C. 7414, 7521, 7522–7525, 7541, 7542, 7543, 7545, 7547, 7550, and 7601.

Subpart A—General Provisions

§ 1090.1 Applicability and relationship to other parts.

(a) This part specifies fuel quality standards for gasoline and diesel fuel in the United States. Additional requirements apply for fuel used in certain marine applications, as specified in paragraph (b) of this section.

(1) The regulations include standards for fuel parameters that directly or indirectly affect vehicle, engine, and equipment emissions, air quality, and public health. The regulations also include standards and requirements for fuel additives and regulated blendstocks that are components of the fuels regulated under this part.

(2) This part also specifies requirements for any person that engages in activities associated with the production, distribution, storage, and sale of fuels, fuel additives, and regulated blendstocks, such as collecting and testing samples for regulated parameters, reporting information to EPA to demonstrate compliance with fuel quality requirements, and performing other compliance measures to implement the standards. Parties that produce and distribute other related products, such as heating oil, may need to meet certain reporting, recordkeeping, labeling, or other requirements of this part.

(b)(1) The International Convention for the Prevention of Pollution from Ships, 1973 as modified by the Protocol of 1978 Annex VI (''MARPOL Annex VI'') is an international treaty that sets maximum fuel sulfur levels for fuel used in vessels, including separate standards for vessels navigating in a designated Emission Control Area (ECA). These standards and related requirements are specified in 40 CFR part 1043. This part also sets corresponding sulfur standards that apply to any person who produces or handles ECA marine fuel.

(2) This part also includes requirements for parties involved in the production and distribution of IMO marine fuel, such as collecting and testing samples of fuels for regulated parameters, reporting information to EPA to demonstrate compliance with fuel quality requirements, and performing other compliance measures to implement the standards.

(c) The requirements for the registration of fuel and fuel additives under 42 U.S.C. 7545(a), (b), and (e) are specified in 40 CFR part 79. Parties that must meet the requirements of this part may also need to comply with the requirements for the registration of fuel and fuel additives under 40 CFR part 79.

(d) The requirements for the Renewable Fuel Standard (RFS) are specified in 40 CFR part 80, subpart M. Parties that must meet the requirements of this part may also need to comply with the requirements for the RFS program under 40 CFR part 80, subpart M.

(e) Nothing in this part is intended to preempt the ability of state or local governments to control or prohibit any fuel or fuel additive for use in motor vehicles and motor vehicle engines that is not explicitly regulated by this part.

§ 1090.5 Implementation dates.

(a) The provisions of this part apply beginning January 1, 2021, unless otherwise specified.

(b) The following provisions of 40 CFR part 80 are applicable after December 31, 2020:

(1) Positive gasoline sulfur and benzene credit balances and deficits from the 2020 compliance period carry forward for demonstrating compliance with requirements of this part. Any restrictions that apply to credits and deficits under 40 CFR part 80, such as a maximum credit life of 5 years, continue to apply under this part.

(2) Unless otherwise specified (*e.g.,* in-line blending waivers as specified in § 1090.1315(b)), any approval granted under 40 CFR part 80 continues to be in effect under this part. For example, if EPA approved the use of alternate labeling under 40 CFR part 80, that approval continues to be valid under this part, subject to any conditions specified for the approval.

(3) Unless otherwise specified, regulated parties must use the provisions of 40 CFR part 80 in 2021 to demonstrate compliance with regulatory requirements for the 2020 calendar year. This applies to calculating credits for the 2020 compliance period, and to any sampling, testing, reporting, and auditing related to fuels, fuel additives, and regulated blendstocks produced or imported in 2020.

(4) Any testing to establish the precision and accuracy of alternative test procedures under 40 CFR part 80 continues to be valid under this part.

(5) Requirements to keep records and retain fuel samples related to actions taken before January 1, 2021, continue to be in effect, as specified in 40 CFR part 80.

§ 1090.10 Contacting EPA.

Parties must submit all reports, registrations, and documents for

approval required under this part electronically to EPA using forms and procedures specified by EPA via the following website: *https://www.epa.gov/fuels-registration-reporting-and-compliance-help.*

§ 1090.15 Confidential business information.

(a) Except as specified in paragraphs (b) and (c) of this section, any information submitted under this part claimed as confidential remains subject to evaluation by EPA under 40 CFR part 2, subpart B.

(b) The following information contained in submissions under this part that have been accepted by EPA for evaluation is not entitled to confidential treatment under 40 CFR part 2, subpart B or 5 U.S.C. 552(b)(4):

(1) Submitter's name.

(2) The name and location of the facility for which relief is requested, if applicable.

(3) The general nature of the request.

(4) The relevant time period for the request, if applicable.

(c) The following information incorporated into EPA determinations on submissions under this section is not entitled to confidential treatment under 40 CFR part 2, subpart B or 5 U.S.C. 552(b)(4):

(1) Submitter's name.

(2) The name and location of the facility for which relief was requested, if applicable.

(3) The general nature of the request.

(4) The relevant time period for the request, if applicable.

(5) The extent to which EPA either granted or denied the request and any relevant conditions.

(d) EPA may disclose the information specified in paragraphs (b) and (c) of this section on its website, or otherwise make it available to interested parties, without additional notice, notwithstanding any claims that the information is entitled to confidential treatment under 40 CFR part 2, subpart B and 5 U.S.C. 552(b)(4).

§ 1090.20 Approval of submissions under this part.

(a) EPA may approve any submission required or allowed under this part if the request for approval satisfies all specified requirements.

(b) EPA will deny any request for approval if the submission is incomplete, contains inaccurate or misleading information, or does not meet all specified requirements.

(c) EPA may revoke any prior approval under this part for cause. For cause includes, but is not limited to, any of the following:

(1) The approval has proved inadequate in practice.

(2) The party fails to notify EPA if information that the approval was based on substantively changed after the approval was granted.

(d) EPA may also revoke and void any approval under this part effective from the approval date for cause. Cause for voiding an approval includes, but is not limited to, any of the following:

(1) The approval was not fully or diligently implemented

(2) The approval was based on false, misleading, or inaccurate information

(3) Failure of a party to fulfill or cause to be fulfilled any term or condition of an approval under this part.

(e) Any person that has an approval revoked or voided under this part is liable for any resulting violation of the requirements of this part.

§ 1090.50 Rounding.

(a) Complying with this part requires rounding final values, such as sulfur test results and volume of gasoline. Do not round intermediate values to transfer data unless the rounded number has at least 6 significant digits.

(b) Unless otherwise specified, round values to the number of significant digits necessary to match the number of decimal places of the applicable standard or specification. Perform all rounding as specified in 40 CFR 1065.20(e)(1) through (6). This convention is consistent with ASTM E29 and NIST SP 811.

(c) When calculating a specified percentage of a given value, the specified percentage is understood to have infinite precision. For example, if an allowable limit is specified as a fuel volume representing 1 percent of total volume produced, calculate the allowable volume by multiplying total volume by exactly 0.01.

(d) Measurement devices that incorporate internal rounding may be used, consistent with the following provisions:

(1) Devices may use any rounding convention if they report 6 or more significant digits.

(2) Devices that report fewer than 6 significant digits may be used, consistent with the accuracy and repeatability specifications of the procedures specified in subpart M of this part.

(e) Use one of the following rounding conventions for all batch volumes in a given compliance period, and for all reporting under this part:

(1) Identify batch volume in gallons to the nearest whole gallon.

(2)(i) Round batch volumes between 1,000 and 10,000 gallons to the nearest 10 gallons.

(ii) Round batch volumes above 10,000 gallons to the nearest 100 gallons.

§ 1090.55 Requirements for independent parties.

This section specifies how third parties demonstrate their independence from the regulated party that hires them and their technical ability to perform the specified services.

(a) *Independence.* The independent third party, their contractors, subcontractors, and their organizations must be independent of the regulated party. All the criteria listed in paragraphs (a)(1) and (2) of this section must be met by every individual involved in the specified activities in this part that the independent third party is hired to perform for a regulated party, except as specified in paragraph (a)(3) of this section.

(1) *Employment criteria.* No person employed by an independent third party, including contractor and subcontractor personnel, who is involved in a specified activity performed by the independent third party under the provisions of this part, may be employed, currently or previously, by the regulated party for any duration within the 3 years preceding the date when the regulated party hired the independent third party to provide services under this part.

(2) *Financial criteria.* (i) The third-party's personnel, the third-party's organization, or any organization or individual that may be contracted or subcontracted by the third party must meet all the following requirements:

(A) Have received no more than one-quarter of their revenue from the regulated party during the year prior to the date of hire of the third party by the regulated party for any purpose.

(B) Have no interest in the regulated party's business. Income received from the third party to perform specified activities under this part is excepted.

(C) Not receive compensation for any specified activity in this part that is dependent on the outcome of the specified activity.

(ii) The regulated party must be free from any interest in the third-party's business.

(3) *Exceptions.* Auditors that meet the requirements in § 1090.1800(b)(1)(i) do not have to satisfy the employment and financial criteria in paragraphs (a)(1) and (2) of this section to be considered independent.

(b) *Technical ability.* The third party must meet all the following requirements in order to demonstrate their technical capability to perform specified activities under this part:

(1) Independent surveyors that conduct surveys under subpart N of this part must have personnel familiar with petroleum marketing, the sampling and testing of gasoline and diesel at retail stations, and the designing of surveys to estimate compliance rates or fuel parameters nationwide. Independent surveyors must demonstrate this technical ability in survey plans submitted under subpart N of this part.

(2) Laboratories attempting to qualify alternative procedures must contract with an independent third party to verify the accuracy and precision of measured values as specified in § 1090.1365. Such independent third parties must demonstrate work experience and a good working knowledge of the voluntary consensus standards specified in §§ 1090.1365 and 1090.1370, with training and expertise corresponding to a bachelor's degree in chemical engineering, or combined bachelor's degrees in chemistry and statistics.

(3) Auditors auditing in-line blending operations must demonstrate work experience and a good working knowledge of the voluntary consensus standards specified in §§ 1090.1365 and 1090.1370.

(c) *Suspension and disbarment.* Any person suspended or disbarred under 40 CFR part 32 or 48 CFR part 9, subpart 9.4, is not qualified to perform review functions under this part.

§ 1090.80 Definitions.

500 ppm LM diesel fuel means diesel fuel subject to the alternative sulfur standards in § 1090.320 for diesel fuel produced by transmix processors that may only be used in locomotive and marine engines that do not require the use of ULSD under 40 CFR parts 1033 and 1042, respectively.

Additization means the addition of detergent to gasoline to create detergent-additized gasoline.

Aggregated import facility means all import facilities within a PADD owned or operated by an importer and treated as a single fuel manufacturing facility to comply with the maximum benzene average standards under § 1090.210(b).

Anhydrous ethanol means ethanol that contains no more than 1.0 volume percent water.

Auditor means any person that conducts audits under subpart R of this part.

Automated detergent blending facility means any facility (including, but not limited to, a truck or individual storage tank) at which detergents are blended with gasoline by means of an injector system calibrated to automatically deliver a specified amount of detergent.

Average standard means a fuel standard applicable over a compliance period.

Batch means a quantity of fuel, fuel additive, or regulated blendstock that has a homogeneous set of properties.

Biodiesel means a diesel fuel that contains at least 80 percent mono-alkyl esters made from nonpetroleum feedstocks.

Blender pump means any fuel dispenser where PCG is blended with a fuel that contains ethanol (including DFE) to produce gasoline that has an ethanol content greater than that of the PCG. Blender pumps are fuel blending facilities if PCG is blended with a fuel that contains anything other than PCG and DFE.

Blending manufacturer means any person who owns, leases, operates, controls, or supervises a fuel blending facility in the United States.

Blendstock means any liquid compound or mixture of compounds (not including fuel or fuel additive) that is used or intended for use as a component of a fuel.

Business day means Monday through Friday, except the legal public holidays specified in 5 U.S.C. 6103 or any other day declared to be a holiday by federal statute or executive order.

Butane means an organic compound with the formula C_4H_{10}.

Butane blending facility means a fuel manufacturing facility where butane is blended into PCG.

California diesel means diesel fuel designated by a diesel fuel manufacturer as for use in California.

California gasoline means gasoline designated by a gasoline manufacturer as for use in California.

Carrier means any distributor who transports or stores or causes the transportation or storage of fuel, fuel additive, or regulated blendstock without taking title to or otherwise having any ownership of the fuel, fuel additive, or regulated blendstock, and without altering either the quality or quantity of the fuel, fuel additive, or regulated blendstock.

Category 1 (C1) marine vessel means a vessel that is propelled by an engine(s) meeting the definition of ''Category 1'' in 40 CFR part 1042.901.

Category 2 (C2) marine vessel means a vessel that is propelled by an engine(s) meeting the definition of ''Category 2'' in 40 CFR part 1042.901.

Category 3 (C3) marine vessel means a vessel that is propelled by an engine(s) meeting the definition of ''Category 3'' in 40 CFR part 1042.901.

CBOB means conventional gasoline for which a gasoline manufacturer has accounted for the effects of oxygenate blending that occurs downstream of the fuel manufacturing facility.

Certified butane means butane that is certified to meet the requirements in § 1090.220.

Certified butane blender means a blending manufacturer that produces gasoline by blending certified butane into PCG, and that uses the provisions of § 1090.1320 to meet the applicable sampling and testing requirements.

Certified butane producer means a regulated blendstock producer that certifies butane as meeting the requirements in § 1090.220.

Certified ethanol denaturant means ethanol denaturant that is certified to meet the requirements in § 1090.235.

Certified ethanol denaturant producer means any person that certifies ethanol denaturant as meeting the requirements in § 1090.235.

Certified pentane means pentane that is certified to meet the requirements in § 1090.225.

Certified pentane blender means a blending manufacturer that produces gasoline by blending certified pentane into PCG, and that uses the provisions of § 1090.1320 to meet the applicable sampling and testing requirements.

Certified pentane producer means a regulated blendstock producer that certifies pentane as meeting the requirements in § 1090.225.

Compliance period means the calendar year (January 1 through December 31).

Conventional gasoline or *CG* means gasoline that is not certified to meet the requirements for RFG in § 1090.245.

Days means calendar days, including weekends and holidays.

Denatured fuel ethanol or *DFE* means anhydrous ethanol that contains a denaturant to make it unfit for human consumption, as required and defined in 27 CFR parts 19 through 21, and that is produced or imported for blending into gasoline.

Detergent means any chemical compound or combination of chemical compounds that is added to gasoline to control deposit formation and meets the requirements in § 1090.240. Detergent may be part of a detergent additive package.

Detergent additive package means an additive package containing detergent and may also contain carrier oils and non-detergent-active components such as corrosion inhibitors, antioxidants, metal deactivators, and handling solvents.

Detergent blender means any person who owns, leases, operates, controls, or supervises the blending operation of a detergent blending facility, or imports detergent-additized gasoline.

Detergent blending facility means any facility (including, but not limited to, a truck or individual storage tank) at which detergent is blended with gasoline.

Detergent manufacturer means any person who owns, leases, operates, controls, or supervises a facility that produces detergent. Detergent manufacturers are fuel additive manufacturers.

Detergent-additized gasoline or *detergent gasoline* means any gasoline that contains a detergent.

Diesel fuel means any of the following:

(1) Any fuel commonly or commercially known as diesel fuel.

(2) Any fuel (including NP diesel fuel) that is intended or used to power a vehicle or engine that is designed to operate using diesel fuel, except for residual or gaseous fuel.

(3) Any fuel that conforms to the specifications of ASTM D975 (incorporated by reference in § 1090.95) and is made available for use in a vehicle or engine designed to operate using diesel fuel.

Diesel fuel manufacturer means a fuel manufacturer who owns, leases, operates, controls, or supervises a fuel manufacturing facility where diesel fuel is produced.

Distillate fuel means diesel fuel and other petroleum fuels with a T90 temperature below 700 °F that can be used in vehicles or engines that are designed to operate using diesel fuel. For example, diesel fuel, jet fuel, heating oil, No. 1 fuel (kerosene), No. 4 fuel, DMX, DMA, DMB, and DMC are distillate fuels. These specific fuel grades are identified in ASTM D975 and ISO 8217. Natural gas, LPG, and gasoline are not distillate fuels.

Distributor means any person who transports, stores, or causes the transportation or storage of fuel, fuel additive, or regulated blendstock at any point between any fuel manufacturing facility, fuel additive manufacturing facility, or regulated blendstock production facility and any retail outlet or WPC facility.

Downstream location means any point in the fuel distribution system other than a fuel manufacturing facility through which the fuel passes after it leaves the gate of the fuel manufacturing facility at which it was certified (*e.g.,* fuel at facilities of distributors, pipelines, terminals, carriers, retailers, kerosene blenders, and WPCs).

E0 means a gasoline that contains no ethanol. This is also known as neat gasoline.

E10 means gasoline that contains at least 9 and no more than 10 volume percent ethanol.

E15 means gasoline that contains more than 10 and no more than 15 volume percent ethanol.

E85 means a fuel that contains more than 50 volume percent but no more than 83 volume percent ethanol and is used, intended for use, or made available for use in flex-fuel vehicles or flex-fuel engines.

E200 means the distillation fraction of a fuel at 200 degrees Fahrenheit expressed as a volume percentage.

E300 means the distillation fraction of a fuel at 300 degrees Fahrenheit expressed as a volume percentage.

ECA marine fuel means diesel, distillate, or residual fuel used, intended for use, or made available for use in C3 marine vessels while the vessels are operating within an Emission Control Area (ECA), or an ECA associated area.

Ethanol means an alcohol of the chemical formula C_2H_5OH.

Ethanol denaturant means PCG, gasoline regulated blendstocks, or natural gasoline liquids that are added to anhydrous ethanol to make the ethanol unfit for human consumption as required and defined in 27 CFR parts 19 through 21.

Facility means any place, or series of places, where any fuel, fuel additive, or regulated blendstock is produced, imported, blended, transported, distributed, stored, or sold.

Flex-fuel engine has the same meaning as *flexible-fuel engine* in 40 CFR 1054.801.

Flex-fuel vehicle has the same meaning as *flexible-fuel vehicle* in 40 CFR 86.1803–01.

Fuel means only the fuels regulated under this part, including gasoline, diesel fuel, and IMO marine fuel.

Fuel additive means a substance that is designated for registration under 40 CFR part 79 and is added to fuel such that it amounts to less than 1.0 volume percent of the resultant mixture, or is an oxygenate added up to a level consistent with levels that are ''substantially similar'' under 42 U.S.C. 7545(f)(1) or as permitted under a waiver granted under 42 U.S.C. 7545(f)(4).

Fuel additive blender means any person who blends fuel additive into fuel in the United States, or any person who owns, leases, operates, controls, or supervises such an operation in the United States.

Fuel additive manufacturer means any person who owns, leases, operates, controls, or supervises a facility where fuel additives are produced or imported into the United States.

Fuel blending facility means any facility, other than a refinery or transmix processing facility, where fuel is produced by combining blendstocks or by combining blendstocks with fuel. Types of blending facilities include, but are not limited to, terminals, storage tanks, plants, tanker trucks, retail outlets, and marine vessels.

Fuel dispenser means any apparatus used to dispense fuel into motor vehicles, nonroad vehicles, engines, equipment, or portable fuel containers (as defined in 40 CFR 59.680).

Fuel manufacturer means any person who owns, leases, operates, controls, or supervises a fuel manufacturing facility. Fuel manufacturers include refiners, importers, blending manufacturers, and transmix processors.

Fuel manufacturing facility means any facility where fuels are produced, imported, or recertified. Fuel manufacturing facilities include refineries, fuel blending facilities, transmix processing facilities, import facilities, and any facility where fuel is recertified.

Fuel manufacturing facility gate means the point where the fuel leaves the fuel manufacturing facility at which it was produced or imported by the fuel manufacturer.

Gasoline means any of the following:

(1) Any fuel commonly or commercially known as gasoline, including BOB.

(2) Any fuel intended or used to power a vehicle or engine designed to operate on gasoline, except for gaseous fuel.

(3) Any fuel that conforms to the specifications of ASTM D4814 (incorporated by reference in § 1090.95) and is made available for use in a vehicle or engine designed to operate on gasoline.

Gasoline before oxygenate blending or *BOB* means gasoline designated for downstream oxygenate blending before being dispensed into a vehicle or engine's fuel tank, unless recertified as specified in § 1090.740. BOB is subject to all requirements and standards that apply to gasoline, unless subject to a specific alternative standard or requirement under this part.

Gasoline manufacturer means a fuel manufacturer who owns, leases, operates, controls, or supervises a fuel manufacturing facility where gasoline is produced. Any person recertifying a BOB under § 1090.740 is considered to be a gasoline manufacturer.

Gasoline treated as blendstock or *GTAB* means imported gasoline that is excluded from the importer's compliance calculations but is treated as blendstock in a related fuel

manufacturing facility that includes the GTAB in a gasoline manufacturer's compliance calculations for the facility under § 1090.1615.

Global marine fuel means diesel fuel, distillate fuel, or residual fuel used, intended for use, or made available for use in steamships or Category 3 marine vessels while the vessels are operating in international waters or in any waters outside the boundaries of an ECA. Global marine fuel is subject to the provisions of MARPOL Annex VI.

Heating oil means a combustible product that is used, intended for use, or made available for use in furnaces, boilers, or similar applications. Kerosene and jet fuel are not heating oil.

IMO marine fuel means fuel that is ECA marine fuel or global marine fuel.

Importer means any person who imports fuel, fuel additive, or regulated blendstock into the United States.

Import facility means any facility where an importer imports fuel, fuel additive, or regulated blendstock.

Independent surveyor means any person who meets the independence requirements in § 1090.55 and conducts a survey under subpart N of this part.

Intake valve deposits or *IVD* means the deposits formed on the intake valve(s) of a gasoline-fueled engine during operation.

Jet fuel means any distillate fuel used, intended for use, or made available for use in aircraft.

Kerosene means any No.1 distillate fuel that is used, intended for use, or made available for use as kerosene.

Liquefied petroleum gas or *LPG* means a liquid hydrocarbon fuel that is stored under pressure and is composed primarily of compounds that are gases at atmospheric conditions (temperature = 25 °C and pressure = 1 atm), excluding natural gas.

Locomotive engine means an engine used in a locomotive as defined in 40 CFR 92.2.

Marine engine has the meaning given under 40 CFR 1042.901.

Methanol means any fuel sold for use in motor vehicles and engines and commonly known or commercially sold as methanol or MXX, where XX represents the percent methanol (CH_3OH) by volume.

Natural gas means a fuel that is primarily composed of methane.

Natural gas liquids or *NGLs* means the hydrocarbons (primarily propane, butane, pentane, hexane, and heptane) that are separated from the gaseous state of natural gas in the form of liquids at a facility, such as a natural gas production facility, gas processing plant, natural gas pipeline, refinery, or similar facility.

Non-automated detergent blending facility means any facility (including a truck or individual storage tank) at which detergent additive is blended using a hand blending technique or any other non-automated method.

Nonpetroleum (NP) diesel fuel means renewable diesel fuel or biodiesel. NP diesel fuel also includes other biomass-based diesel as specified under 40 CFR part 80, subpart M.

Oxygenate means a liquid compound that consists of one or more oxygenated compounds. Examples include DFE and isobutanol.

Oxygenate blender means any person who adds oxygenate to gasoline in the United States, or any person who owns, leases, operates, controls, or supervises such an operation in the United States.

Oxygenate blending facility means any facility (including but not limited to a truck) at which oxygenate is added to gasoline (including BOB), and at which the quality or quantity of gasoline is not altered in any other manner except for the addition of deposit control additives.

Oxygenate import facility means any facility where oxygenate, including DFE, is imported into the United States.

Oxygenate producer means any person who produces or imports oxygenate for gasoline in the United States, or any person who owns, leases, operates, controls, or supervises an oxygenate production or import facility in the United States.

Oxygenate production facility means any facility where oxygenate is produced, including DFE.

Oxygenated compound means an oxygen-containing, ashless organic compound, such as an alcohol or ether, which may be used as a fuel or fuel additive.

PADD means Petroleum Administration for Defense District. These districts are the same as the PADDs used by other federal agencies, except for the addition of PADDs VI and VII. The individual PADDs are identified by region, state, and territory as follows:

PADD	Regional description	State or territory
I	East Coast	Connecticut, Delaware, District of Columbia, Florida, Georgia, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, North Carolina, Pennsylvania, Rhode Island, South Carolina, Vermont, Virginia, West Virginia.
II	Midwest	Illinois, Indiana, Iowa, Kansas, Kentucky, Michigan, Minnesota, Missouri.
III	Gulf Coast	Alabama, Arkansas, Louisiana, Mississippi, New Mexico, Texas.
IV	Rocky Mountain	Colorado, Idaho, Montana, Utah, Wyoming.
V	West Coast	Alaska, Arizona, California, Hawaii, Nevada, Oregon, Washington.
VI	Antilles	Puerto Rico, U.S. Virgin Islands.
VII	Pacific Territories	American Samoa, Guam, Northern Mariana Islands.

Pentane means an organic compound with the formula C_5H_{12}.

Pentane blending facility means a fuel manufacturing facility where pentane is blended into PCG.

Per-gallon standard means the maximum or minimum value for any parameter that applies to every volume unit of a specified fuel, fuel additive, or regulated blendstock.

Person has the meaning given in 42 U.S.C. 7602(e).

Pipeline interface means the mixture between different fuels and products that abut each other during shipment by the refined petroleum products pipeline system.

Pipeline operator means any person who owns, leases, operates, controls, or supervises a pipeline that transports fuel, fuel additive, or regulated blendstock in the United States.

Previously certified gasoline or *PCG* means CG, RFG, or BOB that has been certified as a batch by a gasoline manufacturer.

Product transfer documents or *PTDs* mean documents that reflect the transfer of title or physical custody of fuel, fuel additive, or regulated blendstock (*e.g.,* invoices, receipts, bills of lading, manifests, pipeline tickets) between a transferor and a transferee.

RBOB means reformulated gasoline for which a gasoline manufacturer has accounted for the effects of oxygenate blending that occurs downstream of the fuel manufacturing facility.

Refiner means any person who owns, leases, operates, controls, or supervises a refinery in the United States.

Refinery means a facility where fuels are produced from feedstocks, including crude oil or renewable feedstocks, through physical or chemical processing equipment.

Reformulated gasoline or *RFG* means gasoline that is certified under § 1090.1100(b) to meet the requirements in § 1090.245.

Regulated blendstock means certified butane, certified pentane, TGP, TDP, and GTAB.

Regulated blendstock producer means any person who owns, leases, operates, controls, or supervises a facility where regulated blendstocks are produced or imported.

Renewable diesel fuel means diesel fuel that is made from renewable (nonpetroleum) feedstocks and is not a mono-alkyl ester.

Reseller means any person who purchases fuel identified by the corporate, trade, or brand name of a fuel manufacturer from such manufacturer or a distributor and resells or transfers it to retailers or WPCs, and whose assets or facilities are not substantially owned, leased, or controlled by such manufacturer.

Residual fuel means a petroleum fuel with a T90 temperature at or above 700 °F that can only be used in diesel engines if it is heated before injection. For example, No. 5 fuels and No. 6 fuels are residual fuels. Note that residual fuels might not need heating for storage or pumping. Residual fuel grades are specified in ASTM D396 and ISO 8217.

Responsible Corporate Officer or *RCO* means a person who is authorized by the regulated party to make representations on behalf of or obligate the company as ultimately responsible for any activity regulated under this part (*e.g.,* refining, importing, blending). An example is an officer of a corporation under the laws of incorporation of the state in which the company is incorporated. Examples of positions in non-corporate business structures that qualify are owner, chief executive officer, president, or operations manager.

Retail outlet means any establishment at which gasoline, diesel fuel, methanol, natural gas, E85, or LPG is sold or offered for sale for use in motor vehicles, nonroad engines, nonroad vehicles, or nonroad equipment, including locomotive or marine engines.

Retailer means any person who owns, leases, operates, controls, or supervises a retail outlet.

RFG covered area means the geographic areas specified in § 1090.270 in which only RFG may be sold or dispensed to ultimate consumers.

RFG opt-in area means an area that becomes a covered area under 42 U.S.C. 7545(k)(6) as listed in § 1090.270.

Round (rounded, rounding) has the meaning given in § 1090.50.

Sampling strata means the three types of areas sampled during a survey, which include the following:

(1) Densely populated areas.

(2) Transportation corridors.

(3) Rural areas.

State Implementation Plan or *SIP* means a plan approved or promulgated under 42 U.S.C. 7410 or 7502.

Summer gasoline means gasoline that is subject to the RVP standards in § 1090.215.

Summer season or *high ozone season* means the period from June 1 through September 15 for retailers and WPCs, and May 1 through September 15 for all other persons, or an RVP control period specified in a SIP, whichever is longer.

Tank truck means a truck used for transporting fuel, fuel additive, or regulated blendstock.

Transmix means any of the following mixtures of fuels, which no longer meet the specifications for a fuel that can be used or sold as a fuel without further processing:

(1) Pipeline interface that is not cut into the adjacent products.

(2) Mixtures produced by unintentionally combining gasoline and distillate fuels.

(3) Mixtures produced from normal business operations at terminals or pipelines, such as gasoline or distillate fuel drained from a tank or drained from piping or hoses used to transfer gasoline or distillate fuel to tanks or trucks, or gasoline or distillate fuel discharged from a safety relief valve that are segregated for further processing.

Transmix blender means any person who owns, leases, operates, controls, or supervises a transmix blending facility.

Transmix blending facility means any facility that produces gasoline by blending transmix into PCG.

Transmix distillate product or *TDP* means the diesel fuel blendstock that is produced when transmix is separated into blendstocks at a transmix processing facility.

Transmix gasoline product or *TGP* means the gasoline blendstock that is produced when transmix is separated into blendstocks at a transmix processing facility.

Transmix processing facility means any facility that produces TGP or TDP from transmix by distillation or other refining processes, but does not produce gasoline or diesel fuel by processing crude oil or other products.

Transmix processor means any person who owns, leases, operates, controls, or supervises a transmix processing facility. Transmix processors are fuel manufacturers.

Ultra low-sulfur diesel or *ULSD* means diesel fuel that is certified to meet the requirements in § 1090.305.

United States means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, American Samoa, and the U.S. Virgin Islands.

Volume Additive Reconciliation (VAR) Period means for automated detergent blending facilities a time period lasting no more than 31 days or until an adjustment to a detergent concentration rate that increases the initial rate by more than 10 percent, whichever occurs first. The concentration setting for a detergent injector may be adjusted by more than 10 percent above the initial rate without terminating the VAR Period, provided the purpose of the change is to correct a batch misadditization prior to the transfer of the batch to another party, or to correct an equipment malfunction and the concentration is immediately returned to no more than 10 percent above the initial rate of concentration after the correction. For non-automated detergent blending facilities, the VAR Period constitutes the blending of one batch of gasoline.

Wholesale purchaser-consumer or *WPC* means any person that is an ultimate consumer of fuels and who purchases or obtains fuels for use in motor vehicles, nonroad vehicles, nonroad engines, or nonroad equipment, including locomotive or marine engines, and, in the case of liquid fuels, receives delivery of that product into a storage tank of at least 550-gallon capacity substantially under the control of that person.

Winter gasoline means gasoline that is not subject to the RVP standards in § 1090.215.

Winter season means any time outside of the summer season or high ozone season.

§ 1090.85 Explanatory terms.

This section explains how certain phrases and terms are used in this part, especially those used to clarify and explain regulatory provisions. They do not, however, constitute specific regulatory requirements and as such do not impose any compliance obligation on regulated persons.

(a) *Types of provisions.* The term ''provision'' includes all aspects of the regulations in this part. As described in this section, regulatory provisions include standards, requirements, and prohibitions, along with a variety of

other types of provisions. In certain cases, these terms apply to some but not all the provisions of a part or section. For example, recordkeeping requirements apply to jet fuel even though it is not subject to standards under this part.

(1) A standard is a limit on the formulation, components, or characteristics of any fuel, fuel additive, or regulated blendstock, established by regulation under this part. Compliance with or conformance to a standard is a specific type of requirement, and in some cases a standard may be discussed as a requirement. Thus, a statement about the requirements of a part or section also applies with respect to the standards in the part or section. Examples of standards include the sulfur per-gallon standards for gasoline and diesel fuel.

(2) While requirements state what someone must do, prohibitions state what someone may not do. Prohibitions are often referred to as prohibited acts. Failing to meet any requirement that applies to a person under this part is a prohibited act.

(3) The regulations in this part include provisions that are not standards, requirements, or prohibitions, such as definitions.

(b) A fuel is considered ''subject to'' a specific provision if that provision applies, even if it falls within an exemption authorized under a different part of this regulation. For example, gasoline is subject to the provisions of this part even if it is exempted from the standards under subpart G of this part.

(c) *Singular and plural.* Unless stated otherwise or unless it is clear from the regulatory context, provisions written in singular form include the plural form and provisions written in plural form include the singular form.

(d) *Inclusive lists.* Lists in the regulations in this part prefaced by ''including'' or ''this includes'' are not exhaustive. The terms ''including'' and ''this includes'' should be read to mean ''including but not limited to'' and ''this includes but is not limited to.''

(e) *Notes.* Statements that begin with ''Note:'' or ''Note that'' are intended to clarify specific regulatory provisions stated elsewhere in the regulations in this part. By themselves, such statements are not intended to specify regulatory requirements.

(f) *Examples.* Examples provided in the regulations in this part are typically introduced by either ''for example'' or ''such as.'' Specific examples given in the regulations do not necessarily represent the most common examples. The regulations may specify examples conditionally (that is, specifying that they are applicable only if certain criteria or conditions are met). Lists of examples cannot be presumed to be exhaustive lists.

§ 1090.90 Acronyms and abbreviations.

500 ppm LM diesel fuel	As defined in § 1090.80
ABT	averaging, banking, and trading
ARV	accepted reference value
BOB	Gasoline before oxygenate blending
CARB	California Air Resources Board
CFR	Code of Federal Regulations
CG	conventional gasoline
DFE	denatured fuel ethanol
E0	As defined in § 1090.80
E10	As defined in § 1090.80
E15	As defined in § 1090.80
E200	As defined in § 1090.80
E300	As defined in § 1090.80
ECA marine fuel	As defined in § 1090.80
EPA	Environmental Protection Agency
GTAB	gasoline treated as blendstock
IMO marine fuel	As defined in § 1090.80
LAC	lowest additive concentration
LLOQ	laboratory limit of quantitation
MARPOL Annex VI	The International Convention for the Prevention of Pollution from Ships, 1973 as modified by the Protocol of 1978 Annex VI
NAAQS	National Ambient Air Quality Standard
NARA	National Archives and Records Administration
NGL	natural gas liquids
NIST	National Institute for Standards and Technology
PCG	previously certified gasoline
PLOQ	published limit of quantitation
ppm (mg/kg)	parts per million (or milligram per kilogram)
PTD	product transfer document
R&D	research and development
RCO	responsible corporate officer
RFG	reformulated gasoline
RFS	renewable fuel standard
RVP	Reid vapor pressure
SIP	state implementation plan
SQC	statistical quality control
T10, T50, T90	temperatures representing the points in a distillation process where 10, 50, and 90 percent of the sample evaporates, respectively
TDP	transmix diesel products
TGP	transmix gasoline products
U.S.	United States
U.S.C.	United States Code
ULSD	ultra-low-sulfur diesel fuel
VCSB	voluntary consensus standards body

§ 1090.95 Incorporation by reference.

(a) Certain material is incorporated by reference into this part with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. All approved material is available for inspection at U.S. EPA, Air and Radiation Docket and Information Center, WJC West Building, Room 3334, 1301 Constitution Ave. NW, Washington, DC 20460, (202) 566–1742, and is available from the sources listed in this section. It is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to *www.archives.gov/federal-register/cfr/ibr-locations.html.*

(b) American Institute of Certified Public Accountants, 220 Leigh Farm Rd., Durham, NC 27707–8110, or *www.aicpa.org,* or (888) 777–7077.

(1) Statements on Standards for Attestation Engagements (SSAE) No. 18, Attestation Standards: Clarification and Recodification, Revised April 2016; IBR approved for § 1090.1800(b).

(2) AICPA Code of Professional Conduct, September 1, 2018; IBR approved for § 1090.1800(b).

(3) Statements on Quality Control Standards, July 1, 2019; IBR approved for § 1090.1800(b).

(c) ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, (877) 909–2786, or *www.astm.org.*

(1) ASTM D86–19, Standard Test Method for Distillation of Petroleum Products and Liquid Fuels at Atmospheric Pressure, approved December 1, 2019 (''ASTM D86''); IBR approved for § 1090.1350(b).

(2) ASTM D287–12b (Reapproved 2019), Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method), approved December 1, 2019 (''ASTM D287''); IBR approved for § 1090.1337(c).

(3) ASTM D975–19c, Standard Specification for Diesel Fuel, approved December 15, 2019 (''ASTM D975''); IBR approved for § 1090.80.

(4) ASTM D976–06 (Reapproved 2016), Standard Test Method for Calculated Cetane Index of Distillate Fuels, approved April 1, 2016 (''ASTM D976''); IBR approved for § 1090.1350(b).

(5) ASTM D1298–12b (Reapproved 2017), Standard Test Method for Density, Relative Density, or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method, approved July 15, 2017 (''ASTM D1298''); IBR approved for § 1090.1337(c).

(6) ASTM D1319–19, Standard Test Method for Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption, approved August 1, 2019 (''ASTM D1319''); IBR approved for § 1090.1350(b).

(7) ASTM D2163–14 (Reapproved 2019), Standard Test Method for Determination of Hydrocarbons in Liquefied Petroleum (LP) Gases and Propane/Propene Mixtures by Gas Chromatography, approved May 1, 2019 (''ASTM D2163''); IBR approved for § 1090.1350(b).

(8) ASTM D2622–16, Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-ray Fluorescence Spectrometry, approved January 1, 2016 (''ASTM D2622''); IBR approved for §§ 1090.1350(b), 1090.1360(d), 1090.1365(b), and 1090.1375(c).

(9) ASTM D3120–08 (Reapproved 2019), Standard Test Method for Trace Quantities of Sulfur in Light Liquid Petroleum Hydrocarbons by Oxidative Microcoulometry, approved May 1, 2019 (''ASTM D3120''); IBR approved for § 1090.1365(b).

(10) ASTM D3231–18, Standard Test Method for Phosphorus in Gasoline, approved April 1, 2018 (''ASTM D3231''); IBR approved for § 1090.1350(b).

(11) ASTM D3237–17, Standard Test Method for Lead in Gasoline by Atomic Absorption Spectroscopy, approved June 1, 2017 (''ASTM D3237''); IBR approved for § 1090.1350(b).

(12) ASTM D3606–17, Standard Test Method for Determination of Benzene and Toluene in Spark Ignition Fuels by Gas Chromatography, approved December 1, 2017 (''ASTM D3606''); IBR approved for § 1090.1360(c).

(13) ASTM D4052–18a, Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter, approved December 15, 2018 (''ASTM D4052''); IBR approved for § 1090.1337(c).

(14) ASTM D4057–19, Standard Practice for Manual Sampling of Petroleum and Petroleum Products, approved July 1, 2019 (''ASTM D4057''); IBR approved for §§ 1090.1335(b) and 1090.1605(b).

(15) ASTM D4177–16e1, Standard Practice for Automatic Sampling of Petroleum and Petroleum Products, approved October 1, 2016 (''ASTM D4177''); IBR approved for §§ 1090.1315(b) and 1090.1335(c).

(16) ASTM D4737–10 (Reapproved 2016), Standard Test Method for Calculated Cetane Index by Four Variable Equation, approved July 1, 2016 (''ASTM D4737''); IBR approved for § 1090.1350(b).

(17) ASTM D4806–19a, Standard Specification for Denatured Fuel Ethanol for Blending with Gasolines for Use as Automotive Spark-Ignition Engine Fuel, approved September 15, 2019 (''ASTM D4806''); IBR approved for § 1090.1395(a).

(18) ASTM D4814–20, Standard Specification for Automotive Spark-Ignition Engine Fuel, approved February 1, 2020 (''ASTM D4814''); IBR approved for §§ 1090.80 and 1090.1395(a).

(19) ASTM D5134–13 (Reapproved 2017), Standard Test Method for Detailed Analysis of Petroleum Naphthas through n-Nonane by Capillary Gas Chromatography, approved October 1, 2017 (''ASTM D5134''); IBR approved for § 1090.1350(b).

(20) ASTM D5186–19, Standard Test Method for Determination of the Aromatic Content and Polynuclear Aromatic Content of Diesel Fuels By Supercritical Fluid Chromatography, approved June 1, 2019 (''ASTM D5186''); IBR approved for § 1090.1350(b).

(21) ASTM D5191–19, Standard Test Method for Vapor Pressure of Petroleum Products (Mini Method), approved January 1, 2019 (''ASTM D5191''); IBR approved for §§ 1090.1360(d) and 1090.1365(b).

(22) ASTM D5453–19a, Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Spark Ignition Engine Fuel, Diesel Engine Fuel, and Engine Oil by Ultraviolet Fluorescence, approved July 1, 2019 (''ASTM D5453''); IBR approved for § 1090.1350(b).

(23) ASTM D5500–19, Standard Test Method for Vehicle Evaluation of Unleaded Automotive Spark-Ignition Engine Fuel for Intake Deposit Formation, approved November 1, 2019 (''ASTM D5500''); IBR approved for § 1090.1395(c).

(24) ASTM D5599–18, Standard Test Method for Determination of Oxygenates in Gasoline by Gas Chromatography and Oxygen Selective Flame Ionization Detection, approved June 1, 2018 (''ASTM D5599''); IBR approved for §§ 1090.1360(d) and 1090.1365(b).

(25) ASTM D5769–15, Standard Test Method for Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry, approved December 1, 2015 (''ASTM D5769''); IBR approved for §§ 1090.1350(b), 1090.1360(d), and 1090.1365(b).

(26) ASTM D5842–19, Standard Practice for Sampling and Handling of Fuels for Volatility Measurement, approved November 1, 2019 (''ASTM D5842''); IBR approved for § 1090.1335(d).

(27) ASTM D5854–19a, Standard Practice for Mixing and Handling of Liquid Samples of Petroleum and Petroleum Products, approved May 1, 2019 (''ASTM D5854''); IBR approved for § 1090.1315(b).

(28) ASTM D6201–19a, Standard Test Method for Dynamometer Evaluation of Unleaded Spark-Ignition Engine Fuel for Intake Valve Deposit Formation, approved December 1, 2019 (''ASTM D6201''); IBR approved for § 1090.1395(a).

(29) ASTM D6259–15 (Reapproved 2019), Standard Practice for Determination of a Pooled Limit of Quantitation for a Test Method, approved May 1, 2019 (''ASTM D6259''); IBR approved for § 1090.1355(b).

(30) ASTM D6299–19, Standard Practice for Applying Statistical Quality Assurance and Control Charting Techniques to Evaluate Analytical Measurement System Performance, approved November 1, 2019 (''ASTM D6299''); IBR approved for §§ 1090.1370(c), 1090.1375(a), (b), and (c), and 1090.1440(c).

(31) ASTM D6550–15, Standard Test Method for Determination of Olefin Content of Gasolines by Supercritical-Fluid Chromatography, approved December 1, 2015 (''ASTM D6550''); IBR approved for § 1090.1350(b).

(32) ASTM D6667–14 (Reapproved 2019), Standard Test Method for Determination of Total Volatile Sulfur in Gaseous Hydrocarbons and Liquefied Petroleum Gases by Ultraviolet Fluorescence, approved May 1, 2019 (''ASTM D6667''); IBR approved for §§ 1090.1350(b), 1090.1360(d), 1090.1365(b), and 1090.1375(c).

(33) ASTM D6708–19a, Standard Practice for Statistical Assessment and Improvement of Expected Agreement Between Two Test Methods that Purport to Measure the Same Property of a Material, approved November 1, 2019 (''ASTM D6708''); IBR approved for §§ 1090.1360(c), 1090.1365(d) and (f), and 1090.1375(c).

(34) ASTM D6792–17, Standard Practice for Quality Management Systems in Petroleum Products, Liquid Fuels, and Lubricants Testing Laboratories, approved May 1, 2017 (''ASTM D6792''); IBR approved for §§ 1090.1375(b) and 1090.1440(c).

(35) ASTM D7039–15a, Standard Test Method for Sulfur in Gasoline, Diesel Fuel, Jet Fuel, Kerosine, Biodiesel, Biodiesel Blends, and Gasoline-Ethanol Blends by Monochromatic Wavelength Dispersive X-ray Fluorescence Spectrometry, approved July 1, 2015 (''ASTM D7039''); IBR approved for § 1090.1365(b).

(36) ASTM D7717–11 (Reapproved 2017), Standard Practice for Preparing Volumetric Blends of Denatured Fuel Ethanol and Gasoline Blendstocks for Laboratory Analysis, approved May 1, 2017 (''ASTM D7717''); IBR approved for § 1090.1340(b).

(d) The Institute of Internal Auditors, 1035 Greenwood Blvd., Suite 401, Lake Mary, FL 32746, or *www.theiia.org* or (407) 937–1111.

(1) International Standards for the Professional Practice of Internal Auditing (Standards), Revised October 2016; IBR approved for § 1090.1800(b).

(2) [Reserved]

(e) National Institute of Standards and Technology, 100 Bureau Dr., Stop 1070, Gaithersburg, MD 20899–1070, (301) 975–6478, or *www.nist.gov*.

(1) NIST Handbook 158, 2016 Edition, Field Sampling Procedures for Fuel and Motor Oil Quality Testing—A Handbook for Use by Fuel and Oil Quality Regulatory Officials, April 2016; IBR approved for § 1090.1410(a).

(2) [Reserved]

Subpart B—General Requirements and Provisions for Regulated Parties

§ 1090.100 General provisions.

This subpart provides an overview of the general requirements and other provisions applicable to any regulated party under this part. A person who meets the definition of more than one type of regulated party must comply with the requirements applicable to each of those types of regulated parties. For example, a fuel manufacturer who also transports fuel must meet the requirements applicable to fuel manufacturers and distributors. Regulated parties are required to comply with all applicable requirements of this part, regardless of whether they are identified in this subpart. Any person that produces, sells, transfers, supplies, dispenses, or distributes fuel, fuel additive, or regulated blendstock must comply with all applicable requirements.

(a) *Recordkeeping.* Any party that engages in activities that are regulated under this part must comply with recordkeeping requirements under subpart L of this part.

(b) *Compliance and enforcement.* Any party that engages in activities that are regulated under this part is subject to compliance and enforcement provisions under subpart Q of this part.

(c) *Hardships and exemptions.* Some regulated parties under this part may be eligible, or eligible to petition, for a hardship or exemption under subpart G of this part.

(d) In addition to the requirements in paragraphs (a) through (c) of this section and § 1090.105 that apply to importers based on the fuel, fuel additive, or regulated blendstock being imported, importers must also comply with subpart P of this part.

§ 1090.105 Fuel manufacturers.

This section provides an overview of general requirements applicable to fuel manufacturers. Gasoline manufacturers must comply with the requirements of paragraph (a) of this section and diesel fuel and ECA marine fuel manufacturers must comply with the requirements of paragraph (b) of this section.

(a) *Gasoline manufacturers.* Except as specified otherwise in this subpart, all gasoline manufacturers must comply with the following requirements:

(1) *Producing and certifying compliant gasoline.* Gasoline manufacturers must produce (or import) and certify gasoline under subpart K of this part as meeting the standards of subpart C of this part and must comply with the ABT requirements in subpart H of this part.

(2) *Registration.* Gasoline manufacturers must register with EPA under subpart I of this part.

(3) *PTDs.* On each occasion when a gasoline manufacturer transfers custody of or title to any gasoline, the transferor must provide to the transferee PTDs under subpart K of this part.

(4) *Designation.* Gasoline manufacturers must designate the gasoline they produce under subpart K of this part.

(5) *Reporting.* Gasoline manufacturers must submit reports to EPA under subpart J of this part.

(6) *Sampling, testing, and sample retention.* Gasoline manufacturers must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

(7) *Surveys.* Gasoline manufacturers may participate in applicable fuel surveys under subpart N of this part.

(8) *Annual attest engagement.* Gasoline manufacturers must submit annual attest engagement reports to EPA under subpart R of this part.

(b) *Diesel fuel and ECA marine fuel manufacturers.* Diesel fuel and ECA marine fuel manufacturers must comply with the following requirements, as applicable:

(1) *Producing and certifying compliant diesel fuel and ECA marine fuel.* Diesel fuel and ECA marine fuel

manufacturers must produce (or import) and certify diesel fuel and ECA marine fuel under subpart K of this part as meeting the requirements of subpart D of this part.

(2) *Registration.* Diesel fuel and ECA marine fuel manufacturers must register with EPA under subpart I of this part.

(3) *Reporting.* Diesel fuel manufacturers must submit reports to EPA under subpart J of this part.

(4) *PTDs.* On each occasion when a diesel fuel or ECA marine fuel manufacturer transfers custody or title to any diesel fuel or ECA marine fuel, the transferor must provide to the transferee PTDs under subpart K of this part.

(5) *Sampling, testing, and retention requirements.* Diesel fuel and ECA marine fuel manufacturers must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

(6) *Surveys.* Diesel fuel manufacturers may participate in applicable fuel surveys under subpart N of this part.

(7) *Manufacturers of distillate global marine fuel.* Manufacturers of distillate global marine fuel do not need to comply with the requirements of paragraphs (b)(1) through (5) of this section if they produce global marine fuel that is exempt from the standards in subpart D of this part, as specified in § 1090.650.

§ 1090.110 Detergent blenders.

Detergent blenders must comply with the requirements of this section.

(a) *Gasoline standards.* Detergent blenders must comply with the applicable requirements of subpart C of this part.

(b) *PTDs.* On each occasion when a detergent blender transfers custody of or title to any fuel, fuel additive, or regulated blendstock, the transferor must provide to the transferee PTDs under subpart K of this part.

(c) *Recordkeeping.* Detergent blenders must demonstrate compliance with the requirements of § 1090.240(a) as specified in § 1090.1240.

(d) *Equipment calibration.* Detergent blenders at automated detergent blending facilities must calibrate their detergent blending equipment in accordance with subpart M of this part.

§ 1090.115 Oxygenate blenders.

Oxygenate blenders must comply with the requirements of this section.

(a) *Gasoline standards.* Oxygenate blenders must comply with the applicable requirements of subpart C of this part.

(b) *Registration.* Oxygenate blenders must register with EPA under subpart I of this part.

(c) *PTDs.* On each occasion when an oxygenate blender transfers custody or title to any fuel, fuel additive, or regulated blendstock, the transferor must provide to the transferee PTDs under subpart K of this part.

(d) *Oxygenate blending requirements.* Oxygenate blenders must follow blending instructions as specified for gasoline manufacturers in § 1090.710 unless the oxygenate blender recertifies BOBs under § 1090.740.

§ 1090.120 Oxygenate producers.

This section provides an overview of general requirements applicable to oxygenate producers (*e.g.,* DFE and isobutanol producers). DFE producers must comply with all requirements for oxygenate producers in paragraph (a) of this section and all additional requirements specified in paragraph (b) of this section.

(a) *Oxygenate producers.* Oxygenate producers must comply with the following requirements:

(1) *Gasoline standards.* Oxygenate producers must comply with the applicable requirements of subpart C of this part and certify batches of oxygenate under subpart K of this part.

(2) *Registration.* Oxygenate producers must register with EPA under subpart I of this part.

(3) *Reporting.* Oxygenate producers must submit reports to EPA under subpart J of this part.

(4) *PTDs.* On each occasion when an oxygenate producer transfers custody or title to any fuel, fuel additive, or regulated blendstock, the transferor must provide to the transferee PTDs under subpart K of this part.

(5) *Designation.* Oxygenate producers must designate the oxygenate they produce under subpart K of this part.

(6) *Sampling, testing, and retention requirements.* Oxygenate producers must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

(b) *DFE producers.* In addition to the requirements specified in paragraph (a) of this section, DFE producers must meet all the following requirements:

(1) Use denaturant that complies with the requirements specified in §§ 1090.230(b) and 1090.235.

(2) Participate in a survey program conducted by an independent surveyor under subpart N of this part if the DFE producer produces DFE made available for use in the production of E15.

§ 1090.125 Certified butane producers.

Certified butane producers must comply with the requirements of this section.

(a) *Gasoline standards.* Certified butane producers must comply with the applicable requirements of subpart C of this part and certify batches of certified butane under subpart K of this part.

(b) *PTDs.* On each occasion when a certified butane producer transfers custody of or title to any certified butane, the transferor must provide to the transferee PTDs under subpart K of this part.

(c) *Designation.* Certified butane producers must designate the certified butane they produce under subpart K of this part.

(d) *Sampling, testing, and retention requirements.* Certified butane producers must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

§ 1090.130 Certified butane blenders.

Certified butane blenders that blend certified butane into PCG are gasoline manufacturers that may comply with the requirements of this section in lieu of the requirements in § 1090.105.

(a) *Gasoline standards.* Certified butane blenders must comply with the applicable requirements of subpart C of this part.

(b) *Registration.* Certified butane blenders must register with EPA under subpart I of this part.

(c) *Reporting.* Certified butane blenders must submit reports to EPA under subpart J of this part.

(d) *Sampling, testing, and retention requirements.* Certified butane blenders must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

(e) *PTDs.* When certified butane is blended with PCG, PTDs that accompany the gasoline blended with certified butane must comply with subpart K of this part.

(f) *Survey.* Certified butane blenders may participate in the applicable fuel surveys of subpart N of this part.

(g) *Annual attest engagement.* Certified butane blenders must submit annual attest engagement reports to EPA under subpart R of this part.

§ 1090.135 Certified pentane producers.

Certified pentane producers must comply with the requirements of this section.

(a) *Gasoline standards.* Certified pentane producers must comply with the applicable requirements of subpart C of this part and certify batches of certified pentane under subpart K of this part.

(b) *Registration.* Certified pentane producers must register with EPA under subpart I of this part.

(c) *Reporting.* Certified pentane producers must submit reports to EPA under subpart J of this part.

(d) *PTDs.* On each occasion when a certified pentane producer transfers custody of or title to any certified pentane, the transferor must provide to the transferee PTDs under subpart K of this part.

(e) *Designation.* Certified pentane producers must designate the certified pentane they produce under subpart K of this part.

(f) *Sampling, testing, and retention requirements.* Certified pentane producers and importers must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

§ 1090.140 Certified pentane blenders.

Certified pentane blenders that blend certified pentane into PCG are gasoline manufacturers that may comply with the requirements of this section in lieu of the requirements in § 1090.105.

(a) *Gasoline standards.* Certified pentane blenders must comply with the applicable requirements of subpart C of this part.

(b) *Registration.* Certified pentane blenders must register with EPA under subpart I of this part.

(c) *Reporting.* Certified pentane blenders must submit reports to EPA under subpart J of this part.

(d) *Sampling, testing, and retention requirements.* Certified pentane blenders must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

(e) *PTDs.* When certified pentane is blended with PCG, PTDs that accompany the gasoline blended with pentane must comply with subpart K of this part.

(f) *Survey.* Certified pentane blenders may participate in the applicable fuel surveys of subpart N of this part.

(g) *Annual attest engagement.* Certified pentane blenders must submit annual attest engagement reports to EPA under subpart R of this part.

§ 1090.145 Transmix processors.

Transmix processors must comply with the requirements of this section.

(a) *Transmix requirements.* Transmix processors must comply with the transmix requirements of subpart F of this part and certify batches of fuel under subpart K of this part.

(b) *Registration.* Transmix processors must register with EPA under subpart I of this part.

(c) *PTDs.* On each occasion when a transmix processor produces a batch of fuel or transfers custody of or title to any fuel, fuel additive, or regulated blendstock, the transferor must provide to the transferee PTDs under subpart K of this part.

(d) *Designation.* Transmix processors must designate the batches of fuel they produce under subpart K of this part.

(e) *Sampling, testing, and retention requirements.* Transmix processors must conduct sampling, testing, and sample retention in accordance with subparts F and M of this part.

(f) *Reporting.* Transmix processors must submit reports to EPA under subpart J of this part.

§ 1090.150 Transmix blenders.

Transmix blenders must comply with the requirements of this section.

(a) *Transmix requirements.* Transmix blenders must comply with the transmix requirements of subpart F of this part and certify batches of fuel under subpart K of this part.

(b) *PTDs.* On each occasion when a transmix blender produces a batch of fuel or transfers custody or title to any fuel, fuel additive, or regulated blendstock, the transferor must provide to the transferee PTDs under subpart K of this part.

(c) *Designation.* Transmix blenders must designate the batches of fuel they produce under subpart K of this part.

(d) *Sampling, testing, and retention requirements.* Transmix blenders must conduct sampling, testing, and sample retention in accordance with subparts F and M of this part.

§ 1090.155 Fuel additive manufacturers.

This section provides an overview of general requirements applicable to fuel additive manufacturers. Gasoline additive manufacturers must comply with the requirements of paragraph (a) of this section, diesel fuel additive manufacturers must comply with the requirements of paragraph (b) of this section, and certified ethanol denaturant producers must comply with the requirements of paragraph (c) of this section.

(a) *Gasoline additive manufacturers.* Gasoline additive manufacturers that produce additives with a maximum allowed concentration of less than 1.0 volume percent must meet the following requirements:

(1) *Gasoline standards.* Gasoline additive manufacturers must produce gasoline additives that comply with subpart C of this part and certify gasoline additives under subpart K of this part.

(2) *PTDs.* On each occasion when a gasoline additive manufacturer transfers custody of or title to any gasoline additive, the transferor must provide to the transferee PTDs under subpart K of this part.

(3) *Gasoline detergent manufacturers.* Gasoline detergent manufacturers must comply with the following requirements:

(i) *Part 79 registration and LAC determination.* Gasoline detergent manufacturers must register gasoline detergent(s) under 40 CFR 79.21 at a concentration that is greater than or equal to the LAC reported by the gasoline detergent manufacturer under 40 CFR 79.21(j). Note that EPA provides a list on EPA's website of detergents that have been certified by the gasoline detergent manufacturer as meeting the deposit control requirement (Search for ''List of Certified Detergent Additives'').

(ii) *Gasoline standards.* Report the LAC determined under § 1090.240(b) and provide specific composition information as part of the gasoline detergent manufacturer's registration of the detergent under 40 CFR 79.21(j).

(iii) *PTDs.* On each occasion when a gasoline detergent manufacturer transfers custody of or title to any gasoline detergent, the transferor must provide to the transferee PTDs under subpart K of this part.

(iv) *Sampling, testing, and retention requirements.* Gasoline detergent manufacturers that register detergents must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

(b) *Diesel fuel additive manufacturers.* Diesel fuel additive manufacturers that produce additives with a maximum allowed concentration of less than 1.0 volume percent must meet the following requirements:

(1) *Diesel fuel standards.* Diesel fuel additive manufacturers must produce diesel fuel additives that comply with subpart D of this part and certify batches of diesel fuel additive under subpart K of this part.

(2) *PTDs.* On each occasion when a diesel fuel additive manufacturer transfers custody of or title to any diesel additive, the transferor must provide to the transferee PTDs under subpart K of this part.

(c) *Certified ethanol denaturant producers and importers.* Certified ethanol denaturant producers must meet the following requirements:

(1) *Certification of certified ethanol denaturant.* Certified ethanol denaturant producers and importers must certify that certified ethanol denaturant meets the requirements in § 1090.235.

(2) *Registration.* Certified ethanol denaturant producers and importers must register with EPA under subpart I of this part.

(3) *PTDs.* On each occasion when a certified ethanol denaturant producer transfers custody or title to any fuel, fuel additive, or regulated blendstock, the

transferor must provide to the transferee PTDs under subpart K of this part.

§ 1090.160 Distributors, carriers, and resellers.

Distributors, carriers, and resellers must comply with the requirements of this section.

(a) *Gasoline and diesel standards.* Distributors, carriers, and resellers must comply with the applicable requirements of subparts C and D of this part.

(b) *Registration.* Distributors and carriers must register with EPA under subpart I of this part if they are part of the 500 ppm LM diesel fuel distribution chain under a compliance plan submitted under § 1090.520(g).

(c) *PTDs.* Distributors, carriers, and resellers may have specific PTD requirements under subpart K of this part. For example, a distributor that adds diluent to a gasoline detergent may have to modify the PTD for the gasoline detergent to specify a new minimum concentration that complies with the deposit control requirements in § 1090.240.

§ 1090.165 Retailers and WPCs.

Retailers and WPCs must comply with the requirements of this section.

(a) *Gasoline and diesel standards.* Retailers and WPCs must comply with the applicable requirements of subparts C and D of this part.

(b) *Labeling.* Retailers and WPCs that dispense fuels requiring a label under this part must display fuel labels under subpart O of this part.

(c) *Blender Pumps.* Retailers and WPCs that produce gasoline (*e.g.,* E15) through a blender pump with PCG and E85 that contains anything other than PCG and DFE must comply with the applicable requirements in § 1090.105.

§ 1090.170 Independent surveyors.

Independent surveyors that conduct fuel surveys must comply with the requirements of this section.

(a) *Survey provisions.* Independent surveyors must conduct fuel surveys under subpart N of this part.

(b) *Registration.* Independent surveyors must register with EPA under subpart I of this part.

(c) *Sampling, testing, and retention requirements.* Independent surveyors must conduct sampling, testing, and sample retention in accordance with subpart M of this part.

(d) *Reporting.* Independent surveyors must submit reports to EPA under subpart J of this part.

(e) *Independence requirements.* In order to perform a survey program under subpart N of this part, independent surveyors must meet the independence requirements in § 1090.55.

§ 1090.175 Auditors.

Auditors that conduct audits for responsible parties under this part must comply with the requirements of this section.

(a) *Registration.* Auditors must register with EPA under subpart I of this part.

(b) *Reporting.* Auditors must submit reports to EPA under subpart J of this part.

(c) *Attest engagement.* Auditors must conduct audits under subpart R of this part.

(d) *Independence requirements.* In order to perform an annual attest engagement under subpart R of this part, auditors must meet the independence requirements in § 1090.55 unless they are a certified internal auditor under § 1090.1800(b)(1)(i).

§ 1090.180 Pipeline operators.

Pipeline operators must comply with the requirements of this section.

(a) *Gasoline and diesel standards.* Pipeline operators must comply with the applicable requirements of subparts C and D of this part.

(b) *PTDs.* Pipeline operators must maintain PTDs for the fuel, fuel additive, regulated blendstock, and heating oil of which they take custody.

(c) *Transmix requirements.* Pipeline operators must comply with all applicable requirements in subpart F of this part.

Subpart C—Gasoline Standards

§ 1090.200 Overview and general requirements.

(a) Except as specified in subpart G of this part, gasoline, gasoline additives, and gasoline regulated blendstocks are subject to the standards in this subpart.

(b) Except for the sulfur average standard in § 1090.205(a) and the benzene average standards in § 1090.210(a) and (b), the standards in this part apply to gasoline, gasoline additives, and gasoline regulated blendstocks on a per-gallon basis. Gasoline manufacturers and gasoline additive manufacturers (*e.g.,* oxygenate producers and certified ethanol denaturant producers), and gasoline regulated blendstock producers (*e.g.,* certified butane producers and certified pentane producers) must demonstrate compliance with the per-gallon standards in this subpart by measuring fuel parameters in accordance with subpart M of this part.

(c) The sulfur average standard in § 1090.205(a) and the benzene average standards in § 1090.210(a) and (b) apply to all gasoline produced or imported by a fuel manufacturer during a compliance period, except for truck and rail importers using the provisions of §§ 1090.205(d) and 1090.210(c), certified butane blenders, certified pentane blenders, and transmix blenders. Fuel manufacturers must demonstrate compliance with average standards by measuring fuel parameters in accordance with subpart M of this part and by determining compliance under subpart H of this part.

(d) No person may produce, import, sell, offer for sale, distribute, offer to distribute, supply, offer for supply, dispense, store, transport, or introduce into commerce any gasoline, gasoline additive, or gasoline regulated blendstock that does not comply with any per-gallon standard set forth in this subpart.

(e) No person may sell, offer for sale, supply, offer for supply, dispense, transport, or introduce into commerce for use as fuel in any motor vehicle (as defined in Section 216(2) of the Clean Air Act, 42 U.S.C. 7550(2)) any gasoline that is produced with the use of additives containing lead, that contains more than 0.05 gram of lead per gallon, or that contains more than 0.005 grams of phosphorous per gallon.

§ 1090.205 Sulfur standards.

Except as specified in subpart G of this part, all gasoline is subject to the following sulfur standards:

(a) *Sulfur average standard.* Gasoline manufacturers must meet a sulfur average standard of 10.00 ppm for each compliance period.

(b) *Fuel manufacturing facility gate sulfur per-gallon standard.* Gasoline at any fuel manufacturing facility gate is subject to a maximum sulfur per-gallon standard of 80 ppm. Fuel manufacturers may not account for the downstream addition of oxygenates in determining compliance with this standard.

(c) *Downstream location sulfur per-gallon standard.* Gasoline at any downstream location is subject to a maximum sulfur per-gallon standard of 95 ppm.

(d) *Sulfur standard for importers that import gasoline by rail or truck.* Importers that import gasoline by rail or truck under § 1090.1610 must comply with a maximum sulfur per-gallon standard of 10 ppm instead of the standards in paragraphs (a) through (c) of this section.

§ 1090.210 Benzene standards.

Except as specified in subpart G of this part, all gasoline is subject to the following benzene standards:

(a) *Benzene average standard.* Gasoline manufacturers must meet a benzene average standard of 0.62 volume percent for each compliance period.

(b) *Maximum benzene average standard.* Gasoline manufacturers must meet a maximum benzene average standard of 1.30 volume percent without the use of credits for each compliance period.

(c) *Benzene standard for importers that import gasoline by rail or truck.* Importers that import gasoline by rail or truck under § 1090.1610 must comply with a 0.62 volume percent benzene per-gallon standard instead of the standards in paragraphs (a) and (b) of this section.

§ 1090.215 Gasoline RVP standards.

Except as specified in subpart G of this part and paragraph (c) of this section, all gasoline designated as summer gasoline or located at any location in the United States during the summer season is subject to a maximum RVP per-gallon standard in this section.

(a) *Federal 9.0 psi maximum RVP per-gallon standard.* Gasoline designated as summer gasoline or located at any location in the United States during the summer season must meet a maximum RVP per-gallon standard of 9.0 psi unless the gasoline is subject to one of the following lower maximum RVP per-gallon standards:

(1) *Federal 7.8 maximum RVP per-gallon standard.* Gasoline designated as 7.8 psi summer gasoline, or located in the following areas during the summer season, must meet a maximum RVP per-gallon standard of 7.8 psi:

TABLE 1 TO PARAGRAPH (a)(1)

Area designation	State	Counties
Denver-Boulder-Greeley-Ft. Collins-Loveland.	Colorado	Adams Arapahoe, Boulder, Broomfield, Denver, Douglas, Jefferson, Larimer,[1] Weld.[2]
Reno	Nevada	Washoe.
Portland	Oregon	Clackamas (only the Air Quality Maintenance Area), Multnomah (only the Air Quality Maintenance Area), Washington (only the Air Quality Maintenance Area).
Salem	Oregon	Marion (only the Salem Area Transportation Study), Polk (only the Salem Area Transportation Study).
Beaumont-Port Arthur	Texas	Hardin, Jefferson, Orange.
Salt Lake City	Utah	Davis, Salt Lake.

[1] That portion of Larimer County, CO that lies south of a line described as follows: Beginning at a point on Larimer County's eastern boundary and Weld County's western boundary intersected by 40 degrees, 42 minutes, and 47.1 seconds north latitude, proceed west to a point defined by the intersection of 40 degrees, 42 minutes, 47.1 seconds north latitude and 105 degrees, 29 minutes, and 40.0 seconds west longitude, thence proceed south on 105 degrees, 29 minutes, 40.0 seconds west longitude to the intersection with 40 degrees, 33 minutes and 17.4 seconds north latitude, thence proceed west on 40 degrees, 33 minutes, 17.4 seconds north latitude until this line intersects Larimer County's western boundary and Grand County's eastern boundary. (Includes part of Rocky Mtn. Nat. Park).

[2] That portion of Weld County, CO that lies south of a line described as follows: Beginning at a point on Weld County's eastern boundary and Logan County's western boundary intersected by 40 degrees, 42 minutes, 47.1 seconds north latitude, proceed west on 40 degrees, 42 minutes, 47.1 seconds north latitude until this line intersects Weld County's western boundary and Larimer County's eastern boundary.

(2) *RFG maximum RVP per-gallon standard.* Gasoline designated as Summer RFG or located in RFG covered areas specified in § 1090.270 during the summer season must meet a maximum RVP per-gallon standard of 7.4 psi.

(3) *California gasoline.* Gasoline designated as California gasoline or used in areas subject to the California reformulated gasoline regulations must comply with those regulations under Title 13, California Code of Regulations, sections 2250–2273.5.

(4) *SIP-controlled gasoline.* Gasoline designated as SIP-controlled gasoline or used in areas subject to a SIP-approved state fuel rule that requires an RVP of less than 9.0 psi must meet the requirements of the federally approved SIP.

(b) *Ethanol 1.0 psi waiver.* (1) Except as specified in paragraph (b)(3) of this section, any gasoline subject to a federal 9.0 psi or 7.8 psi maximum RVP per-gallon standard in paragraph (a) of this section that meets the requirements of paragraph (b)(2) of this section is not in violation of this section if its RVP does not exceed the applicable standard by more than 1.0 psi.

(2) To qualify for the special regulatory treatment specified in paragraph (b)(1) of this section, gasoline must meet the applicable RVP per-gallon standard in this section prior to the addition of ethanol and must contain ethanol at a concentration of at least 9 volume percent and no more than 15 volume percent.

(3) RFG and gasoline subject to a state RVP requirement that does not allow for the ethanol 1.0 psi waiver does not qualify for the special regulatory treatment specified in paragraph (b)(1) of this section.

(c) *Exceptions.* The RVP per-gallon standard in paragraph (a) of this section for the area in which the gasoline is located does not apply to that gasoline if a person can demonstrate one of the following:

(1) The gasoline is designated as winter gasoline and was not sold, offered for sale, supplied, offered for supply, dispensed, or introduced into commerce for use during the summer season and was not delivered to any retail station or wholesale purchaser consumer during the summer season.

(2) The gasoline is designated as summer gasoline for use in an area other than the area in which it is located and was not sold, offered for sale, supplied, offered for supply, dispensed, or introduced into commerce in the area in which the gasoline is located. In this case, the standard that applies to the gasoline is the standard applicable to the area for which the gasoline is designated.

§ 1090.220 Certified butane standards.

Butane designated as certified butane under § 1090.1100(e) for use under the butane blending provisions of § 1090.1320(c) must meet the following per-gallon standards:

(a) *Butane content.* Minimum 92 volume percent.

(b) *Benzene content.* Maximum 0.03 volume percent.

(c) *Sulfur content.* Maximum 10 ppm.

(d) *Chemical composition.* Be composed solely of carbon, hydrogen, oxygen, nitrogen, and sulfur.

§ 1090.225 Certified pentane standards.

Pentane designated as certified pentane under § 1090.1100(f) for use under the pentane blending provisions

of § 1090.1320(c) must meet the following per-gallon standards:

(a) *Pentane content.* Minimum 95 volume percent.

(b) *Benzene content.* Maximum 0.03 volume percent.

(c) *Sulfur content.* Maximum 10 ppm.

(d) *Chemical composition.* Be composed solely of carbon, hydrogen, oxygen, nitrogen, and sulfur.

§ 1090.230 Gasoline oxygenate standards.

(a) All oxygenates designated for blending with gasoline or blended with gasoline must meet the following per-gallon standards:

(1) *Sulfur content.* Maximum 10 ppm.

(2) *Chemical composition.* Be composed solely of carbon, hydrogen, oxygen, nitrogen, and sulfur.

(b) DFE designated for blending into gasoline or blended with gasoline must meet the following additional requirements:

(1) *Denaturant type.* Only PCG, gasoline blendstocks, NGLs, or certified ethanol denaturant that meets the requirements in § 1090.235 may be used as denaturants.

(2) *Denaturant concentration.* The concentration of all denaturants used in DFE must not exceed 3.0 volume percent.

§ 1090.235 Ethanol denaturant standards.

(a) *Standard for all ethanol denaturant.* All ethanol denaturant, certified or uncertified, used to produce DFE must be composed solely of carbon, hydrogen, nitrogen, oxygen, and sulfur.

(b) *Standards for certified ethanol denaturant.* Certified ethanol denaturant must meet the following requirements:

(1) *Sulfur per-gallon standard.* The sulfur content must not be greater than 330 ppm. If the certified ethanol denaturant producer represents a batch of denaturant as having a maximum sulfur content less than or equal to 330 ppm on the PTD (for example, less than or equal to 120 ppm), then the actual sulfur content must be less than or equal to the stated value.

(2) *Denaturant type.* Only PCG, gasoline blendstocks, or NGLs may be used to produce certified ethanol denaturant.

§ 1090.240 Gasoline deposit control standards.

(a) Except as specified in subpart G of this part, all gasoline that is sold, offered for sale, dispensed, supplied, offered for supply, or transported to the ultimate consumer for use in motor vehicles or in any off-road engines, or that is transported to a gasoline retailer or WPC must be treated with a detergent meeting the requirements of paragraph (b) of this section at a rate at least as high as the detergent's LAC over VAR period.

(b) The LAC of the detergent must be determined by the gasoline detergent manufacturer using one of the following methods:

(1) The detergent must comply with one of the deposit control testing methods specified in § 1090.1395.

(2) The detergent must have been certified prior to January 1, 2021, under the intake valve deposit control requirements of 40 CFR 80.165(b) for any of the detergent certification options under 40 CFR 80.163. Di-tertiary butyl disulfide may have been used to meet the test fuel specifications under 40 CFR 80.164 associated with the intake valve deposit control requirements of 40 CFR 80.165(b). Parties compliant with this paragraph are exempted from the port fuel injector deposit control requirements of 40 CFR 80.165(a).

(3) Gasoline detergent manufacturers must produce detergents consistent with their detergent certifications for detergents certified prior to January 1, 2021, and with the specific composition information submitted as part of the registration of detergents under 40 CFR 79.21(j) thereafter.

§ 1090.245 RFG standards.

The standards in this section apply to gasoline that is designated as RFG or RBOB or that is used in the RFG covered areas listed in § 1090.270. Gasoline that meets the requirements of this section is deemed to be in compliance with the requirements of 42 U.S.C. 7545(k).

(a) *Sulfur standards.* RFG or RBOB must comply with the sulfur average standard in § 1090.205(a). RFG and RBOB must comply with sulfur per-gallon standards in § 1090.205(b) and (c).

(b) *Benzene standards.* RFG or RBOB must comply with the benzene standards in § 1090.210.

(c) *RVP standard.* Summer RFG or Summer RBOB must comply with the RFG RVP standard in § 1090.215(a)(2).

(d) *Heavy metals standard.* RFG or RBOB must not contain any heavy metals, including, but not limited to, lead or manganese. EPA may waive this prohibition for a heavy metal (other than lead) if EPA determines that addition of the heavy metal to the gasoline will not increase, on an aggregate mass or cancer-risk basis, toxic air pollutant emissions from motor vehicles.

(e) *Certified butane and certified pentane blending limitation.* Certified butane and certified pentane may not be blended with Summer RFG or Summer RBOB under § 1090.1320.

§ 1090.250 Anti-dumping standards.

Gasoline that meets all applicable standards in this subpart is deemed to be in compliance with the anti-dumping requirements of 42 U.S.C. 7545(k)(8).

§ 1090.255 Gasoline additive standards.

(a) Any gasoline additive that is added to, intended for adding to, used in, or offered for use in gasoline at any downstream location must meet all the following requirements:

(1) *Registration.* The gasoline additive must be registered by a gasoline additive manufacturer under 40 CFR part 79.

(2) *Sulfur content.* The gasoline additive must contribute less than or equal to 3 ppm on a per-gallon basis to the sulfur content of gasoline when used at the maximum recommended concentration.

(3) *Treatment rate.* Except for oxygenates, the gasoline additive(s) must be used at a maximum treatment rate less than or equal to a combined total of 1.0 volume percent.

(b) Any fuel additive blender who is not otherwise subject to any other requirement in this part and only blends a gasoline additive that meets the requirements of paragraph (a) of this section into gasoline is not subject to any requirement in this part solely due to this gasoline additive blending, except the downstream gasoline sulfur per-gallon standard in § 1090.205(c), if all the following conditions are met:

(1) The fuel additive blender blends the gasoline additive into gasoline at a concentration less than or equal to 1.0 volume percent.

(2) The fuel additive blender does not add any other blendstock or fuel additive into the gasoline except for oxygenates meeting the requirements in § 1090.230.

(c) Any person who blends any fuel additive that does not meet the requirements of paragraphs (a) and (b) of this section is a gasoline manufacturer and must comply with all requirements applicable to gasoline manufacturer in this part.

(d) Any gasoline additive intended for use or used to comply with the gasoline deposit control requirement in § 1090.240(a) must have been certified by the gasoline detergent manufacturer under § 1090.240(b).

§ 1090.260 Gasoline substantially similar provisions.

(a) Gasoline and gasoline additives (including oxygenates) are subject to the substantially similar requirement in 42 U.S.C. 7545(f) unless waived under 42 U.S.C. 7545(f)(4).

(b) No fuel or fuel additive manufacturer may introduce into

commerce gasoline or gasoline additives (including oxygenates) that violate any conditions set forth in a waiver under 42 U.S.C. 7545(f)(4).

(c) No fuel or fuel additive manufacturers may introduce into commerce gasoline or gasoline additives (including oxygenates) that violate any parameters articulated in the definition of ''substantially similar.''

§ 1090.265 Requirements for E15.

(a) No person may sell, introduce, cause or permit the sale or introduction of gasoline containing greater than 10 volume percent ethanol (*i.e.,* greater than E10) into any model year 2000 or older light-duty gasoline motor vehicle, any heavy-duty gasoline motor vehicle or engine, any highway or off-highway motorcycle, or any gasoline-powered nonroad engines, vehicles, or equipment.

(b) Paragraph (a) of this section does not prohibit a person from producing, selling, introducing, or causing or allowing the sale or introduction of gasoline containing greater than 10 volume percent ethanol into any flex-fuel vehicle or flex-fuel engine.

§ 1090.270 RFG covered areas.

For purposes of this part, the RFG covered areas are as follows:

(a) RFG covered areas specified in 42 U.S.C. 7545(k)(10)(D):

TABLE 1 TO PARAGRAPH (a)

Area designation	State	Counties	Independent cities
Los Angeles-Anaheim-Riverside.	California	Los Angeles, Orange, Ventura, San Bernardino,[1] Riverside[2]	
San Diego County	California	San Diego	
Greater Connecticut	Connecticut	Hartford, Middlesex, New Haven, New London, Tolland, Windham, Fairfield (only the City of Shelton), Litchfield (all except the towns of Bridgewater and New Milford).	
New York-Northern New Jersey-Long Island-Connecticut.	Connecticut	Fairfield (all except the City of Shelton), Litchfield (only the towns of Bridgewater and New Milford).	
	New Jersey	Bergen, Essex, Hudson, Hunterdon, Middlesex, Monmouth, Morris, Ocean, Passaic, Somerset, Sussex, Union.	
	New York	Bronx, Kings, Nassau, New York, Orange, Putnam, Queens, Richmond, Rockland, Suffolk, Westchester.	
Philadelphia-Wilmington-Trenton.	Delaware	Kent, New Castle	
	Maryland	Cecil	
	New Jersey	Burlington, Camden, Cumberland, Gloucester, Mercer, Salem.	
	Pennsylvania	Bucks, Chester, Delaware, Montgomery, Philadelphia	
Chicago-Gary-Lake County	Illinois	Cook, Du Page, Kane, Lake, McHenry, Will, Grundy (only Aux Sable Township and Goose Lake Township), Kendall (only Oswego Township).	
	Indiana	Lake, Porter	
Baltimore	Maryland	Anne Arundel, Baltimore, Carroll, Harford, Howard	Baltimore.
Houston-Galveston-Brazoria	Texas	Brazoria, Chambers, Fort Bend, Galveston, Harris, Liberty, Montgomery, Waller.	
Milwaukee-Racine	Wisconsin	Kenosha, Milwaukee, Ozaukee, Racine, Washington, Waukesha.	

[1] That portion of San Bernardino County, CA that lies south of latitude 35 degrees, 10 minutes north and west of longitude 115 degrees, 45 minutes west.

[2] That portion of Riverside County, CA that lies to the west of a line described as follows: Beginning at the northeast corner of Section 4, Township 2 South, Range 5 East, a point on the boundary line common to Riverside and San Bernardino Counties; then southerly along section lines to the centerline of the Colorado River Aqueduct; then southeasterly along the centerline of said Colorado River Aqueduct to the southerly line of Section 36, Township 3 South, Range 7 East; then easterly along the township line to the northeast corner of Section 6, Township 4 South, Range 9 East; then southerly along the easterly line of Section 6 to the southeast corner thereof; then easterly along section lines to the northeast corner of Section 10, Township 4 South, Range 9 East; then southerly along section lines to the southeast corner of Section 15, Township 4 South, Range 9 East; then easterly along the section lines to the northeast corner of Section 21, Township 4 South, Range 10 East; then southerly along the easterly line of Section 21 to the southeast corner thereof; then easterly along the northerly line of Section 27 to the northeast corner thereof; then southerly along section lines to the southeast corner of Section 34, Township 4 South, Range 10 East; then easterly along the township line to the northeast corner of Section 2, Township 5 South, Range 10 East; then southerly along the easterly line of Section 2, to the southeast corner thereof; then easterly along the northerly line of Section 12 to the northeast corner thereof; then southerly along the range line to the southwest corner of Section 18, Township 5 South, Range 11 East; then easterly along section lines to the northeast corner of Section 24, Township 5 South, Range 11 East; and then southerly along the range line to the southeast corner of Section 36, Township 8 South, Range 11 East, a point on the boundary line common to Riverside and San Diego Counties.

(b) RFG covered areas based on being reclassified as Severe ozone nonattainment areas under 42 U.S.C. 7511(b):

TABLE 2 TO PARAGRAPH (b)

Area designation	State or district	Counties	Independent cities
Washington, DC-Maryland-Virginia.	District of Columbia.	Washington	
	Maryland	Calvert, Charles, Frederick, Montgomery, Prince George's	

TABLE 2 TO PARAGRAPH (b)—Continued

Area designation	State or district	Counties	Independent cities
	Virginia	Arlington, Fairfax, Loudoun, Prince William, Stafford	Alexandria, Fairfax, Falls Church, Manassas, Manassas Park.
Sacramento Metro	California	Sacramento, Yolo, El Dorado (except Lake Tahoe and its drainage area), Placer,[1] Solano,[2] Sutter[3].	
San Joaquin Valley	California	Fresno, Kings, Madera, Merced, San Joaquin, Stanislaus, Tulare, Kern[4].	

[1] All portions of Placer County except that portion of the County within the drainage area naturally tributary to Lake Tahoe including said Lake, plus that area in the vicinity of the head of the Truckee River described as follows: commencing at the point common to the aforementioned drainage area crestline and the line common to Townships 15 North and 16 North, Mount Diablo Base and Meridian (M.D.B.&M.), and following that line in a westerly direction to the northwest corner of Section 3, Township 15 North, Range 16 East, M.D.B.&M., thence south along the west line of Sections 3 and 10, Township 15 North, Range 16 East, M.D.B.&M., to the intersection with the said drainage area crestline, thence following the said drainage area boundary in a southeasterly, then northeasterly direction to and along the Lake Tahoe Dam, thence following the said drainage area crestline in a northeasterly, then northwesterly direction to the point of beginning.

[2] That portion of Solano County that lies north and east of a line described as follows: beginning at the intersection of the westerly boundary of Solano County and the ¼ section line running east and west through the center of Section 34; T. 6 N., R. 2 W., M.D.B.&M.; thence east along said ¼ section line to the east boundary of Section 36, T. 6 N., R. 2 W.; thence south ½ mile and east 2.0 miles, more or less, along the west and south boundary of Los Putos Rancho to the northwest corner of Section 4, T. 5 N., R. 1 W.; thence east along a line common to T. 5 N. and T. 6 N. to the northeast corner of Section 3, T. 5 N., R. 1 E.; thence south along section lines to the southeast corner of Section 10, T. 3 N., R. 1 E.; thence east along section lines to the south ¼ corner of Section 8, T. 3 N., R. 2 E.; thence east to the boundary between Solano and Sacramento Counties.

[3] That portion of Sutter County south of a line connecting the northern border of Yolo Co. to the SW tip of Yuba Co. and continuing along the southern Yuba Co. border to Placer Co.

[4] Boundary between the Kern County and San Joaquin Valley air districts that generally follows the ridge line of the Sierra Nevada and Tehachapi Mountain Ranges. That portion of Kern County that lies west and north of a line described as follows: beginning at the Kern-Los Angeles County boundary and running north and east along the northwest boundary of the Rancho La Liebre Land Grant to the point of intersection with the range line common to Range 16 West and Range 17 West, San Bernardino Base and Meridian; north along the range line to the point of intersection with the Rancho El Tejon Land Grant boundary; then southeast, northeast, and northwest along the boundary of the Rancho El Tejon Grant to the northwest corner of Section 3, Township 11 North, Range 17 West; then west 1.2 miles; then north to the Rancho El Tejon Land Grant boundary; then northwest along the Rancho El Tejon line to the southeast corner of Section 34, Township 32 South, Range 30 East, Mount Diablo Base and Meridian; then north to the northwest corner of Section 35, Township 31 South, Range 30 East; then northeast along the boundary of the Rancho El Tejon Land Grant to the southwest corner of Section 18, Township 31 South, Range 31 East; then east to the southeast corner of Section 13, Township 31 South, Range 31 East; then north along the range line common to Range 31 East and Range 32 East, Mount Diablo Base and Meridian, to the northwest corner of Section 6, Township 29 South, Range 32 East; then east to the southwest corner of Section 31, Township 28 South, Range 32 East; then north along the range line common to Range 31 East and Range 32 East to the northwest corner of Section 6, Township 28 South, Range 32 East; then west to the southeast corner of Section 36, Township 27 South, Range 31 East; then north along the range line common to Range 31 East and Range 32 East to the Kern-Tulare County boundary.

(c) RFG covered areas based on being classified ozone nonattainment areas at the time that the state requested to opt into RFG under 42 U.S.C. 7545(k)(6)(A)(i):

TABLE 3 TO PARAGRAPH (c)

Area designation at the time of opt-in	State	Counties	Independent cities
Sussex County	Delaware	Sussex	
St. Louis, Missouri-Illinois	Illinois	Jersey, Madison, Monroe, St. Clair	
	Missouri	Franklin, Jefferson, St. Charles, St. Louis	St. Louis.
Kentucky portion of Louisville	Kentucky	Jefferson, Bullitt,[1] Oldham[2]	
Kent and Queen Anne's Counties.	Maryland	Kent, Queen Anne's	
Statewide	Massachusetts	All	
Strafford, Merrimack, Hillsborough, Rockingham Counties.	New Hampshire.	Hillsborough, Merrimack, Rockingham, Strafford	
Atlantic City	New Jersey	Atlantic, Cape May	
New Jersey portion of Allentown- Bethlehem-Easton.	New Jersey	Warren	
Dutchess County	New York	Dutchess	
Essex County	New York	Essex (the portion of Whiteface Mountain above 4,500 feet in elevation).	
Statewide	Rhode Island	All	
Dallas-Fort Worth	Texas	Collin, Dallas, Denton, Tarrant	
Norfolk-Virginia Beach, Newport News (Hampton Roads).	Virginia	James City, York	Chesapeake, Hampton, Newport News, Norfolk, Poquoson, Portsmouth, Suffolk, Virginia Beach, Williamsburg.

TABLE 3 TO PARAGRAPH (c)—Continued

Area designation at the time of opt-in	State	Counties	Independent cities
Richmond	Virginia	Charles City, Chesterfield, Hanover, Henrico	Colonial Heights, Hopewell, Richmond.

[1] In Bullitt County, KY, beginning at the intersection of Ky 1020 and the Jefferson-Bullitt County Line proceeding to the east along the county line to the intersection of county road 567 and the Jefferson-Bullitt County Line; proceeding south on county road 567 to the junction with Ky 1116 (also known as Zoneton Road); proceeding to the south on KY 1116 to the junction with Hebron Lane; proceeding to the south on Hebron Lane to Cedar Creek; proceeding south on Cedar Creek to the confluence of Floyds Fork turning southeast along a creek that meets Ky 44 at Stallings Cemetery; proceeding west along Ky 44 to the eastern most point in the Shepherdsville city limits; proceeding south along the Shepherdsville city limits to the Salt River and west to a point across the river from Mooney Lane; proceeding south along Mooney Lane to the junction of Ky 480; proceeding west on Ky 480 to the junction with Ky 2237; proceeding south on Ky 2237 to the junction with Ky 61 and proceeding north on Ky 61 to the junction with Ky 1494; proceeding south on Ky 1494 to the junction with the perimeter of the Fort Knox Military Reservation; proceeding north along the military reservation perimeter to Castleman Branch Road; proceeding north on Castleman Branch Road to Ky 44; proceeding a very short distance west on Ky 44 to a junction with Ky 1020 and proceeding north on Ky 1020 to the beginning.

[2] In Oldham County, KY, beginning at the intersection of the Oldham-Jefferson County Line with the southbound lane of Interstate 71; proceeding to the northeast along the southbound lane of Interstate 71 to the intersection of Ky 329 and the southbound lane of Interstate 71; proceeding to the northwest on Ky 329 to the intersection of Zaring Road on Ky 329; proceeding to the east-northeast on Zaring Road to the junction of Cedar Point Road and Zaring Road; proceeding to the north-northeast on Cedar Point Road to the junction of Ky 393 and Cedar Point Road; proceeding to the south-southeast on Ky 393 to the junction of county road 746 (the road on the north side of Reformatory Lake and the Reformatory); proceeding to the east-northeast on county road 746 to the junction with Dawkins Lane (also known as Saddlers Mill Road) and county road 746; Proceeding to follow an electric power line east-northeast across from the junction of county road 746 and Dawkins Lane to the east-northeast across Ky 53 on to the La Grange Water Filtration Plant; proceeding on to the east-southeast along the power line then south across Fort Pickens Road to a power substation on Ky 146; proceeding along the power line south across Ky 146 and the Seaboard System Railroad track to adjoin the incorporated city limits of La Grange; then proceeding east then south along the La Grange city limits to a point abutting the north side of Ky 712; proceeding east-southeast on Ky 712 to the junction of Massie School Road and Ky 712; proceeding to the south-southwest and then north-northwest on Massie School Road to the junction of Ky 53 and Massie School Road; proceeding on Ky 53 to the north-northwest to the junction of Moody Lane and Ky 53; proceeding on Moody Lane to the south-southwest until meeting the city limits of La Grange; then briefly proceeding north following the La Grange city limits to the intersection of the northbound lane of Interstate 71 and the La Grange city limits; proceeding southwest on the northbound lane of Interstate 71 until intersecting with the North Fork of Currys Fork; proceeding south-southwest beyond the confluence of Currys Fork to the south-southwest beyond the confluence of Floyds Fork continuing on to the Oldham-Jefferson County Line and proceeding northwest along the Oldham-Jefferson County Line to the beginning.

(d) RFG covered area that is located in the ozone transport region established by 42 U.S.C. 7511c(a) that a state has requested to opt into RFG under 42 U.S.C. 7545(k)(6)(B)(i)(I):

TABLE 4 TO PARAGRAPH (d)

State	Counties
Maine	Androscoggin, Cumberland, Kennebec, Knox, Lincoln, Sagadahoc, York.

§ 1090.275 Changes to RFG covered areas and procedures for opting out of RFG.

(a) *New RFG covered areas.* (1) Effective 1 year after an area has been reclassified as a Severe ozone nonattainment area under 42 U.S.C. 7511(b), such Severe area becomes a covered area under the RFG program as required by 42 U.S.C. 7545(k)(10)(D). The geographic extent of each such covered area must be the nonattainment area boundaries as specified in 40 CFR part 81, subpart C, for the ozone NAAQS that was the subject of the reclassification.

(2) Any classified ozone nonattainment area identified in 40 CFR part 81, subpart C, as Marginal, Moderate, Serious, or Severe may be included as a covered area upon the request of the governor of the state in which the area is located. EPA must:

(i) Publish the governor's request in the **Federal Register** upon receipt.

(ii) Establish an effective date that is not later than 1 year after the request is received unless EPA determines that there is insufficient capacity to supply RFG as governed by 42 U.S.C. 7545(k)(6)(A)(ii).

(3) Any ozone attainment area in the ozone transport region established by 42 U.S.C. 7511c(a) may be included as a covered area upon petition by the governor of the state in which the area is located as governed by 42 U.S.C. 7545(k)(6)(B)(i). EPA must:

(i) Publish the governor's request in the **Federal Register** as soon as practicable after it is received.

(ii) Establish an effective date that is not later than 180 days after the request is received unless EPA determines that there is insufficient capacity to supply RFG as governed by 42 U.S.C. 7545(k)(6)(B)(iii).

(b) *Opting out of RFG.* Any area that opted into RFG under 42 U.S.C. 7545(k)(6)(A) or (B) and has not subsequently been reclassified as a Severe ozone nonattainment area may opt out of RFG using the opt-out procedure in paragraph (d) of this section.

(c) *Eligibility for opting out of RFG.* The governor of the state in which any covered area under 42 U.S.C. 7545(k)(10)(D) is located may request that EPA remove the prohibition specified in 42 U.S.C. 7545(k)(5) in such area by following the opt-out procedure specified in paragraph (d) of this section upon one of the following:

(1) Redesignation to attainment for such area for the most stringent ozone NAAQS in effect at the time of redesignation.

(2) Designation as an attainment area for the most stringent ozone NAAQS in effect at the time of the designation. The area must also be redesignated to attainment for the prior ozone NAAQS.

(d) *Procedure for opting out of RFG.* EPA may approve a request from a state asking for removal of any RFG opt-in area, or portion of an RFG opt-in area, from inclusion as a covered area listed in § 1090.270(c) and (d), if it meets the requirements of paragraph (d)(1) of this section. If EPA approves such a request, an effective date will be set as specified

in paragraph (d)(2) of this section. EPA will notify the state in writing of EPA's action on the request and the effective date of the removal when the request is approved.

(1) An opt-out request must be signed by the governor of a state, or their authorized representative, and must include all the following:

(i) A geographic description of each RFG opt-in area, or portion of each RFG opt-in area, which is covered by the request.

(ii) A description of all ways in which emissions reductions from RFG are relied upon in any approved SIP or any submitted SIP that has not yet been approved by EPA.

(iii) For any RFG opt-in areas covered by the request where emissions reductions from RFG are relied upon as specified in paragraph (d)(1)(ii) of this section, the request must include all the following information:

(A) Identify whether the state is withdrawing any submitted SIP that has not yet been approved.

(B)(*1*) Identify whether the state intends to submit a SIP revision to any approved SIP or any submitted SIP that has not yet been approved, which relies on emissions reductions from RFG, and describe any control measures that the state plans to submit to EPA for approval to replace the emissions reductions from RFG.

(*2*) A description of the state's plans and schedule for adopting and submitting any revision to any approved SIP or any submitted SIP that has not yet been approved.

(C) If the state is not withdrawing any submitted SIP that has not yet been approved and does not intend to submit a revision to any approved SIP or any submitted SIP that has not yet been approved, describe why no revision is necessary.

(iv) The governor of a state, or their authorized representative, must submit additional information upon request by EPA.

(2)(i) Except as specified in paragraph (d)(2)(ii) of this section, EPA will set an effective date of the RFG opt-out as requested by the governor, but no less than 90 days from EPA's written notification to the state approving the RFG opt-out request.

(ii) Where emissions reductions from RFG are included in an approved SIP or any submitted SIP that has not yet been approved, other than as a contingency measure consisting of a future opt-in to RFG, EPA will set an effective date of the RFG opt-out as requested by the governor, but no less than 90 days from the effective date of EPA approval of the SIP revision that removes the emissions reductions from RFG, and, if necessary, provides emissions reductions to make up for those from RFG opt-out.

(iii) Notwithstanding the provisions of paragraphs (d)(2)(i) and (ii) of this section, for an area in the ozone transport region that opted into RFG under 42 U.S.C. 7545(k)(6)(B), EPA will not set the effective date for removal of the area earlier than 4 years after the commencement date of opt-in.

(4) EPA will publish a notice in the **Federal Register** announcing the approval of any RFG opt-out request and its effective date.

(5) Upon the effective date for the removal of any RFG opt-in area or portion of an RFG opt-in area included in an approved request, such geographic area will no longer be considered an RFG covered area.

(e) *Revising list of RFG covered areas.* EPA will periodically publish a final rule revising the list of RFG covered areas in § 1090.270.

§ 1090.280 Procedures for relaxing the federal 7.8 psi RVP standard.

(a) EPA may approve a request from a state asking for relaxation of the federal 7.8 psi gasoline standard for any area, or portion of an area, required to use such gasoline, if it meets the requirements of paragraph (b) of this section. If EPA approves such a request, an effective date will be set as specified in paragraph (c) of this section. EPA will notify the state in writing of EPA's action on the request and the effective date of the relaxation when the request is approved.

(b) The request must be signed by the governor of the state, or their authorized representative, and must include all the following:

(1) A geographic description of each federal 7.8 psi gasoline area, or portion of such area, which is covered by the request.

(2) A description of all ways in which emissions reduction from the federal 7.8 psi gasoline are relied upon in any approved SIP or in any submitted SIP that has not yet been approved by EPA.

(3) For any federal 7.8 psi gasoline area covered by the request where emissions reductions from the federal 7.8 psi gasoline are relied upon as specified in paragraph (b)(2) of this section, the request must include the following information:

(i) Identify whether the state is withdrawing any submitted SIP that has not yet been approved.

(ii)(A) Identify whether the state intends to submit a SIP revision to any approved SIP or any submitted SIP that has not yet been approved, which relies on emissions reductions from federal 7.8 psi gasoline, and describe any control measures that the state plans to submit to EPA for approval to replace the emissions reductions from federal 7.8 psi gasoline.

(B) A description of the state's plans and schedule for adopting and submitting any revision to any approved SIP or any submitted SIP that has not yet been approved.

(iii) If the state is not withdrawing any submitted SIP that has not yet been approved and does not intend to submit a revision to any approved SIP or any submitted SIP that has not yet been approved, describe why no revision is necessary.

(4) The governor of a state, or their authorized representative, must submit additional information upon request by EPA.

(c)(1) Except as specified in paragraph (c)(2) of this section, EPA will set an effective date of the relaxation of the federal 7.8 psi gasoline standard as requested by the governor, but no less than 90 days from EPA's written notification to the state approving the relaxation request.

(2) Where emissions reductions from the federal 7.8 psi gasoline are included in an approved SIP or any submitted SIP that has not yet been approved, EPA will set an effective date of the relaxation of the federal 7.8 psi gasoline standard as requested by the governor, but no less than 90 days from the effective date of EPA approval of the SIP revision that removes the emissions reductions from the federal 7.8 psi gasoline, and, if necessary, provides emissions reductions to make up for those from the federal 7.8 psi gasoline relaxation.

(d) EPA will publish a notice in the **Federal Register** announcing the approval of any federal 7.8 psi gasoline relaxation request and its effective date.

(e) Upon the effective date for the relaxation of the federal 7.8 psi gasoline standard in a subject area or portion of a subject area included in an approved request, such geographic area will no longer be considered a federal 7.8 psi gasoline area.

(f) EPA will periodically publish a final rule revising the list of areas subject to the federal 7.8 psi gasoline standard in § 1090.215(a)(1).

Subpart D—Diesel Fuel and ECA Marine Fuel Standards

§ 1090.300 Overview and general requirements.

(a) Diesel fuel is subject to the ULSD standards in § 1090.305, except as follows:

(1) Alternative sulfur standards apply for 500 ppm LM diesel fuel and ECA

marine fuel as specified in §§ 1090.320 and 1090.325, respectively.

(2) Exemption provisions apply as specified in subpart G of this part.

(b) Diesel fuel additives must meet the requirements in § 1090.310.

(c) Diesel fuel manufacturers and diesel fuel additive manufacturers must demonstrate compliance with the standards in this subpart by measuring fuel parameters in accordance with subpart M of this part.

(d) All the standards in this part apply to diesel fuel and diesel fuel additives on a per-gallon basis.

(e)(1) No person may produce, import, sell, offer for sale, distribute, offer to distribute, supply, offer for supply, dispense, store, transport, or introduce into commerce any diesel fuel, ECA marine fuel, or diesel fuel additive that exceeds any standard set forth in this subpart.

(2) Notwithstanding paragraph (e)(1) of this section, importers may import diesel fuel that does not comply with the standards set forth in this subpart if all the following conditions are met:

(i) The importer offloads the imported diesel fuel into one or more tanks that are physically located at the same import facility at which the imported diesel fuel first arrives in the United States or at a facility to which the imported diesel fuel is directly transported from the import facility at which the imported diesel fuel first arrived in the United States.

(ii) The importer uses the imported diesel fuel to produce one or more new batches of diesel fuel.

(iii) The importer certifies the new batch of diesel fuel under § 1090.1100(c) and demonstrates that it complies with the standards in this subpart by measuring fuel parameters in accordance with subpart M of this part before title or custody to any new batch of diesel fuel is transferred.

(f) No person may introduce used motor oil, or used motor oil blended with diesel fuel, into the fuel system of model year 2007 or later diesel motor vehicles or engines or model year 2011 or later nonroad diesel vehicles or engines (not including locomotive or marine diesel engines).

§ 1090.305 ULSD standards.

(a) *Overview.* Except as specified in § 1090.300(a)(1) and (2), diesel fuel must meet the ULSD per-gallon standards of this section.

(b) *Sulfur standard.* Maximum sulfur content of 15 ppm.

(c) *Cetane index or aromatic content.* Diesel fuel must meet one of the following standards:

(1) Minimum cetane index of 40.

(2) Maximum aromatic content 35 volume percent.

§ 1090.310 Diesel fuel additives standards.

This section specifies how the ULSD sulfur standard applies to additives blended into diesel fuel that is subject to the standards in § 1090.305.

(a) Except as specified in paragraph (b) and (c) of this section, diesel fuel additives must have a sulfur concentration less than or equal to 15 ppm on a per-gallon basis.

(b) Diesel fuel additives do not have to comply with paragraph (a) of this section if all the following conditions are met:

(1) The additive is added to or used in diesel fuel in a quantity less than 1.0 volume percent of the resultant additive/diesel fuel mixture.

(2) The PTD complies with the requirements in § 1090.1170(b).

(3) The additive is not commercially available as a retail product for ultimate consumers.

(c) The provisions of this section do not apply to additives used with 500 ppm LM diesel fuel or ECA marine fuel.

§ 1090.315 Heating oil, kerosene, and jet fuel provisions.

Heating oil, kerosene, and jet fuel may not be sold for use in motor vehicles or non-road equipment and are not subject to the ULSD standards in § 1090.305 unless also designated as ULSD under § 1090.1115(a).

§ 1090.320 500 ppm LM diesel fuel standards.

(a) *Overview.* Transmix processors and pipeline operators that produce and distribute 500 ppm LM diesel fuel under § 1090.520 for use only in the eligible locomotives and marine engines must meet the per-gallon standards of this section.

(b) *Sulfur standard.* Maximum sulfur content of 500 ppm.

(c) *Cetane index or aromatic content.* The standard for cetane index or aromatic content in § 1090.305(c) applies to 500 ppm LM diesel fuel.

§ 1090.325 ECA marine fuel standards.

(a) *Overview.* Expect as specified in paragraph (c) of this section, ECA marine fuel must meet the per-gallon standards and provisions of this section.

(b) *Standards.* ECA marine fuel is subject to the following per-gallon standards.

(1) *Sulfur per-gallon standard.* Maximum sulfur content of 1,000 ppm.

(2) [Reserved]

(c) *Exceptions.* The standards in paragraph (b) of this section do not apply to the following:

(1) Residual fuel made available for use in a steamship or C3 marine vessel if the U.S. government allows the vessel to be exempt or excluded from MARPOL Annex VI fuel standards. Diesel fuel and other distillate fuel used in diesel engines operated on such vessels is subject to the standards in this section instead of the standards in § 1090.305 or § 1090.320.

(2) Distillate global marine fuel that is exempt under § 1090.650.

Subpart E—Reserved

Subpart F—Transmix and Pipeline Interface Provisions

§ 1090.500 Scope.

(a) This subpart contains provisions for transmix blenders, transmix processors, and distributors that produce and distribute the specified fuels from transmix.

(b) Any person other than a transmix blender that uses the provisions of this subpart must be registered with EPA under subpart I of this part.

§ 1090.505 Gasoline produced from blending transmix into PCG.

(a) Except as specified in paragraph (f) of this section, transmix blenders who blend transmix into PCG under § 1090.150 must comply with the requirements of this section.

(b)(1) The resultant transmix-blended gasoline must not exceed a distillation end-point of 437 degrees Fahrenheit.

(2) The resultant transmix-blended gasoline must meet the downstream sulfur per-gallon standard in § 1090.205(c) and the applicable RVP standard in § 1090.215.

(3) The transmix blender must comply with the recordkeeping requirements in § 1090.1255.

(4) The transmix blender must maintain and follow a written quality assurance program designed to assure that the type and amount of transmix blended into PCG will not cause violations of the applicable fuel quality standards.

(c) Except as specified in paragraph (d) of this section, as a part of the quality assurance program, transmix blenders must collect samples of gasoline after blending transmix and test the samples to ensure the end-point temperature of the final transmix-blended gasoline does not exceed 437 degrees Fahrenheit, using one of the following sampling methods:

(1) For transmix that is blended in a tank (including a tank on a barge), collect a representative sample of the final transmix-blended gasoline following each occasion transmix is blended.

(2) For transmix that is blended by a computer controlled in-line blending

system, the transmix blender must collect composite samples of the final transmix-blended gasoline at least twice each calendar month during which transmix is blended. In-line samples may be collected to comply with the requirements of this paragraph if the applicable requirements in paragraph (d)(2) of this section are met.

(d) Any transmix blender may petition EPA for approval of a quality assurance program that does not include the minimum sampling and testing requirements in paragraph (c) of this section. To seek approval for such an alternative quality assurance program, the transmix blender must submit a petition to EPA that includes all the following:

(1) A detailed description of the quality assurance procedures to be carried out at each location where transmix is blended into PCG, including a description of how the transmix blender proposes to determine the ratio of transmix that can be blended with PCG without violating any of the applicable standards in this part, and a description of how the transmix blender proposes to determine that the gasoline produced by the transmix blending operation meets the applicable standards.

(2) If the transmix is blended by a computer controlled in-line blending system, the transmix blender must also include the information required for refiners related to the approval by EPA of the use of an in-line blending system under § 1090.1315.

(3) A letter signed by the RCO or their delegate stating that the information contained in the submission is true to the best of their belief must accompany the petition.

(4) Transmix blenders that petition EPA to use an alternative quality assurance program must comply with any request by EPA for additional information or any other requirements that EPA includes as part of EPA's evaluation of the petition. However, the transmix blender may withdraw their petition or approved use of an alternative quality assurance program at any time, upon notice to EPA.

(5) EPA reserves the right to modify the requirements of an approved alternative quality assurance program, in whole or in part, at any time, or withdraw approval of such an alternative quality assurance program if EPA determines that the transmix blender's operation does not effectively or adequately control, monitor, or document the end-point temperature of the gasoline produced, or if EPA determines that any other circumstance exists that merits modification of the requirements of an approved alternative quality assurance program.

(e) In the event that the test results for any sample collected under a quality assurance program indicate that the gasoline does not comply with any of the applicable standards in this part, the transmix blender must do all the following:

(1) Immediately take steps to stop the sale of the gasoline that was sampled.

(2) Take reasonable steps to determine the cause of the noncompliance and prevent future instances of noncompliance.

(3) Notify EPA of the noncompliance.

(4) If the transmix was blended by a computer controlled in-line blending system, increase the rate of sampling and testing to a minimum frequency of once per week and a maximum frequency of once per day and continue the increased frequency of sampling and testing until the results of 10 consecutive samples and tests indicate that the gasoline complies with applicable standards, at which time the sampling and testing may be conducted at the original frequency.

(f) Small volumes of fuel that are captured in pipeline sumps or trapped in pipeline pumps or valve manifolds and that are injected back into batches of gasoline or diesel fuel are exempt from the transmix blending requirements in this section.

§ 1090.510 Gasoline produced from TGP.

(a) *General provisions.* (1) Transmix processors who produce gasoline from TGP under § 1090.145 must meet the requirements of this section.

(2) Transmix processors may not use any feedstock other than transmix to produce TGP or TDP.

(3) Transmix processors may produce gasoline using only TGP, a combination of TGP and PCG, a combination of TGP and blendstock(s), or a combination TGP, PCG, and blendstock(s) under the provisions of this section.

(b) *Demonstration of compliance with sulfur per-gallon standard.* Transmix processors must demonstrate that each batch of gasoline they produce meets one of the following sulfur standards, as applicable, by measuring the sulfur content of each batch of gasoline in accordance with subpart M of this part:

(1) Each batch of gasoline produced solely from TGP or a combination of TGP and PCG must comply with the downstream sulfur per-gallon standard in § 1090.205(c).

(2) Each batch of gasoline produced from a combination of TGP and any blendstock must comply with the fuel manufacturing facility gate sulfur per-gallon standard in § 1090.205(b).

(c) *Demonstration of compliance with sulfur and benzene average standards.* (1) Transmix processors must exclude TGP and PCG used to produce gasoline under the provisions of this section and PCG blended with TGP from their compliance calculations to demonstrate compliance with the sulfur and benzene average standards in §§ 1090.205(a) and 1090.210, respectively. Transmix processors that produce gasoline from only TGP or TGP and PCG are deemed to be in compliance with the sulfur and benzene average standards in §§ 1090.205(a) and 1090.210, respectively.

(2) Transmix processors must include any blendstocks other than TGP and exclude any TGP and PCG used to produce gasoline under the provisions of this section in calculations to demonstrate compliance with the sulfur and benzene average standards in §§ 1090.205(a) and 1090.210, respectively.

(3) Transmix processors must comply with the provisions in § 1090.1325 for gasoline produced by adding blendstock to TGP.

(d) *Demonstration of compliance with RVP standard.* Transmix processors must demonstrate that each batch of gasoline they produce meets the applicable RVP standard in § 1090.215 by measuring the RVP of each batch in accordance with subpart M of this part.

(e) *Distillation point determination.* Transmix processors must determine the following distillation parameters for each batch of gasoline they produce in accordance with subpart M of this part:

(1) T10.

(2) T50.

(3) T90.

(4) End-point.

(5) Distillation residue.

§ 1090.515 ULSD produced from TDP.

Except as specified in § 1090.520, transmix processors must demonstrate that each batch of diesel fuel produced from TDP meets the ULSD standards in § 1090.305 by measuring the sulfur content of each batch of diesel fuel in accordance with subpart M of this part.

§ 1090.520 500 ppm LM diesel fuel produced from TDP.

(a) *Overview.* Transmix processors who produce 500 ppm LM diesel fuel from TDP must comply with the requirements of this section and the standards for 500 ppm LM diesel fuel specified in § 1090.320.

(b) *Blending component limitation.* Transmix processors may only use the following components to produce 500 ppm LM diesel fuel:

(1) TDP.

(2) ULSD.

(3) Diesel fuel additives that comply with the requirements in § 1090.310.

(c) *Volume requirements.* Parties that handle 500 ppm LM diesel fuel must calculate the volume of 500 ppm LM diesel fuel received versus the volume delivered and used on a compliance period basis. An increase in the volume of 500 ppm LM diesel fuel delivered compared to the volume received must be due solely to one or more of the following:

(1) Normal pipeline interface cutting practices under paragraph (e)(1) of this section.

(2) Thermal expansion due to a temperature difference between the times when the volume of 500 ppm LM diesel fuel received and the volume of 500 ppm LM diesel fuel delivered were measured.

(3) The addition of ULSD to a retail outlet or WPC 500 ppm LM diesel fuel storage tank under paragraph (e)(2) of this section.

(d) *Use restrictions.* 500 ppm LM diesel fuel may only be used in locomotive and marine engines that are not required to use ULSD under 40 CFR 1033.815 and 40 CFR 1042.660, respectively. No person may use 500 ppm LM diesel fuel in locomotive or marine engines that are required to use ULSD, in any nonroad vehicle or engine, or in any motor vehicle engine.

(e) *Segregation requirement.* Transmix processors and distributors must segregate 500 ppm LM diesel fuel from other fuels except as follows:

(1) Pipeline operators may ship 500 ppm LM diesel fuel by pipeline provided that the 500 ppm LM diesel fuel does not come into physical contact in the pipeline with distillate fuels that have a sulfur content greater than 15 ppm. If 500 ppm LM diesel fuel is shipped by pipeline adjacent to ULSD, the pipeline operator must cut ULSD into the 500 ppm LM diesel fuel.

(2) WPCs and retailers of 500 ppm LM diesel fuel may introduce ULSD into a storage tank that contains 500 ppm LM diesel fuel, provided that the other requirements of this section are satisfied. The resulting mixture must be designated as 500 ppm LM diesel fuel.

(f) *Party limit.* No more than 4 separate parties may handle the 500 ppm LM diesel fuel between the producer and the ultimate consumer.

(g) *Compliance plan.* For each facility, a transmix processor that produces 500 ppm LM diesel fuel must obtain approval from EPA for a compliance plan at least 60 days prior to producing 500 ppm LM diesel fuel. The compliance plan must detail how the transmix processor intends to meet all the following requirements:

(1) Demonstrate how the 500 ppm LM diesel fuel will be segregated by the producer through to the ultimate consumer from fuel having other designations under paragraph (e) of this section.

(2) Demonstrate that the end users of 500 ppm LM diesel fuel will also have access to ULSD for use in those engines that require ULSD.

(3) Identify the parties that handle the 500 ppm LM diesel fuel through to the ultimate consumer.

(4) Identify all ultimate consumers that are supplied with the 500 ppm LM diesel fuel.

(5) Demonstrate how misfueling of 500 ppm LM diesel fuel into vehicles, engines, or equipment that require the use of ULSD will be prevented.

(6) Include an EPA registration number.

§ 1090.525 Handling practices for pipeline interface that is not transmix.

(a) Subject to the limitations in paragraph (b) of this section, pipeline operators may cut pipeline interface from two batches of gasoline subject to EPA standards that are shipped adjacent to each other by pipeline into either or both these batches of gasoline provided that this action does not cause or contribute to a violation of the standards in this part.

(b) During the summer season, pipeline operators may not cut pipeline interface from two batches of gasoline subject to different RVP standards that are shipped adjacent to each other by pipeline into the gasoline batch that is subject to the more stringent RVP standard. For example, during the summer season, pipeline operators may not cut pipeline interface from a batch of RFG shipped adjacent to a batch of conventional gasoline into the batch of RFG.

(c) 500 ppm LM diesel fuel may be shipped via pipeline as specified in § 1090.520(e)(1).

Subpart G—Exemptions, Hardships, and Special Provisions

§ 1090.600 General provisions.

(a) Gasoline, diesel fuel, or IMO marine fuel that is exempt under this section is exempt from all other provisions of this part, unless otherwise stated.

(b) Fuel not meeting all the requirements and conditions specified in this subpart for an exemption is subject to all applicable standards and requirements of this part.

§ 1090.605 National security and military use exemptions.

(a) Fuel, fuel additive, and regulated blendstock that is produced, imported, sold, offered for sale, supplied, offered for supply, stored, dispensed, or transported for use in the following tactical military vehicles, engines, or equipment, including locomotive and marine engines, are exempt from the standards specified in this part:

(1) Tactical military vehicles, engines, or equipment, including locomotive and marine engines, that have an EPA national security exemption from the motor vehicle emission standards under 40 CFR parts 85 or 86, or from the nonroad engine emission standards under 40 CFR parts 89, 92, 94, 1042, or 1068.

(2) Tactical military vehicles, engines, or equipment, including locomotive and marine engines, that are not subject to a national security exemption from vehicle or engine emissions standards specified in paragraph (a)(1) of this section but, for national security purposes (*e.g.,* for purposes of readiness, including training, for deployment overseas), need to be fueled on the same fuel as the vehicles, engines, or equipment that EPA has granted such a national security exemption.

(b) The exempt fuel must meet all the following requirements:

(1) It must be accompanied by PTDs meeting the requirements of subpart K of this part.

(2) It must be segregated from non-exempt fuel at all points in the distribution system.

(3) It must be dispensed from a fuel pump stand, fueling truck, or tank that is labeled with the appropriate designation of the fuel.

(4) It may not be used in any vehicles, engines, or equipment, including locomotive and marine engines, other than those specified in paragraph (a) of this section.

§ 1090.610 Temporary research, development, and testing exemptions.

(a) *Requests for an exemption.* (1) Any person may receive an exemption from the provisions of this part for fuel used for research, development, or testing (''R&D'') purposes by submitting the information specified in paragraph (c) of this section as specified in § 1090.10.

(2) Any person that is performing emissions certification testing for a motor vehicle or motor vehicle engine under 42 U.S.C. 7525 or nonroad engine or nonroad vehicle under 42 U.S.C. 7546 is exempt from the provisions of this part for the fuel they are using for emissions certification testing if they

have an exemption under 40 CFR parts 85 and 86 to perform such testing.

(b) *Criteria for an R&D exemption.* For an R&D exemption to be granted, the person requesting an exemption must meet all the following conditions:

(1) Demonstrate a purpose that constitutes an appropriate basis for exemption.

(2) Demonstrate that an exemption is necessary.

(3) Design an R&D program that is reasonable in scope.

(4) Have a degree of control consistent with the purpose of the program and EPA's monitoring requirements.

(c) *Information required to be submitted.* To aid in demonstrating each of the elements in paragraph (b) of this section, the person requesting an exemption must include, at a minimum, all the following information:

(1) A concise statement of the purpose of the program demonstrating that the program has an appropriate R&D purpose.

(2) An explanation of why the stated purpose of the program is unable to be achieved in a practicable manner without meeting the requirements of this part.

(3) A demonstration of the reasonableness of the scope of the program, including all the following:

(i) An estimate of the program's duration in time (including beginning and ending dates).

(ii) An estimate of the maximum number of vehicles, engines, and equipment involved in the program, and the number of miles and engine hours that will be accumulated on each.

(iii) The manner in which the information on vehicles, engines, or equipment used in the program will be recorded and made available to EPA upon request.

(iv) The quantity of the fuel that does not comply with the requirements of this part, as applicable.

(v) The specific applicable standard(s) of this part that would apply to the fuel expected to be used in the program.

(4) With regard to control, a demonstration that the program affords EPA a monitoring capability, including all the following:

(i) A description of the technical and operational aspects of the program.

(ii) The site(s) of the program (including facility name, street address, city, county, state, and ZIP code).

(iii) The manner in which information on vehicles, engines, and equipment used in the program will be recorded and made available to EPA upon request.

(iv) The manner in which information on the fuel used in the program (including quantity, fuel properties, name, address, telephone number, and contact person of the supplier, and the date received from the supplier) will be recorded and made available to EPA upon request.

(v) The manner in which the party will ensure that the fuel will be segregated from fuel meeting the requirements of subparts C and D of this part, as applicable, and how fuel pumps will be labeled to ensure proper use of the fuel.

(vi) The name, business address, telephone number, and title of the person(s) in the organization requesting an exemption from whom further information on the application may be obtained.

(vii) The name, business address, telephone number, and title of the person(s) in the organization requesting an exemption who is responsible for recording and making available the information specified in this paragraph, and the location where such information will be maintained.

(viii) Any other information requested by EPA to determine whether the test program satisfies the criteria of paragraph (b) of this section.

(d) *Additional requirements.* (1) The PTDs associated with fuel must comply with subpart K of this part.

(2) The fuel must be designated by the fuel manufacturer or supplier, as applicable, as exempt fuel.

(3) The fuel must be kept segregated from non-exempt fuel at all points in the distribution system.

(4) The fuel must not be sold, distributed, offered for sale or distribution, dispensed, supplied, offered for supply, transported to or from, or stored by a fuel retail outlet, or by a WPC facility, unless the WPC facility is associated with the R&D program that uses the fuel.

(5) At the completion of the program, any emission control systems or elements of design that are damaged or rendered inoperative must be replaced on vehicles remaining in service, or the responsible person will be liable for a violation of 42 U.S.C. 7522(a)(3) unless sufficient evidence is supplied that the emission controls or elements of design were not damaged.

(e) *Approval of exemption.* EPA may grant an R&D exemption upon a demonstration that the requirements of this section have been met. The R&D exemption may include such terms and conditions as EPA determines necessary to monitor the exemption and to carry out the purposes of this part, including restoration of emission control systems.

(1) The volume of fuel subject to the approval must not exceed the estimated amount in paragraph (c)(3)(iv) of this section, unless EPA grants a greater amount.

(2) Any exemption granted under this section will expire at the completion of the test program or 1 year from the date of approval, whichever occurs first, and may only be extended upon re-application consistent will all requirements of this section.

(3) In granting an exemption, EPA may include terms and conditions, including replacement of emission control devices or elements of design, which EPA determines are necessary for monitoring the exemption and for assuring that the purposes of this part are met.

(4) If any information required by paragraph (c) of this section changes after approval of the exemption, the responsible person must notify EPA in writing immediately. Failure to do so may result in disapproval of the exemption or may make it void *ab initio* and may make the party liable for a violation of this part.

(f) *Notification of completion.* Any person with an approved exemption under this section must notify EPA in writing within 30 days after completion of the R&D program.

§ 1090.615 Racing and aviation exemptions.

(a) Fuel, fuel additive, and regulated blendstock that is used in aircraft, or racing vehicles or racing boats in sanctioned racing events, is exempt from the standards in subparts C and D of this part if all the requirements of this section are met.

(b) The fuel, fuel additive, or regulated blendstock is identified on PTDs and any fuel dispenser from which such fuel, fuel additive, or regulated blendstock is dispensed, as restricted for use either in aircraft, or in racing motor vehicles or racing boats that are used only in sanctioned racing events.

(c) The fuel, fuel additive, or regulated blendstock is completely segregated from all other non-exempt fuel, fuel additive, or regulated blendstock throughout production, distribution, and sale to the ultimate consumer.

(d) The fuel, fuel additive, or regulated blendstock is not made available for use as gasoline or diesel fuel subject to the standards in subparts C and D of this part, as applicable, or dispensed for use in motor vehicles or nonroad engines, vehicles, or equipment, including locomotive and marine engines, except for those used only in sanctioned racing events.

(e) Any party that transports fuel exempt under this section must take reasonable precautions to avoid the contamination of nonexempt fuel. For example, parties should prepare tanker trucks under API recommended practice 1595 or the Energy Institute & Joint Inspection Group standard 1530 to avoid contamination of nonexempt fuel when the same tanker truck is used to transport exempt and nonexempt fuels.

§ 1090.620 Exemptions for Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Fuel that is produced, imported, sold, offered for sale, supplied, offered for supply, stored, dispensed, or transported for use in the territories of Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands, is exempt from the standards in subparts C and D of this part if all the following requirements are met:

(a) The fuel is designated by the fuel manufacturer as gasoline, diesel fuel, or IMO marine fuel for use only in Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands.

(b) The fuel is used only in Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands.

(c) The fuel is accompanied by PTDs meeting the requirements of subpart K of this part.

(d) The fuel is completely segregated from non-exempt gasoline, diesel fuel, and IMO marine fuel at all points throughout production, distribution, and sale to the ultimate consumer from the point the fuel is designated as exempt fuel for use only in Guam, American Samoa, or the Commonwealth of the Northern Mariana Islands, while the exempt fuel is in the United States (including an ECA or an ECA associated area under 40 CFR 1043.20) but outside these territories.

§ 1090.625 Exemptions for California gasoline and diesel fuel.

(a) *California gasoline and diesel fuel exemption.* California gasoline or diesel fuel that complies with all the requirements of this section is exempt from all other provisions of this part.

(b) *California gasoline and diesel fuel requirements.* (1) Each batch of California gasoline or diesel fuel must be designated as such by its fuel manufacturer.

(2) Designated California gasoline or diesel fuel must be kept segregated from fuel that is not California gasoline or diesel fuel at all points in the distribution system.

(3) Designated California gasoline or diesel fuel must ultimately be used only in the state of California.

(4) Transferors and transferees of California gasoline or diesel fuel produced outside the state of California must meet the PTD requirements of subpart K of this part.

(5) Each transferor and transferee of California gasoline or diesel fuel produced outside the state of California must maintain copies of the PTDs as specified in subpart L of this part.

(6) California gasoline or diesel fuel may not be used in any part of the United States outside of the state of California unless the manufacturer or distributor recertifies or redesignates the batch of California gasoline or diesel fuel as specified in paragraph (d) or (e) of this section.

(c) *Use of California test methods and offsite sampling procedures.* For any gasoline or diesel fuel that is not California gasoline or diesel fuel and that is either produced at a facility located in the state of California or is imported from outside the United States into the state of California, the manufacturer may do any of the following:

(1) Use the sampling and testing methods approved in Title 13 of the California Code of Regulations instead of the sampling and testing methods required by subpart M of this part.

(2) Determine the sulfur content, benzene content, and RVP (during the summer) of gasoline at offsite tankage (which would otherwise be prohibited under § 1090.1615(c)) if the following requirements are met:

(i) The samples are properly collected under the terms of a current and valid protocol agreement between the manufacturer and the California Air Resources Board with regard to sampling at the offsite tankage and consistent with the requirements specified in Title 13, California Code of Regulations, section 2250 *et seq.* (May 1, 2003).

(ii) The manufacturer provides a copy of the protocol agreement to EPA upon request.

(d) *California gasoline used outside of California.* California gasoline may either be recertified as gasoline under this part or may be used in any part of the United States outside of the state of California if the fuel designated as California gasoline meets all applicable requirements for California reformulated gasoline under Title 13 of the California Code of Regulations and the manufacturer or distributor of such fuel does all the following:

(1) The manufacturer or distributor properly redesignates the fuel under § 1090.1110(b)(2)(v).

(2) The manufacturer or distributor generates PTDs under subpart K of this part.

(3) The manufacturer or distributor keeps records under subpart L of this part.

(4) The manufacturer or distributor does not include the California gasoline in their average standard compliance calculations.

(e) *California diesel used outside California.* California diesel fuel may be used in any part of the United States outside of the state of California and is deemed to meet the standards in subpart D of this part without recertification if the fuel designated as California diesel fuel meets all applicable requirements for diesel fuel under Title 13 of the California Code of Regulations and the manufacturer or distributor of such fuel does all the following:

(1) The manufacturer or distributor properly redesignates the fuel under § 1090.1115(b)(3)(iii).

(2) The manufacturer or distributor generates PTDs under subpart K of this part.

(3) The manufacturer or distributor keeps records under subpart L of this part.

§ 1090.630 Exemptions for Alaska, Hawaii, Puerto Rico, and the U.S. Virgin Islands summer gasoline.

Summer gasoline that is produced, imported, sold, offered for sale, supplied, offered for supply, stored, dispensed, or transported for use in the Alaska, Hawaii, Puerto Rico, or the U.S. Virgin Islands, is exempt from the RVP standards in § 1090.215 if all the following requirements are met:

(a) The summer gasoline is designated by the fuel manufacturer as summer gasoline for use only in Alaska, Hawaii, Puerto Rico, or the U.S. Virgin Islands.

(b) The summer gasoline is used only in Alaska, Hawaii, Puerto Rico, or the U.S. Virgin Islands.

(c) The summer gasoline is accompanied by PTDs meeting the requirements of subpart K of this part.

(d) The summer gasoline is completely segregated from non-exempt gasoline at all points throughout production, distribution, and sale to the ultimate consumer from the point the summer gasoline is designated as exempt fuel for use only in Alaska, Hawaii, Puerto Rico, or the U.S. Virgin Islands, while the exempt summer gasoline is in the United States but outside these states or territories.

§ 1090.635 Refinery extreme unforeseen hardship exemption.

(a) In appropriate extreme, unusual, and unforeseen circumstances (*e.g.,*

circumstances like a natural disaster or refinery fire; not financial or supplier difficulties) that are clearly outside the control of the refiner and that could not have been avoided by the exercise of prudence, diligence, and due care, EPA may permit a refiner, for a brief period, to distribute fuel that is exempt from the standards in subparts C and D of this part if all the following requirements are met:

(1) It is in the public interest to do so (*e.g.,* distribution of the nonconforming fuel will not damage vehicles or engines and is necessary to meet projected shortfalls that are unable to otherwise be compensated for).

(2) The refiner exercised prudent planning and was not able to avoid the violation and has taken all reasonable steps to minimize the extent of the nonconformity.

(3) The refiner can show how the requirements for making compliant fuel, and/or purchasing credits to partially or completely offset the nonconformity, will be expeditiously achieved.

(4) The refiner agrees to make up any air quality detriment associated with the nonconforming fuel, where practicable.

(5) The refiner pays to the U.S. Treasury an amount equal to the economic benefit of the nonconformity minus the amount expended under paragraph (a)(4) of this section, in making up the air quality detriment.

(b) Hardship applications under this section must be submitted to EPA as specified in § 1090.10 and must contain a letter signed by the RCO, or their delegate, stating that the information contained in the application is true to the best of their knowledge.

§ 1090.640 Exemptions from the gasoline deposit control requirements.

(a) Gasoline that is used to produce E85 is exempt from the gasoline deposit control requirements in § 1090.240.

(b) Any person that uses the exemption in paragraph (a) of this section must keep records to demonstrate that such exempt gasoline was used to produce E85 and was not distributed from a terminal for use as gasoline.

§ 1090.645 Exemption for exports of fuels, fuel additives, and regulated blendstocks.

Fuel, fuel additive, and regulated blendstock that is exported for sale outside of the United States is exempt from the standards in subparts C and D of this part if all the following requirements are met:

(a) The fuel manufacturer, fuel additive manufacturer, or regulated blendstock producer designated the fuel, fuel additive, or regulated blendstock for export as specified in § 1090.1650(a).

(b) The fuel, fuel additive, or regulated blendstock designated for export is accompanied by PTDs meeting the requirements of subpart K of this part.

(c) The fuel, fuel additive, or regulated blendstock is ultimately exported from the United States.

(d) The fuel, fuel additive, or regulated blendstock must be completely segregated from non-exempt fuels, fuel additives, and regulated blendstocks at all points throughout the production and distribution system, from the point the fuel, fuel additive, or regulated blendstock is produced or imported to the point where the fuel, fuel additive, or regulated blendstock is ultimately exported from the United States.

(e) Any fuel dispensed from a retail outlet within the geographic boundaries of the United States is not exempt under this section.

§ 1090.650 Distillate global marine fuel exemption.

(a) The standards of subpart D of this part do not apply to distillate global marine fuel that is produced, imported, sold, offered for sale, supplied, offered for supply, stored, dispensed, or transported for use in steamships or Category 3 marine vessels when operating outside of ECA boundaries.

(b) The exempt fuel must meet all the following:

(1) It must not exceed 0.50 weight percent sulfur (5,000 ppm).

(2) It must be accompanied by PTDs as specified in § 1090.1165.

(3) It must be designated as specified in § 1090.1115.

(4) It must be segregated from non-exempt fuel at all points in the distribution system.

(5) It must not be used in vehicles, engines, or equipment other than those referred to in paragraph (a) of this section.

(c)(1) Fuel not meeting the requirements specified in paragraph (b) of this section is subject to the standards, requirements, and prohibitions that apply for ULSD under this part.

(2) Any person who produces, imports, sells, offers for sale, supplies, offers for supply, stores, dispenses, or transports distillate global marine fuel without meeting the applicable recordkeeping requirements in subpart L of this part may not claim the fuel is exempt from the standards, requirements, and prohibitions that apply for ULSD under this part.

Subpart H—Averaging, Banking, and Trading Provisions

§ 1090.700 Compliance with average standards.

(a) *Compliance with the sulfur average standard.* For each of their facilities, gasoline manufacturers must demonstrate compliance with the sulfur average standard in § 1090.205(a) by using the equations in paragraphs (a)(1) and (2) of this section.

(1) *Compliance sulfur value calculation.* (i) The compliance sulfur value is determined as follows:

$$CSV_y = S_{tot,y} + D_{S,(y-1)} + D_{S_Oxy_Total} - C_S$$

Where:

CSV_y = Compliance sulfur value for compliance period y, in ppm-gallons.

$S_{tot,y}$ = The total amount of sulfur produced in compliance period y, per paragraph (a)(1)(ii) of this section, in ppm-gallons.

$Ds_{,(y-1)}$ = Sulfur deficit from the previous compliance period, per § 1090.715(a)(1), in ppm-gallons.

$D_{S_Oxy_Total}$ = The total sulfur deficit from BOB recertification, per § 1090.740(b)(3), in ppm-gallons.

C_S = Sulfur credits used by the gasoline manufacturer, per § 1090.720, in ppm-gallons.

(ii) The total amount of sulfur produced is determined as follows:

$$S_{tot,y} = \sum_{i=1}^{n} (V_i \cdot S_i)$$

Where:

V_i = The volume of gasoline produced or imported in batch i, in gallons.

S_i = The sulfur content of batch i, in ppm.

n = The number of batches of gasoline produced or imported during the compliance period.

i = Individual batch of gasoline produced or imported during the compliance period.

If the calculation of $S_{tot,y}$ results in a negative number, replace it with zero.

(2) *Sulfur compliance calculation.* (i) Compliance with the sulfur average standard in § 1090.205(a) is achieved if the following equation is true:

$$CSV_y \leq \left(\sum_{i=1}^{n} V_i \cdot 10\right)$$

(ii) Compliance with the sulfur average standard in § 1090.205(a) is not achieved if a deficit is incurred two or more consecutive years. A gasoline manufacturer incurs a deficit under § 1090.715 if the following equation is true:

$$CSV_y > \left(\sum_{i=1}^{n} V_i \cdot 10\right)$$

(b) *Compliance with the benzene average standards.* For each of their facilities, gasoline manufacturers must

demonstrate compliance with the benzene average standard in § 1090.210(a) by using the equations in paragraphs (b)(1) and (2) of this section and with the maximum benzene average standard in § 1090.210(b) by using the equations in paragraphs (b)(3) and (4) of this section.

(1) *Compliance benzene value calculation.* (i) The compliance benzene value is determined as follows:

$$CBV_y = B_{tot,y} + D_{Bz,(y-1)} + \sum_{i=1}^{m} D_{Bz_Oxy_Total} - C_{Bz}$$

Where:

CBV_y = Compliance benzene value for year y, in benzene gallons.

$B_{tot,y}$ = The total amount of benzene produced in compliance period y, per paragraph (b)(1)(ii) of this section, in benzene gallons.

$D_{Bz,(y-1)}$ = Benzene deficit from the previous compliance period, per § 1090.715(a)(2), in benzene gallons.

$D_{Bz_Oxy_Total}$ = Benzene deficit from BOB recertification, per § 1090.740(b)(4), in benzene gallons.

C_{Bz} = Benzene credits used by the gasoline manufacturer, per § 1090.720, in benzene gallons.

(ii) The total amount of benzene produced is determined as follows:

$$B_{tot,y} = \sum_{i=1}^{n} \left(\frac{V_i \cdot B_i}{100}\right)$$

V_i = The volume of gasoline produced or imported in batch i, in gallons.

B_i = The benzene content of batch i, in volume percent.

m = The number of batches of BOB gasoline recertified during the compliance period.

n = The number of batches of gasoline produced or imported during the compliance period.

i = Individual batch of gasoline produced or imported during the compliance period.

If the calculation of $B_{tot,y}$ results in a negative number, replace it with zero.

(2) *Benzene average compliance calculation.* (i) Compliance with the benzene average standard in § 1090.210(a) is achieved if the following equation is true:

$$CBV_y \leq \sum_{i=1}^{n} V_i \cdot 0.0062$$

(ii) Compliance with the benzene average standard in § 1090.210(a) is not achieved if a deficit is incurred two or more consecutive years. A gasoline manufacturer incurs a deficit under § 1090.715 if the following equation is true:

$$CBV_y > \sum_{i=1}^{n} V_i \cdot 0.0062$$

(3) *Average benzene concentration calculation.* The average benzene concentration is determined as follows:

$$B_{a,y} = \frac{\sum_{i=1}^{n}(V_i \cdot B_i)}{\sum_{i=1}^{n} V_i}$$

Where:

$B_{a,y}$ = Average benzene concentration for compliance period y, in volume percent benzene.

(4) *Maximum benzene average compliance calculation.* Compliance with the maximum benzene average standard in § 1090.210(b) is achieved for calendar year y if the following equation is true:

$B_{a,y} \leq 1.30$ vol%

(5) The average benzene concentration calculated in paragraph (b)(3) of this section must be rounded and reported to two decimal places in accordance with § 1090.50.

(c) *Accounting for oxygenate added at a downstream location.* A gasoline manufacturer that complies with the requirements in § 1090.710 may include the volume of oxygenate added at a downstream location and the effects of such blending on sulfur and benzene content in compliance calculations under this subpart.

(d) *Inclusions.* Gasoline manufacturers must include the following products that they produced or imported during the compliance period in their compliance calculations:

(1) CG.

(2) RFG.

(3) BOB.

(4) Added gasoline volume resulting from the production of gasoline from PCG as follows:

(i) For PCG by subtraction as specified in § 1090.1320(a)(1), include the PCG batch as a batch with a negative volume and positive sulfur and benzene content and include the new batch of gasoline as a batch with a positive volume and positive sulfur and benzene content in compliance calculations under this section. Any negative compliance sulfur or benzene value must be reported as zero and not as a negative result.

(ii) For PCG by addition as specified in § 1090.1320(a)(2), include only the blendstock added to make the new batch of gasoline as a batch with a positive volume and positive sulfur and benzene content of in compliance calculations under this section. Do not include any test results or volumes for the PCG or new batch of gasoline in these calculations.

(5) Inclusion of a particular batch of gasoline for compliance calculations for a compliance period is based on the date the batch is produced, not shipped. For example, a batch produced on December 30, 2021, but shipped on January 2, 2022, would be included in the compliance calculations for the 2021 compliance period. However, the volume included in the 2021 compliance period for that batch would be the entire batch volume, even though the shipment of all or some of the batch did not occur until 2022.

(e) *Exclusions.* Gasoline manufacturers must exclude the following products from their compliance calculations:

(1) Gasoline that was not produced by the gasoline manufacturer.

(2) Regulated blendstock, unless the regulated blendstock is added to PCG or TGP under § 1090.1320 or § 1090.1325, respectively.

(3) PCG, except as specified in paragraph (d)(4)(i) of this section.

(4) Certified butane and certified pentane blended under § 1090.1320.

(5) TGP.

(6) Gasoline exempted under subpart G of this part from the average standards of subpart C of this part (*e.g.,* California gasoline, racing fuel, etc.).

§ 1090.705 Facility level compliance.

(a) Except as specified in paragraph (b) of this section, gasoline manufacturers must comply with average standards at the individual facility level.

(b) Gasoline importers must comply with average standards at the company level, except that they must aggregate all import facilities within a PADD as a single facility to comply with the maximum benzene average standard in § 1090.210(b) as specified in § 1090.1600(b).

§ 1090.710 Downstream oxygenate accounting.

The requirements of this section apply to BOB for which a gasoline manufacturer is accounting for the effects of the oxygenate blending that occurs downstream of the fuel manufacturing facility in the gasoline manufacturer's average standard compliance calculations of this subpart. This section includes requirements on distributors to ensure that oxygenate is

added in accordance with the blending instructions specified by the gasoline manufacturer in order to ensure fuel quality standards are met.

(a) *Provisions for gasoline manufacturers.* In order to account for the effects of oxygenate blending downstream, a gasoline manufacturer must meet all the following requirements:

(1) Produce or import BOB such that the gasoline continues to meet the applicable gasoline standards in subpart C of this part after the addition of the specified type and amount of oxygenate.

(2) Conduct tests on each batch of BOB produced or imported that represents the gasoline after each specified type and amount of oxygenate is added to the batch of BOB by creating a hand blend in accordance with § 1090.1340 and determining the properties of the hand blend using the methods specified in subpart M of this part. When creating the hand blend, gasoline manufacturers must not add any more oxygenate to the BOB than the amount of oxygenate specified on the PTD for the BOB under paragraph (a)(5) of this section.

(3) Participate in the national sampling oversight program specified in § 1090.1440 or have an approved in-line blending waiver under § 1090.1315.

(4) Transfer ownership of the BOB only to an oxygenate blender that is registered with EPA under subpart I of this part or to an intermediate owner with the restriction that it only be transferred to a registered oxygenate blender.

(5) Specify each oxygenate type and amount (or range of amounts) that the gasoline manufacturer certified for compliance of the hand blend on the PTD for the BOB, as specified in § 1090.1160(b)(1).

(6) Participate in the national fuels survey program under subpart N of this part.

(b) *Requirements for oxygenate blenders.* Oxygenate blenders must add oxygenate of each type and amount (or within the range of amounts) as specified on the PTD for all BOB received, except as specified in paragraph (c)(2) of this section.

(c) *Limitations.* (1) Only the gasoline manufacturer that first certifies the BOB may account for the downstream addition of oxygenate under this section. On any occasion where any person downstream of the fuel manufacturing facility gate of the gasoline manufacturer that produced or imported gasoline or BOB adds oxygenate to such product, the person may not include the volume and sulfur and benzene content of the oxygenate in any compliance calculations for demonstrating compliance with the average standards specified in subpart C of this part or for credit generation under this subpart. All applicable per-gallon standards specified in subpart C of this part continue to apply.

(2) A person downstream of the fuel manufacturing facility gate may redesignate BOB for use as gasoline without the addition of the specified type and amount of oxygenate if the provisions of § 1090.740 are met. Parties that redesignate BOB for use as gasoline without the addition of the specified type and amount of oxygenate are gasoline manufacturers and must meet all applicable requirements for gasoline manufacturers specified in this part.

§ 1090.715 Deficit carryforward.

(a) A gasoline manufacturer incurs a compliance deficit if they exceed the average standard specified in subpart C of this part for a given compliance period. The deficit incurred must be determined as specified in paragraph (a)(1) of this section for sulfur and paragraph (b)(2) of this section for benzene.

(1) The sulfur deficit incurred is determined as follows:

$$D_{S,y} = CSV_y - \left(\sum_{i=1}^{n} V_i \cdot 10\right)$$

Where:

$D_{S,y}$ = Sulfur deficit incurred for compliance period y, in ppm-gallons.

CSV_y = Compliance sulfur value for compliance period y, per § 1090.700(a)(1), in ppm-gallons.

V_i = The volume of gasoline produced or imported in batch i, in gallons.

n = The number of batches of gasoline produced or imported during the compliance period.

i = Individual batch of gasoline produced or imported during the compliance period.

(2) The benzene deficit incurred is determined as follows:

$$D_{Bz,y} = CBV_y - \left(\sum_{i=1}^{n} V_i \cdot 0.0062\right)$$

Where:

$D_{Bz,y}$ = Benzene deficit incurred for compliance period y, in benzene gallons.

CBV_y = Compliance benzene value for compliance period y, per § 1090.700(b)(1), in ppm-gallons.

V_i = The volume of gasoline produced or imported in batch i, in gallons.

n = The number of batches of gasoline produced or imported during the compliance period.

i = Individual batch of gasoline produced or imported during the compliance period.

(b) Gasoline manufacturers must use all sulfur or benzene credits previously generated or obtained at any of their facilities to achieve compliance with an average standard specified in subpart C of this part before carrying forward a sulfur or benzene deficit at any of their facilities.

(c) Gasoline manufacturers that incur a deficit under this section must satisfy that deficit during the next compliance period regardless of whether the gasoline manufacturer produces gasoline during next compliance period.

§ 1090.720 Credit use.

(a) *General credit use provisions.* Only gasoline manufacturers may generate, use, transfer, or own credits generated under this subpart, as specified in § 1090.725(a)(1). Credits may be used by a gasoline manufacturer to comply with the average standards specified in subpart C of this part. Gasoline manufacturers may also bank credits for future use, transfer credits to another facility within a company (*i.e.,* intracompany trading), or transfer credits to another gasoline manufacturer, if all applicable requirements of this subpart are met.

(b) *Credit life.* Credits are valid for use for 5 years after the compliance period for which they are generated.

(c) *Limitations on credit use.* (1) Credits that have expired may not be used for demonstrating compliance with the average standards specified in subpart C of this part or be used to replace invalid credits under § 1090.735.

(2) A gasoline manufacturer possessing credits must use all credits prior to falling into compliance deficit under § 1090.715.

(3) Credits may not be used to meet per-gallon standards.

(4) Credits may not be used to meet the maximum benzene average standard in § 1090.210(b).

(d) *Credit use limitation.* Credits may only be used if the gasoline manufacturer owns them at the time of use.

(e) *Credit reporting.* Gasoline manufacturers that generate, transact, or use credits under this subpart must report to EPA as specified in § 1090.905 using forms and procedures specified by EPA.

(f) *Part 80 credit use.* Valid credits generated under 40 CFR 80.1615 and 80.1290 may be used by gasoline manufacturers to comply with the average standards in subpart C of this part, subject to the provisions of this subpart.

§ 1090.725 Credit generation.

(a) *Parties that may generate credits.* (1) Only gasoline manufacturers may generate credits for use towards an average standard specified in subpart C of this part. No person other than a gasoline manufacturer may generate credits.

(2) No credits may be generated for gasoline produced by the following activities: Transmix processing, transmix blending, oxygenate blending, certified butane blending, certified pentane blending, or importation of gasoline by rail and truck using the alternative sampling and testing requirements in § 1090.1610.

(3) No sulfur credits may be generated at a facility if that facility used sulfur credits in that same compliance period.

(4) No benzene credits may be generated at a facility if that facility used benzene credits in that same compliance period.

(b) *Credit year.* Credits generated under this section must be identified by the compliance period of generation. For example, credits generated on gasoline produced in 2021 must be identified as 2021 credits.

(c) *Sulfur credit generation.* (1) The number of sulfur credits generated is determined as follows:

$$C_{S,y} = \left(\sum_{i=1}^{n} V_i \cdot 10\right) - CSV_y$$

Where:

$C_{S,y}$ = Sulfur credits generated for compliance period y, in ppm-gallons.

V_i = The volume of gasoline produced or imported in batch i, in gallons.

n = The number of batches of gasoline produced or imported during the compliance period.

i = Individual batch of gasoline produced or imported during the compliance period.

CSV_y = Compliance sulfur value for compliance period y, per § 1090.700(a)(1), in ppm-gallons.

(2) The value of $C_{S,y}$ must be positive to generate credits.

(3) Sulfur credits calculated under paragraph (c)(1) of this section must be expressed to the nearest ppm-gallon. Fractional values must be rounded in accordance with § 1090.50.

(d) *Benzene credit generation.* (1) The number of benzene credits generated is determined as follows:

$$C_{Bz,y} = \left(\sum_{i=1}^{n} V_i \cdot 0.0062\right) - CBV_y$$

Where:

$C_{Bz,y}$ = Benzene credits generated for compliance period y, in benzene gallons.

V_i = The volume of gasoline produced or imported in batch i, in gallons.

n = The number of batches of gasoline produced or imported during the compliance period.

i = Individual batch of gasoline produced or imported during the compliance period.

CBV_y = Compliance benzene value for compliance period y, per § 1090.700(b)(1), in benzene gallons.

(2) The value of $C_{Bz,y}$ must be positive to generate credits.

(3) Benzene credits calculated under paragraph (d)(1) of this section must be expressed to the nearest benzene gallon. Fractional values must be rounded in accordance with § 1090.50.

(e) *Credit generation limitation.* Gasoline manufacturers may only generate credits after they have finished producing or importing gasoline for the compliance period.

(f) *Credit reporting.* Gasoline manufacturers that generate credits under this section must report to EPA all information regarding the generation transaction as specified in § 1090.905 using forms and procedures specified by EPA.

§ 1090.730 Credit transfers.

Gasoline manufacturers may only obtain credits from another gasoline manufacturer to meet an average standard specified in subpart C of this part if all applicable requirements of this section are met.

(a) The credits are generated as specified in § 1090.725 and reported as specified in § 1090.905.

(b) The credits are used for compliance with the limitations regarding the appropriate periods for credit use in § 1090.720.

(c) Any credit transfer must take place no later than the compliance deadline specified in § 1090.900(d) following the compliance period when the credits are obtained.

(d) The credit has not been transferred between EPA registered companies more than twice. The first transfer by the gasoline manufacturer that generated the credit (''transferor'') may only be made to a gasoline manufacturer that intends to use the credit (''transferee''). If the transferee is unable to use the credit, it may make the second, and final, transfer only to a gasoline manufacturer that intends to use the credit. Intracompany credit transfers are unlimited.

(e) The transferor must apply any credits necessary to meet the transferor's applicable average standard before transferring credits to any other gasoline manufacturer.

(f) No person may transfer credits if the transfer would cause them to incur a deficit.

(g) Unless the transferor and transferee are the same party (*i.e.,* intracompany transfers), the transferor must supply to the transferee records as specified in § 1090.1210(g) indicating the years the credits were generated, the identity of the gasoline manufacturer that generated the credits, and the identity of the transferring party.

(h) The transferor and the transferee report to EPA all information regarding the transaction as specified in § 1090.905 using forms and procedures specified by EPA.

§ 1090.735 Invalid credits and remedial actions.

For credits that have been calculated or generated improperly, or are otherwise determined to be invalid, all the following provisions apply:

(a) Invalid credits may not be used to achieve compliance with an average standard, regardless of the good faith belief that the credits were validly generated.

(b) Any validly generated credits existing in the transferring gasoline manufacturer's credit balance after correcting the credit balance, and after the transferor applies credits as needed to meet the average standard at the end of the compliance period, must first be applied to correct the invalid transfers before the transferring gasoline manufacturer trades or banks the credits.

(c) The gasoline manufacturer that used the credits, and any transferor of the credits, must adjust their credit

records, reports, and average standard compliance calculations as necessary to reflect the use of valid credits only. Updates to any reports must be done in accordance with subpart J of this part using forms and procedures specified by EPA.

§ 1090.740 Downstream BOB recertification.

(a)(1) Gasoline manufacturers may recertify a BOB that another gasoline manufacturer has specified blending instructions for oxygenate(s) under § 1090.710(a)(5) for a different type or amount of oxygenate (including gasoline recertification to contain no oxygenate) if the recertifying gasoline manufacturer meets all the requirements of this section.

(2) Gasoline manufacturers must comply with applicable requirements of this part and incur deficits to be included in the compliance calculations in § 1090.700.

(3) Unless otherwise required under this part, gasoline manufacturers that recertify 200,000 or less gallons of BOB under this section do not need to arrange for an auditor to conduct audits under subpart R of this part.

(b) Gasoline manufacturers that recertify a BOB under this section must calculate sulfur and benzene deficits for each batch and the total deficits for sulfur and benzene as follows:

(1) *Sulfur deficits from downstream BOB recertification.* Calculate the sulfur deficit from BOB recertification for each individual batch of BOB recertified as follows:

$$D_{S_Oxy_Batch} = 11\text{ppm} \cdot V_{Base} \cdot \left[\frac{1}{(1 - PTD_{Oxy})} - 1\right]$$

Where:

$D_{S_Oxy_Batch}$ = Sulfur deficit resulting from recertifying the batch of BOB, in ppm-gallons.

V_{Base} = The volume of BOB in the batch being recertified, in gallons.

PTD_{Oxy} = The volume fraction of oxygenate that would have been added to the BOB as specified on PTDs.

(2) *Total sulfur deficit from downstream BOB recertification.* Calculate the total sulfur deficit from downstream BOB recertification as follows:

$$D_{S_Oxy_Total,y} = \sum_{i=1}^{n} D_{S_Oxy_Batch_i}$$

Where:

$D_{S_Oxy_Total,y}$ = The total sulfur deficit from downstream BOB recertification for compliance period y, in ppm-gallons.

$D_{S_Oxy_Batch_i}$ = The sulfur deficit for batch i of recertified BOB, per paragraph (b)(1) of this section, in ppm-gallons.

n = The number of batches of BOB recertified during compliance period y.

i = Individual batch of BOB recertified during compliance period y.

(3) *Benzene deficits from downstream BOB recertification.* Calculate the benzene deficit from BOB recertification for each individual batch of BOB recertified as follows:

$$D_{Bz_Oxy_Batch} = 0.0068 \cdot V_{Base} \cdot \left[\frac{1}{(1 - PTD_{Oxy})} - 1\right]$$

Where:

$D_{Bz_Oxy_Batch}$ = Benzene deficit resulting from recertifying the batch of BOB, in benzene gallons.

V_{Base} = The volume of BOB in the batch being recertified, in gallons.

PTD_{Oxy} = The volume fraction of oxygenate that would have been added to the BOB as specified on PTDs.

(4) *Total benzene deficit from downstream BOB recertification.* Calculate the total benzene deficit from downstream BOB recertification as follows:

$$D_{Bz_Oxy_Total,y} = \sum_{i=1}^{n} D_{Bz_Oxy_Batch_i}$$

Where:

$D_{Bz_Oxy_Total,y}$ = The total benzene deficit from downstream BOB recertification for compliance period y, in benzene gallons.

$D_{Bz_Oxy_Batch_i}$ = The benzene deficit for batch i of recertified BOB, per paragraph (b)(3) of this section, in benzene gallons.

n = The number of batches of BOB recertified during compliance period y.

i = Individual batch of BOB recertified during compliance period y.

(5) *Deficit rounding.* The deficits calculated in paragraphs (b)(1) through (4) of this section must be rounded and reported to the nearest sulfur ppm-gallon or benzene gallon in accordance with § 1090.50, as applicable.

(c) Gasoline manufacturers do not incur a deficit, nor may they generate credits, for negative values from the equations in paragraph (b) of this section.

(d) Deficits incurred under this section must be fulfilled in the compliance period in which they occur and may not be carried forward under § 1090.715.

§ 1090.745 Informational annual average calculations.

(a) Gasoline manufacturers must calculate and report annual average sulfur and benzene levels for each of their facilities as described in this section. The values calculated and reported under this section are not used

to demonstrate compliance with average standards under this part.

(b) Gasoline manufacturers must calculate and report the unadjusted average sulfur level as follows:

$$S_{a,y} = \frac{\sum_{i=1}^{n}(V_i \cdot S_i)}{\sum_{i=1}^{n} V_i}$$

Where:

$S_{a,y}$ = The facility unadjusted average sulfur level for compliance period y, in ppm. Report $S_{a,y}$ to two decimal places.

V_i = The volume of gasoline produced or imported in batch i, in gallons.

S_i = The sulfur content of batch i, in ppm.

n = The number of batches of gasoline produced or imported during the compliance period.

i = Individual batch of gasoline produced or imported during the compliance period.

(c) Gasoline manufacturers must calculate and report the net average sulfur level as follows:

$$S_{NET,y} = \frac{CSV_y}{\sum_{i=1}^{n} V_i}$$

Where:

$S_{NET,y}$ = The facility net average sulfur level for compliance period y, in ppm. Report $S_{NET,y}$ to two decimal places.

CSV_y = The compliance sulfur value for compliance period y, per § 1090.700(a)(1).

(d) Gasoline manufacturers must calculate and report the net average benzene level as follows:

$$B_{NET,y} = \frac{CBV_y}{\sum_{i=1}^{n} V_i}$$

Where:

$B_{NET,y}$ = The facility net average benzene level for compliance period y, in volume percent benzene. Report $B_{NET,y}$ to two decimal places.

CBV_y = The compliance benzene value for compliance period y, per § 1090.700(b)(1).

Subpart I—Registration

§ 1090.800 General provisions.

(a) *Who must register.* The following parties must register with EPA prior to engaging in any activity under this part:

(1) Fuel manufacturers, including:

(i) Gasoline manufacturers.

(ii) Diesel fuel manufacturers.

(iii) ECA marine fuel manufacturers.

(iv) Certified butane blenders.

(v) Certified pentane blenders.

(vi) Transmix processors.

(2) Oxygenate blenders.

(3) Oxygenate producers, including DFE producers.

(4) Certified pentane producers.

(5) Certified ethanol denaturant producers.

(6) Distributors, carriers, and pipeline operators who are part of the 500 ppm LM fuel distribution chain under a compliance plan submitted under § 1090.520(g).

(7) Independent surveyors.

(8) Auditors.

(9) Third parties that submit reports on behalf of any regulated party under this part. Such parties must register and associate their registration with the regulated party for whom they are reporting.

(b) *Dates for registration.* The deadlines for registration are as follows:

(1) *New registrants.* Except as specified in paragraph (b)(2) of this section, parties not currently registered with EPA must register with EPA no later than 60 days in advance of the first date that such person engages in any activity under this part requiring registration under paragraph (a) of this section.

(2) *Existing registrants.* Parties that are already registered with EPA under 40 CFR part 80 as of January 1, 2021, are deemed to be registered for purposes of this part, except that such parties are responsible for reviewing and updating their registration information consistent with the requirements of this part, as specified in paragraph (c) of this section.

(c) *Updates to registration.* A registered party must submit updated registration information to EPA within 30 days of any occasion when the registration information previously supplied becomes incomplete or inaccurate.

(d) *Forms and procedures for registration.* All registrants must use forms and procedures specified by EPA.

(e) *Company and facility identification.* EPA will provide registrants with company and facility identifiers to be used for recordkeeping and reporting under this part.

(f) *English language.* Registration information submitted to EPA must be in English.

§ 1090.805 Contents of registration.

(a) *General information required for all registrants.* The following general information must be submitted to EPA by all entities required to register:

(1) *Company information.* For the company of the party, all the following information:

(i) The company name.

(ii) Company address, which must be the physical address of the business (*i.e.,* not a post office box).

(iii) Mailing address, if different from company address.

(iv) Name, title, telephone number, and email address of an RCO. The RCO may delegate responsibility to a person who is familiar with the requirements of this part and who is no lower in the organization than a fuel manufacturing facility manager, or equivalent.

(2) *Facility information.* For each separate facility, all the following information:

(i) The facility name.

(ii) The physical location of the facility.

(iii) A contact name and telephone number for the facility.

(iv) The type of facility.

(3) *Location of records.* For each separate facility, or for each importer's operations in a single PADD, all the following information:

(i) Whether records are kept on-site or off-site of the facility, or for importers, the registered address.

(ii) If records are kept off-site, the primary off-site storage name, physical location, contact name, and telephone number.

(4) *Activities.* A description of the activities that are engaged in by the company and its facilities (*e.g.,* refining, importing, etc.).

(b) *Additional information required for certified pentane producers.* In addition to the information in paragraph (a) of this section, certified pentane producers must also submit the following information:

(1) A description of the production facility that demonstrates that the facility is capable of producing certified pentane that is compliant with the requirements of this part without significant modifications to the existing facility.

(2) A description of how the certified pentane will be shipped from the production facility to the certified pentane blender(s) and the associated quality assurance practices that demonstrate that contamination during distribution can be adequately controlled so as not to cause the certified pentane to be in violation of the standards in this part.

§ 1090.810 Voluntary cancellation of company or facility registration.

(a) *Criteria for voluntary cancellation.* A party may request cancellation of the registration of the company or any of its facilities at any time. Such request must use forms and procedures specified by EPA.

(b) *Effect of voluntary cancellation.* A party whose registration is canceled:

(1) Will still be liable for violation of any requirements under this part.

(2) Will not be listed on any public list of actively registered companies that is maintained by EPA.

(3) Will not have access to any of the electronic reporting systems associated with this part.

(4) Will still be required to meet any applicable requirements under this part (*e.g.,* the recordkeeping provisions under subpart L of this part).

(c) *Re-registration.* If a party whose registration has been voluntarily cancelled wants to re-register, they must do all the following:

(1) Notify EPA of their intent to re-register.

(2) Provide any required information and correct any identified deficiencies.

(3) Refrain from initiating a new registration unless directed to do so by EPA.

(4) Submit updated information as needed.

§ 1090.815 Deactivation (involuntary cancellation) of registration.

(a) *Criteria for deactivation.* EPA may deactivate the registration of any party required to register under this part, using the process specified in paragraph (b) of this section, if any of the following criteria are met:

(1) The party has not accessed their account or engaged in any registration or reporting activity within the most recent 24 months.

(2) The party has failed to comply with the registration requirements of this subpart.

(3) The party has failed to submit any required notification or report within 30 days of the required submission date.

(4) Any required attest engagement has not been received within 30 days of the required submission date.

(5) The party fails to pay a penalty or to perform any requirement under the terms of a court order, administrative order, consent decree, or administrative settlement between the party and EPA.

(6) The party submits false or incomplete information.

(7) The party denies EPA access or prevents EPA from completing authorized activities under section 114 or 208 of the Clean Air Act despite presenting a warrant or court order. This includes a failure to provide reasonable assistance.

(8) The party fails to keep or provide the records required by subpart L of this part.

(9) The party otherwise circumvents the intent of the Clean Air Act or of this part.

(b) *Process for deactivation.* Except as specified in paragraph (c) of this section, EPA will use the following process whenever it decides to deactivate the registration of a party:

(1) EPA will provide written notification to the RCO identifying the reasons or deficiencies for which EPA intends to deactivate the party's registration. The party will have 30 calendar days from the date of the notification to correct the deficiencies identified or explain why there is no need for corrective action.

(2) If the basis for EPA's notice of intent to deactivate registration is the absence of activity under paragraph (a)(1) of this section, a stated intent to engage in activity will be sufficient to avoid deactivation of registration.

(3) If the party does not correct identified deficiencies under paragraphs (a)(2) through (9) of this section, EPA may deactivate the party's registration without further notice to the party.

(c) *Immediate deactivation.* In instances in which public health, public interest, or safety requires otherwise, EPA may deactivate the registration of the party without any notice to the party. EPA will provide written notification to the RCO identifying the reasons EPA deactivated the registration of the party.

(d) *Effect of deactivation.* A party whose registration is deactivated:

(1) Will still be liable for violation of any requirement under this part.

(2) Will not be listed on any public list of actively registered companies that is maintained by EPA.

(3) Will not have access to any of the electronic reporting systems associated with this part.

(4) Will still be required to meet any applicable requirements under this part (*e.g.,* the recordkeeping provisions under subpart L of this part).

(e) *Re-registration.* If a party whose registration has been deactivated wishes to re-register, they must do all the following:

(1) Notify EPA of their intent to re-register.

(2) Provide any required information and correct any identified deficiencies.

(3) Refrain from initiating a new registration unless directed to do so by EPA.

(4) Remedy the circumstances that caused the party to be deactivated in the first place.

(5) Submit updated information as needed.

§ 1090.820 Changes of ownership.

(a) When a company or any of its facilities will change ownership, the company must notify EPA within 30 days after the date of sale or change in ownership.

(b) The notification required under paragraph (a) of this section must include all the following:

(1) The effective date of the transfer of ownership of the facility and a summary of any changes to the registration information for the affected companies and facilities.

(2) Documents that demonstrate the sale or change in ownership of the facility.

(3) A letter, signed by an RCO from the company that currently owns or will own the company or facility and, if possible, an RCO from the company that previously registered the company or facility that details the effective date of the transfer of ownership of the company or facility and summarizes any changes to the registration information.

(4) Any additional information requested by EPA to complete the change in registration.

Subpart J—Reporting

§ 1090.900 General provisions.

(a) *Forms and procedures for reporting.* (1) All reporting, including all transacting of credits under this part, must be submitted electronically using forms and procedures specified by EPA.

(2) Values must be reported in the units (*e.g.,* gallons, ppm, etc.) and to the number of decimal places specified in this part or in reporting formats and procedures, whichever is more precise.

(b) *English language.* All reports submitted under this subpart must be submitted in English.

(c) *Rounding.* All values measured, calculated, or reported under this subpart must be rounded in accordance with § 1090.50.

(d) *Report submission.* All annual reports required under this subpart, except attest engagement reports, must be submitted by March 31 for the preceding compliance period (*e.g.,* reports covering the calendar year 2021 must be submitted to EPA by no later than March 31, 2022). Attest engagement reports must be submitted by June 1 for the preceding compliance period (*e.g.,* attest engagement reports covering calendar year 2021 must be submitted to EPA by no later than June 1, 2022). Independent survey quarterly reports must be submitted by the deadlines in Table 1 to § 1090.925(a).

§ 1090.905 Annual, batch, and credit transaction reporting for gasoline manufacturers.

(a) *Annual compliance demonstration for sulfur.* Gasoline manufacturers, for each of their facilities, must submit a report for each compliance period that includes all the following information:

(1) *Company-level reporting.* For the company, as applicable:

(i) The EPA-issued company and facility identifiers.

(ii) Provide information for sulfur credits, and separately by compliance period of creation, as follows:

(A) The number of sulfur credits owned at the beginning of the compliance period.

(B) The number of sulfur credits that expired at the end of the compliance period.

(C) The number of sulfur credits that will be carried over into the next compliance period.

(D) Any other information as EPA may require.

(2) *Facility-level reporting.* For each refinery or importer, as applicable:

(i) The EPA-issued company and facility identifiers.

(ii) The compliance sulfur value, per § 1090.700(a)(1), in ppm-gallons.

(iii) The total volume of gasoline produced or imported, in gallons.

(iv) Provide information for sulfur credits, and separately by compliance period of creation, as follows:

(A) The number of sulfur credits generated during the compliance period.

(B) The number of sulfur credits retired during the compliance period.

(C) The sulfur credit deficit that was carried over from the previous compliance period.

(D) The sulfur credit deficit that will be carried over into the next compliance period.

(E) The total sulfur deficit from downstream BOB recertification, per § 1090.740(b)(2).

(v) The unadjusted average sulfur concentration, per § 1090.745(b), in ppm.

(vi) The net average sulfur level, per § 1090.745(c), in ppm.

(vii) Any other information as EPA may require.

(b) *Annual compliance demonstration for benzene.* Gasoline manufacturers, for each of their facilities, must submit a report for each compliance period that includes all the following information:

(1) *Company-level reporting.* For the company, as applicable:

(i) The EPA-issued company and facility identifiers and compliance level.

(ii) Provide information for benzene credits, and separately by compliance period of creation, as follows:

(A) The number of benzene credits owned at the beginning of the compliance period.

(B) The number of benzene credits that expired at the end of the compliance period.

(C) The number of benzene credits that will be carried over into the next compliance period.

(D) Any other information as EPA may require.

(2) *Facility-level reporting.* For each refinery or importer, as applicable:

(i) The EPA-issued company and facility identifiers.

(ii) The compliance benzene value, per § 1090.700(b)(1), in benzene gallons.

(iii) The total volume of gasoline produced or imported, in gallons.

(iv) The average benzene concentration, per § 1090.700(b)(3), in percent volume.

(v) The net average benzene level, per § 1090.745(d), in percent volume.

(vi) Provide information for benzene credits, and separately by compliance period of creation, as follows:

(A) The number of benzene credits generated during the compliance period.

(B) The number of benzene credits retired during the compliance period.

(C) The benzene credit deficit that was carried over from the previous compliance period

(D) The benzene credit deficit that will be carried over into the next compliance period.

(E) The total benzene deficit from downstream BOB recertification, per § 1090.740(b)(4).

(vii) Any other information as EPA may require.

(c) *Batch reporting.* Gasoline manufacturers, for each of their facilities, must report the following information on a per-batch basis for gasoline and gasoline regulated blendstocks:

(1) For gasoline, and BOB for which the fuel manufacturer does not include the addition of downstream oxygenate in their compliance calculations as specified in § 1090.710:

(i) The EPA-issued company and facility identifiers.

(ii) The batch number.

(iii) The date the batch was produced or imported.

(iv) The batch volume, in gallons.

(v) The designation of the gasoline or BOB as RFG, CG, RBOB, or CBOB.

(vi) The tested sulfur content of the batch, in ppm, and the test method used to measure the sulfur content.

(vii) The tested benzene content of the batch, as a volume percentage, and the test method used to measure the benzene content. Gasoline produced by a transmix processor using only TGP or both TGP and PCG under § 1090.510 is exempt from this requirement under § 1090.1325. Transmix processors that use this exemption must report whether the batch was produced using TGP or both TGP and PCG.

(viii) For all batches of summer gasoline or BOB:

(A) The applicable RVP standard, as specified in § 1090.215.

(B) The tested RVP of the batch, in psi, and the test method used to measure the RVP.

(ix) If the gasoline contains oxygenate, the type and tested content of each oxygenate, as a volume percentage, and the test method used to measure the content of each oxygenate.

(2) For BOB in which the oxygenate to be blended with the BOB is reported by, and included in, the compliance calculations of the gasoline manufacturer that produced the BOB:

(i) The EPA-issued company and facility identifiers.

(ii) The batch identification.

(iii) The date the batch of BOB was produced or imported.

(iv) The batch volume, in gallons. This volume is the sum of the produced or imported BOB volume plus the anticipated volume from the addition of oxygenate downstream that the gasoline manufacturer specified to be blended with the BOB.

(v) The designation of the BOB (CBOB or RBOB) used to prepare the hand blend of BOB and oxygenate under § 1090.1340.

(vi) The tested sulfur content for both the BOB and the hand blend of BOB and oxygenate prepared under § 1090.1340, and the test method used to measure the sulfur content.

(vii) The tested benzene content for the hand blend of BOB and oxygenate prepared under § 1090.1340, and the test method used to measure the benzene content.

(viii) For all batches of summer BOB:

(A) The applicable RVP standard, as specified in § 1090.215, for the neat CBOB, or hand blend of RBOB and oxygenate prepared under § 1090.1340.

(B) The tested RVP for the neat CBOB or hand blend of RBOB and oxygenate prepared under § 1090.1340, in psi, and the test method used to measure the RVP.

(ix) The type and content of each oxygenate, as a volume percentage, in the hand blend of BOB and oxygenate prepared under § 1090.1340, and, if measured, the test method used for each oxygenate.

(3) For blendstock added to PCG by gasoline manufacturers complying by subtraction under § 1090.1320(a)(1):

(i) For the PCG prior to the addition of blendstock:

(A) The EPA-issued company and facility identifiers for the facility at which the PCG is blended to produce a new batch.

(B) The batch number assigned by the facility at which the PCG is blended to produce a new batch.

(C) The date the batch was received or, for PCG that was not received from another company, the date the PCG was designated to be used to produce a new batch of gasoline.

(D) The batch volume, including the volume of any oxygenate that would

have been added to the PCG, as a negative number in gallons.

(E) The designation of the PCG.

(F) The tested sulfur content of the batch, in ppm, and the test method used to measure the sulfur content.

(G) The tested benzene content of the batch, as a volume percentage, and the test method used to measure the benzene content.

(H) For all batches of summer gasoline or BOB:

(*1*) The applicable RVP standard, as specified in § 1090.215.

(*2*) The tested RVP of the batch, in psi, and the test method used to measure the RVP.

(I) If the PCG contains oxygenate, the type and tested content of each oxygenate, as a volume percentage, and the test method used to measure the content of each oxygenate.

(J) Identification of the batch as PCG.

(ii) For the batch of gasoline or BOB produced using PCG and blendstock:

(A) For batches of finished gasoline or neat BOB, all the information specified in paragraph (c)(1) of this section.

(B) For batches of BOB in which the oxygenate to be blended with the BOB is included in the gasoline manufacturer's compliance calculations, all the information specified in paragraph (c)(2) of this section.

(4) For blendstock added by gasoline manufacturers to PCG and complying by addition per § 1090.1320(a)(2) (*i.e.,* treat the blendstock as a separate batch):

(i) For the blendstock, the sulfur content, benzene content, and each oxygenate type and content of the batch, and for summer gasoline, the RVP of the batch.

(ii) For batches produced by adding blendstock to PCG, the sulfur content of the batch, and for summer gasoline, the RVP of the batch.

(5) For certified butane blended by certified butane blenders and certified pentane blended by certified pentane blenders:

(i) For the certified butane or certified pentane batch:

(A) The batch number.

(B) The date the batch was received by the blender.

(C) The batch volume, in gallons.

(D) The designation of the batch (certified butane or certified pentane).

(E) The volume percentage of butane in butane batches, or pentane in pentane batches, provided by the butane or pentane supplier.

(F) The sulfur content of the batch, in ppm, provided by the butane or pentane supplier.

(G) The benzene content of the batch, in volume percent, provided by the butane or pentane supplier.

(H) The RVP of the batch, in psi, provided by the butane or pentane supplier for butane or pentane blended into PCG from May 1 through September 15.

(ii) For the batch of blended product (*i.e.,* PCG plus butane or PCG plus pentane):

(A) The batch number.

(B) The date the batch was produced.

(C) The batch volume, in gallons.

(D) The designation of the blended product.

(E) The tested RVP of the batch, in psi, and the test method used to measure the RVP.

(6) For manufacturers of TGP and any blendstocks added to TGP:

(i) For the TGP, the sulfur content of the batch, and for summer gasoline, the RVP of the batch.

(ii) For blendstocks added to TGP, where the TGP is treated like PCG, one of the following:

(A) The information specified in paragraph (c)(3) of this section.

(B) The information specified in paragraph (c)(4) of this section.

(7) For GTAB:

(i) The EPA-issued company and facility identifiers.

(ii) The batch number.

(iii) The date the batch was imported.

(iv) The batch volume, in gallons.

(v) The designation of the product as GTAB.

(8) Any other information as EPA may require.

(d) *Credit transactions.* Any party that is required to demonstrate annual compliance under paragraph (a) or (b) of this section must submit information related to individual transactions involving sulfur and benzene credits, including all the following:

(1) The generation, purchase, sale, or retirement of such credits.

(2) If any credits were obtained from or transferred to other fuel manufacturers, and for each other party, their name and EPA-issued company identifier, the number of credits obtained from or transferred to the other party, and the year the credits were generated.

(3) Any other information as EPA may require.

§ 1090.910 Reporting for gasoline manufacturers that recertify BOB to gasoline.

Any person that recertifies BOB under § 1090.740 must report the information of this section, as applicable.

(a) *Batch reporting.* (1) Any person that recertifies a BOB under § 1090.740 with less oxygenate than specified by the fuel manufacturer of the BOB must report the following for each batch:

(i) The EPA-issued company and facility identifiers for the recertifying gasoline manufacturer.

(ii) The batch number assigned by the recertifying gasoline manufacturer.

(iii) The date the batch was recertified.

(iv) The batch volume, as a negative number in gallons. The volume is the amount of oxygenate that the recertifying gasoline manufacturer did not blend with the BOB.

(v) The designation of the batch.

(vi) A sulfur content of 11 ppm.

(vii) A benzene content of 0.068 volume percent.

(viii) The type and content of each oxygenate, as a volume percentage.

(ix) The sulfur deficit for the batch calculated under § 1090.740(b)(1).

(x) The benzene deficit for the batch calculated under § 1090.740(b)(3).

(2) Any person that recertifies a BOB under § 1090.740 with more oxygenate than specified by the fuel manufacturer of the BOB does not need to report the batch.

(b) *Annual sulfur and benzene compliance reporting.* Any person that recertifies a BOB under § 1090.740 must include any deficits incurred from recertification in reports under § 1090.905(a) and (b).

(c) *Credit transactions.* Any person that recertifies a BOB under § 1090.740 must report any credit transactions under § 1090.905(d).

§ 1090.915 Batch reporting for oxygenate producers and importers.

Any oxygenate producer, for each of their production facilities, and any importer for the oxygenate they import, must submit a report for each compliance period that includes all the following information:

(a) The EPA-issued company and facility identifiers.

(b) The total volume of oxygenate produced or imported.

(c) For each batch of oxygenate produced or imported during the compliance period, all the following:

(1) The batch number.

(2) The date the batch was produced or imported.

(3) One of the following product types:

(i) Denatured ethanol using certified ethanol denaturant complying with § 1090.235(b).

(ii) Denatured ethanol from non-certified ethanol denaturant.

(iii) A specified oxygenate other than ethanol (*e.g.,* isobutanol).

(4) The volume of the batch, in gallons.

(5) The tested sulfur content of the batch, in ppm, and the test method used to measure the sulfur content.

(d) Any other information as EPA may require.

§ 1090.920 Reports by certified pentane producers.

Any producer of certified pentane for use by certified pentane blenders must submit a report for each facility at which certified pentane was produced or imported that contains all the following information:

(a) The EPA-issued company and facility identifiers.

(b) For each batch of certified pentane produced or imported during the compliance period, all the following:

(1) The batch number.

(2) The date the batch was produced or imported.

(3) The batch volume, in gallons.

(4) The tested pentane content of the batch, as a volume percentage, and the test method used to measure the pentane content.

(5) The tested sulfur content of the batch, in ppm, and the test method used to measure the sulfur content.

(6) The tested benzene of the batch, as a volume percentage, and the test method used to measure the benzene content.

(7) The tested RVP of the batch, in psi, and the test method used to measure the RVP.

(c) Any other information as EPA may require.

§ 1090.925 Reports by independent surveyors.

(a) *General procedures.* (1) Independent surveyors must electronically submit any plans, notifications, or reports required under this subpart using forms and procedures specified by EPA.

(2) For each report required under this section, the independent surveyor must affirm that the survey was conducted in accordance with an EPA-approved survey plan and that the survey results are accurate.

(3) The independent surveyor must include EPA-issued company identifiers on each report required under this section.

(4) Independent surveyors must submit quarterly reports required under paragraph (b) of this section by the following deadlines:

TABLE 1 TO § 1090.925(a)—QUARTERLY REPORTING DEADLINES

Calendar quarter	Time period covered	Quarterly report deadline
Quarter 1	January1–March 31	June 1.
Quarter 2	April 1–June 30	September 1.
Quarter 3	July 1–September 30	December 1.
Quarter 4	October 1–December 31	March 31.

(b) *Quarterly reporting.* Independent surveyors must submit the following information quarterly, as applicable:

(1) For each retail outlet or gasoline manufacturing facility sampled by the independent surveyor:

(i) The identification information for the retail outlet or gasoline manufacturing facility, as assigned by the surveyor in a consistent manner and as described in the survey plan.

(ii) The displayed fuel manufacturer brand name at the retail outlet, if any.

(iii) The physical location (*i.e.,* address) of the retail outlet or gasoline manufacturing facility.

(2) For each gasoline sample collected by the independent surveyor:

(i) A description of the labeling of the fuel dispenser(s) (*e.g.,* ''E0'', ''E10'', ''E15'', etc.) from which the independent surveyor collected the sample.

(ii) The date and time the independent surveyor collected the sample.

(iii) The test results for the sample, and the test methods used, as determined by the independent surveyor, including the following parameters:

(A) The oxygen content, in weight percent.

(B) The type and amount of each oxygenate, by weight and volume percent.

(C) The sulfur content, in ppm.

(D) The benzene content, in volume percent.

(E) The specific gravity.

(F) The RVP in psi, if tested.

(G) The aromatic content in volume percent, if tested.

(H) The olefin content in volume percent, if tested.

(I) The distillation parameters (*i.e.,* E200, E300, T50, T90), if tested.

(3) For each diesel sample collected at a retail outlet by the independent surveyor:

(i) A description of the labeling of the fuel dispenser(s) (*e.g.,* ''ULSD'') from which the independent surveyor collected the sample.

(ii) The date and time the independent surveyor collected the sample.

(iii) The tested sulfur content of the sample, and the test method used, as determined by the independent surveyor, in ppm.

(4) Any other information as EPA may require.

(c) *Annual reporting.* Independent surveyors must submit the following information annually by March 31.

(1) An identification of the parties that participated in the survey during the compliance period.

(2) An identification of each geographic area included in a survey.

(3) Summary statistics for each identified geographic area, including the following:

(i) The number of samples collected and tested.

(ii) The mean, median, and range expressed in appropriate units for each measured gasoline and diesel parameter.

(iii) The standard deviation for each measured gasoline and diesel parameter.

(iv) The estimated compliance rate for each measured gasoline and diesel parameter subject to a per-gallon standard in subpart C or D of this part.

(v) A summary of potential non-compliance issues.

(4) Any other information as EPA may require.

§ 1090.930 Reports by auditors.

(a) Attest engagement reports required under subpart R of this part must be submitted by independent auditors who are registered with EPA and associated with a company, or companies, via registration under subpart I of this part. Each attest engagement must clearly identify the company and compliance level (*e.g.,* facility), time period, and scope covered by the report. Attest engagement reports covered by this section include those required under this part, and under 40 CFR part 80, subpart M, beginning with the report due June 1, 2022.

(b) An attest engagement report must be submitted to EPA covering each compliance period by June 1 of the following calendar year. The auditor must make the attest engagement

available to the company for which it was performed.

(c) The attest engagement must comply with subpart R of this part and the attest engagement report must clearly identify the methodologies followed and any findings, exceptions, etc.

(d) A single attest engagement submission by the auditor may include procedures performed under this part and under 40 CFR part 80, subpart M. If a single submission method is used, the auditor must clearly and separately describe the procedures and findings for each program.

(e) If the attest engagement reveals discrepancies or instances of noncompliance requiring corrective action, then the RCO must submit a statement acknowledging them and stating that they are undertaking corrective action.

§ 1090.935 Reports by diesel manufacturers.

(a) *Batch reporting.* (1) For each compliance period, manufacturers of ULSD must submit the following information:

(i) The EPA-issued company and facility identifiers for the manufacturer of ULSD.

(ii) The highest sulfur content level observed for a batch of ULSD produced during the compliance period on a company level, in ppm.

(iii) The average sulfur content level of all batches produced during the compliance period on a company level, in ppm.

(iv) A list of all batches of ULSD that exceeded the sulfur standard in § 1090.305(b) by facility. For each such batch, report the following:

(A) The batch number.

(B) The date the batch was produced.

(C) The volume of the batch, in gallons.

(D) The sulfur content of the batch, in ppm.

(E) The corrective action taken, if any.

(b) [Reserved]

Subpart K—Batch Certification, Designation, and Product Transfer Documents

Batch Certification and Designation

§ 1090.1100 Batch certification requirements.

(a) *General provisions.* (1) Fuel manufacturers, fuel additive manufacturers, and regulated blendstock producers must certify batches of fuels, fuel additives, and regulated blendstocks as specified in this section.

(2) Fuel manufacturers, fuel additive manufacturers, and regulated blendstock producers do not need to certify fuel, fuel additive, or regulated blendstock that is exempt under subpart G of this part.

(3) For purposes of this part, the volume of a batch is the sum of all shipments or transfers of fuel, fuel additive, or regulated blendstock out of the tank or vessel in which the fuel, fuel additive, or regulated blendstock was certified. If a volume of fuel, fuel additive, or regulated blendstock is placed in a tank, certified (if not previously certified), and is not changed in some way, it is considered to be the same batch even if several shipments or transfers are made out of that tank.

(4) For fuel produced at a facility that has an in-line blending waiver under § 1090.1315, the volume of the batch is the volume of product that is homogeneous under the requirements of § 1090.1337 and is produced during a period not to exceed 3 days.

(5) No person may introduce into commerce gasoline, diesel fuel, or ECA marine fuel that is not certified under this section.

(b) *Gasoline.* (1) Gasoline manufacturers must certify gasoline as specified in paragraph (b)(2) of this section prior to introducing the fuel into commerce.

(2) To certify batches of gasoline, gasoline manufacturers must do all the following:

(i) Register with EPA as a refiner, blending manufacturer, importer, transmix processor, certified butane blender, or certified pentane blender under subpart I of this part, as applicable, prior to producing gasoline.

(ii) Ensure that each batch of gasoline meets the applicable requirements of subpart C of this part using the applicable procedures specified in subpart M of this part. Transmix processors and transmix blenders must also meet all applicable requirements in subpart F of this part to ensure that each batch of gasoline meets the applicable requirements in subpart C of this part.

(iii) Assign batch numbers as specified in § 1090.1120.

(iv) Designate batches of gasoline as specified in § 1090.1110.

(3) PCG may be mixed with other PCG without re-certification if the resulting mixture complies with the applicable standards in subpart C of this part and is designated appropriately under § 1090.1110. Resulting mixtures of PCG are not new batches and should not be assigned new batch numbers.

(4) Any person that mixes summer gasoline with summer or winter gasoline that has a different designation must do one of the following:

(i) Designate the resulting mixture as meeting the least stringent RVP designation of any batch that is mixed. For example, a distributor who mixes Summer RFG with 7.8 psi Summer CG must designate the mixture as 7.8 psi Summer CG.

(ii) Determine the RVP of the mixture using the procedures specified in subpart M of this part and designate the new batch under § 1090.1110 to reflect the RVP of the resulting mixture.

(5) Any person that mixes summer gasoline with winter gasoline to transition any storage tank from winter to summer gasoline is exempt from the requirement in paragraph (b)(4)(ii) of this section but must ensure that the gasoline meets the applicable RVP standard in § 1090.215.

(c) *Diesel fuel and ECA marine fuel.* (1) Diesel fuel and ECA marine fuel manufacturers must certify diesel fuel as specified in paragraph (c)(2) of this section prior to introducing the fuel into commerce.

(2) To certify batches of diesel fuel and ECA marine fuel, diesel fuel and ECA marine fuel manufacturers must do all the following:

(i) Register with EPA as a refiner, blending manufacturer, importer, or transmix processor under subpart I of this part, as applicable, prior to producing diesel fuel or ECA marine fuel.

(ii) Ensure that each batch of diesel fuel or ECA marine fuel meets the applicable requirements of subpart D of this part using the applicable procedures specified in subpart M of this part. Transmix processors must also meet all applicable requirements specified in subpart F of this part to ensure that each batch of diesel fuel or ECA marine fuel meets the applicable requirements in subpart D of this part.

(iii) Assign batch numbers as specified in § 1090.1120.

(iv) Designate batches of diesel fuel as specified in § 1090.1115.

(d) *Oxygenates.* (1) Oxygenate producers must certify oxygenates intended to be blended into gasoline as specified in paragraph (d)(2) of this section.

(2) To certify batches of oxygenates, oxygenate producers and importers must do all the following:

(i) Register with EPA as an oxygenate producer under subpart I of this part prior to producing or importing oxygenate intended for blending into gasoline.

(ii) Ensure that each batch of oxygenate meets the requirements in § 1090.230 by using the applicable procedures specified in subpart M of this part.

(iii) Assign batch numbers as specified in § 1090.1120.

(iv) Designate batches of oxygenate as intended for blending with gasoline as specified in § 1090.1110(c).

(e) *Certified butane.* (1) Certified butane producers must certify butane intended to be blended by a blending manufacturer under § 1090.1320 as specified in paragraph (e)(2) of this section.

(2) To certify batches of certified butane, certified butane producers must do all the following:

(i) Ensure that each batch of certified butane meets the requirements in § 1090.220 by using the applicable procedures specified in subpart M of this part.

(A) Testing must occur after the most recent delivery into the certified butane producer's storage tank, and prior to transferring the certified butane batch for delivery.

(B) The certified butane producer must provide documentation of the test results for each batch of certified butane to the certified butane blender.

(ii) Designate batches of certified butane as intended for blending with gasoline as specified in § 1090.1110(d).

(f) *Certified pentane.* (1) Certified pentane producers must certify pentane intended to be blended by a blending manufacturer under § 1090.1320 as specified in paragraph (f)(2) of this section.

(2) To certify batches of certified pentane, certified pentane producers must do all the following:

(i) Register with EPA as a certified pentane producer under subpart I of this part prior to producing certified pentane.

(ii) Ensure that each batch of certified pentane meets the requirements in § 1090.225 by using the applicable procedures specified in subpart M of this part.

(A) Testing must occur after the most recent delivery into the certified pentane producer's storage tank, before transferring the certified pentane batch for delivery.

(B) The certified pentane producer must provide documentation of the test results for each batch of certified pentane to the certified pentane blender.

(iii) Assign batch numbers as specified in § 1090.1120.

(iv) Designate batches of certified pentane as intended for blending with gasoline as specified in § 1090.1110(d).

(g) *Certified ethanol denaturant.* (1) Certified ethanol denaturant producers must certify certified ethanol denaturant intended to be used to make DFE that meets the requirements in § 1090.235 as specified in paragraph (g)(2) of this section.

(2) To certify batches of certified ethanol denaturant, certified ethanol denaturant producers must do all the following:

(i) Register with EPA as a certified ethanol denaturant producer under subpart I of this part prior to producing certified ethanol denaturant.

(ii) Ensure that each batch of certified ethanol denaturant meets the requirements in § 1090.235 by using the applicable procedures specified in subpart M of this part.

(iii) Assign batch numbers as specified in § 1090.1120.

(iv) Designate batches of certified ethanol denaturant as intended for blending with gasoline as specified in § 1090.1110(e).

§ 1090.1105 Designation of batches of fuels, fuel additives, and regulated blendstocks.

(a) Fuel manufacturers, fuel additive manufacturers, and regulated blendstock producers must designate batches of fuel, fuel additive, and regulated blendstock as specified in this subpart.

(b) Fuel manufacturers, fuel additive manufacturers, and regulated blendstock producers must include designations on PTDs as specified in this subpart and must make the designation prior to the batch leaving the facility where it was produced.

(c) By designating a batch of fuel, fuel additive, or regulated blendstock under this subpart, the designating party is acknowledging that the batch is subject to all applicable standards under this part.

(d) A person must comply with all provisions of this part even if they fail to designate or improperly designate a batch of fuel, fuel additive, or regulated blendstock.

(e) No person may use the designation provisions of this subpart to circumvent any standard or requirement in this part.

§ 1090.1110 Designation requirements for gasoline.

(a) *Designation requirements for gasoline manufacturers.* Gasoline manufacturers must accurately and clearly designate each batch of gasoline as follows:

(1) Gasoline manufacturers must designate each batch of gasoline as one of the following fuel types:

(i) Winter RFG or RBOB.

(ii) Summer RFG or RBOB.

(iii) Winter CG or CBOB.

(iv) Summer CG or CBOB.

(v) Exempt gasoline under subpart G of this part (including additional identifying information).

(vi) California gasoline.

(2) Gasoline manufacturers must further designate gasoline designated as Summer CG or Summer CBOB as follows:

(i) 7.8 psi Summer CG or CBOB.

(ii) 9.0 psi Summer CG or CBOB.

(iii) SIP-controlled Summer CG or CBOB.

(3) CBOB and RBOB manufacturers must further designate the CBOB or RBOB with the type(s) and amount(s) of oxygenate specified to be blended with the CBOB or RBOB as specified in § 1090.710.

(b) *Designation requirements for gasoline distributors.* Gasoline distributors must accurately and clearly designate each batch or portion of a batch of gasoline for which they transfer custody to another facility as follows:

(1) Distributors must accurately and clearly classify each batch or portion of each batch of gasoline as specified by the gasoline manufacturer in paragraph (a) of this section.

(2) Distributors may redesignate batches or portions of batches of gasoline for which they transfer custody to another facility without recertifying the batch or portion of the batch as follows:

(i) Winter RFG or RBOB may be redesignated as Winter CG or CBOB.

(ii) Winter CG or CBOB may be redesignated as Winter RFG or RBOB.

(iii) Summer RFG or RBOB and Summer CG or CBOB may be redesignated to a less stringent RVP designation. For example, a distributor could redesignate without recertification a portion of a batch of Summer RFG to 7.8 psi Summer CG or 9.0 psi Summer CG.

(iv) Summer RFG or RBOB and Summer CG or CBOB may be redesignated as Winter RFG or RBOB or Winter CG or CBOB.

(v)(A) California gasoline may be redesignated as RFG or CG, with appropriate season designation and RVP designation under paragraph (a) of this section, if the requirements specified in § 1090.625(d) are met.

(B) California gasoline that is not redesignated under paragraph (b)(2)(v)(A) of this section may instead be recertified as gasoline under § 1090.1100(b).

(vi) CG and RFG may not be redesignated as BOB.

(3) Distributors that redesignate batches or portions of gasoline under paragraph (b)(2) of this section must accurately and clearly designate the batch or portion of the batch of gasoline as specified in paragraph (a) of this section.

(c) *Designation requirements for oxygenate producers.* Oxygenate

producers must accurately and clearly designate each batch of oxygenate intended for blending with gasoline as one of the following oxygenate types:

(1) DFE.

(2) The name of the specific oxygenate (*e.g.,* iso-butanol).

(d) *Designation requirements for certified butane and certified pentane.* Certified butane and certified pentane producers must accurately and clearly designate each batch of certified butane and certified pentane as one of the following types:

(1) Certified butane.

(2) Certified pentane.

(e) *Designation requirements for certified ethanol denaturant.* Certified ethanol denaturant producers must accurately and clearly designate batches of certified ethanol denaturant as ''certified ethanol denaturant''.

§ 1090.1115 Designation requirements for diesel and distillate fuels.

(a) *Designation requirements for diesel and distillate fuel manufacturers.* (1) Except as specified in paragraphs (a)(3) and (4) of this section, diesel and distillate fuel manufacturers must accurately and clearly designate each batch of diesel or distillate fuel as at least one of the following fuel types:

(i) ULSD. Diesel fuel manufacturers may also designate the fuel as 15 ppm MVNRLM.

(ii) LM 500 diesel fuel.

(iii) Heating oil.

(iv) Jet fuel.

(v) Kerosene.

(vi) ECA marine fuel.

(vii) Distillate global marine fuel.

(viii) Exempt diesel or distillate fuel under subpart G of this part (including additional identifying information).

(2) Only fuel manufacturers that comply with the requirements in § 1090.520 may designate fuel as LM 500 diesel fuel.

(3) Any batch of diesel or distillate fuel that is certified and designated as ULSD may also be designated as heating oil, kerosene, or jet fuel if it is also suitable for use as heating oil, kerosene, or jet fuel.

(4) Any batch of diesel or distillate fuel that is certified and designated as ULSD may also be designated as ECA marine fuel or distillate global marine fuel if the applicable requirements in § 1090.325 are met.

(b) *Designation requirements for distributors of diesel and distillate fuels.* Distributors of diesel and distillate fuels must accurately and clearly designate each batch of diesel or distillate fuel for which they transfer custody as follows:

(1) Distributors must accurately and clearly designate such diesel or distillate fuel by sulfur content while it is in their custody (*e.g.,* as 15 ppm or 500 ppm).

(2) Distributors must accurately and clearly designate such diesel or distillate fuel as specified by the diesel or distillate fuel manufacturer under paragraph (a) of this section.

(3) Distributors may redesignate batches or portions of batches of diesel or distillate fuel for which they transfer custody to another facility without recertifying the batch or portion of the batch as follows:

(i) ULSD that is also suitable for use as kerosene or jet fuel (commonly referred to as dual use kerosene) may be designated as ULSD, kerosene, or jet fuel (as applicable).

(ii) ULSD may be redesignated as LM 500 diesel fuel, heating oil, jet fuel, kerosene, ECA marine fuel, or distillate global marine fuel without recertification if all applicable requirements under this part are met for the new fuel designation.

(iii) California diesel may be redesignated as ULSD if the requirements specified in § 1090.625(e) are met.

(iv) Heating oil, kerosene, or jet fuel may be redesignated as ULSD if the requirements specified in § 1090.315 are met.

(v) 500 ppm LM diesel fuel may be redesignated as ECA marine fuel, distillate global marine fuel, heating oil, or blendstock. Any person that redesignates 500 ppm LM diesel fuel to ECA marine fuel or distillate global marine fuel must maintain records from the producer of the 500 ppm LM diesel fuel (*i.e.,* PTDs accompanying the fuel under § 1090.1165) to demonstrate compliance with the 500 ppm sulfur standard in § 1090.320(b).

(c) No person may designate distillate fuel with a sulfur content greater than the sulfur standard in § 1090.305(b) as ULSD.

§ 1090.1120 Batch numbering.

(a) Fuel manufacturers, fuel additive manufacturers, and regulated blendstock producers must assign a number (the ''batch number'') to each batch of gasoline, diesel fuel, oxygenate, certified pentane, or certified ethanol denaturant either produced or imported. The batch number must, if available, consist of the EPA-assigned company registration number of the party that either produced or imported the fuel, fuel additive, or regulated blendstock, the EPA-assigned facility registration number where the fuel, fuel additive, or regulated blendstock was produced or imported, the last two digits of the year that the batch was either produced or imported, and a unique number for the batch, beginning with the number one (1) for the first batch produced or imported each calendar year and each subsequent batch during the calendar year being assigned the next sequential number (*e.g.,* 4321–54321–20–000001, 4321–54321–20–000002, etc.). EPA assigns company and facility registration numbers as specified in subpart I of this part.

(b) Certified butane or certified pentane blended with PCG during a period of up to one month may be included in a single batch for purposes of reporting to EPA. However, certified butane and certified pentane must be reported as separate batches.

(c) Gasoline manufacturers that recertify BOBs under § 1090.740 may include up to a single month's volume as a single batch for purposes of reporting to EPA.

Product Transfer Documents

§ 1090.1150 General PTD provisions.

(a) *General.* (1) On each occasion when any person transfers custody or title to any product covered under this part other than when fuel is sold or dispensed for use in motor vehicles at a retail outlet or WPC facility, the transferor must provide to the transferee PTDs that include all the following information:

(i) The name and address of the transferor.

(ii) The name and address of the transferee.

(iii) The volume of the product being transferred, in gallons.

(iv) The location of the product at the time of the transfer.

(v) The date of the transfer.

(2) The specific designations required for gasoline-related products specified in § 1090.1110 or distillate-related products specified in § 1090.1115.

(b) *Use of codes.* Except for transfers to truck carriers, retailers, or WPCs, product codes may be used to convey the information required under this subpart, if such codes are clearly understood by each transferee.

§ 1090.1155 PTD requirements for exempted fuels.

(a) In addition to the information required under § 1090.1150, on each occasion when any person transfers custody or title to any exempted fuel under subpart G of this part, the transferor must provide to the transferee PTDs that include the following statements, as applicable:

(1) *National security exemption language.* For fuels with a national security exemption specified in § 1090.605: ''This fuel is for use in

vehicles, engines, or equipment under an EPA-approved national security exemption only.''

(2) *R&D exemption language.* For fuels used for an R&D purpose specified in § 1090.610: ''For use in research, development, and test programs only.''

(3) *Racing fuel language.* For fuels used for racing purposes specified in § 1090.615: ''This fuel is for racing purposes only.''

(4) *Aviation fuel language.* For fuels used in aircraft specified in § 1090.615: ''This fuel is for aviation use only.''

(5) *Territory fuel exemption language.* For fuels for use in American Samoa, Guam, or the Commonwealth of the Northern Mariana Islands specified in § 1090.620: ''This fuel is for use only in Guam, American Samoa, or the Northern Mariana Islands.''

(6) *California gasoline language.* For California gasoline specified in § 1090.625: ''California gasoline''.

(7) *California diesel language.* For California diesel specified in § 1090.625: ''California diesel''.

(8) *Alaska, Hawaii, Puerto Rico, and U.S. Virgin Islands summer gasoline language.* For summer gasoline for use in Alaska, Hawaii, Puerto Rico, or the U.S. Virgin Islands specified in § 1090.630: ''This summer gasoline is for use only in Alaska, Hawaii, Puerto Rico, or the U.S. Virgin Islands.''

(9) *Exported fuel language.* For exported fuels specified in § 1090.645: ''This fuel is for export from the United States only.''

(b) In statements required by paragraph (a) of this section, where ''fuel'' is designated in a statement, the specific fuel type (for example, ''diesel fuel'' or ''gasoline'') may be used in place of the word ''fuel''.

§ 1090.1160 Gasoline, gasoline additive, and gasoline regulated blendstock PTD provisions.

(a) *General requirements.* For each occasion that any person transfers custody of any gasoline, gasoline additive, or gasoline regulated blendstock, the transferor must provide the transferee PTDs that include the following information:

(1) All applicable information required under § 1090.1150 and this section.

(2) An accurate and clear statement of the applicable designation of the gasoline, gasoline additive, or gasoline regulated blendstock under § 1090.1110.

(b) *BOB language requirements.* For batches of BOB, in addition to the information required under paragraph (a) of this section, the following information must be included on the PTD:

(1) *Oxygenate type(s) and amount(s).* Statements specifying each oxygenate type and amount (or range of amounts) that the fuel manufacturer certified a hand blend under § 1090.710 for the BOB.

(2) *Summer BOB language requirements.* Except as specified in paragraph (b)(2)(iv) of this section, for batches of summer BOB, identification of the product with one of the following statements indicating the applicable RVP standard in § 1090.215.

(i) ''9.0 psi CBOB. This product does not meet the requirements for summer reformulated gasoline.''

(ii) ''7.8 psi CBOB. This product does not meet the requirements for summer reformulated gasoline.''

(iii) ''RBOB. This product meets the requirements for summer reformulated or conventional gasoline.''

(iv) For BOBs designed to produce a finished gasoline that must meet an RVP per-gallon standard required by any SIP approved or promulgated under 42 U.S.C. § 7410 or § 7502, additional or substitute language to satisfy the state program may be used as necessary but must include at a minimum the applicable RVP standard established under the SIP.

(c) *RFG and CG requirements.* For batches of RFG and CG, in addition to the information required under paragraph (a) of this section, the following information must be included on the PTD:

(1) *Summer gasoline language requirements.* (i) Except as specified in paragraph (c)(1)(ii) of this section, for summer gasoline, identification of the product with one of the following statements indicating the applicable RVP standard:

(A) For gasoline that meets the 9.0 psi RVP standard in § 1090.215(a): ''9.0 psi Gasoline.''

(B) For gasoline that meets the 7.8 psi RVP standard in § 1090.215(a)(1): ''7.8 psi Gasoline.''

(C) For gasoline that meets the RFG 7.4 psi RVP standard in § 1090.215(a)(2): ''Reformulated Gasoline.''

(ii) For finished gasoline that meets an RVP per-gallon standard required by any SIP approved or promulgated under 42 U.S.C. § 7410 or 7502, additional or substitute language to satisfy the state program may be used as necessary.

(2) *Ethanol content language requirements.* (i) For gasoline-ethanol blends, one of the following statements that accurately describes the gasoline:

(A) For gasoline containing no ethanol (''E0''), the following statement: ''E0: Contains no ethanol.''

(B) For finished gasoline containing less than 9 volume percent ethanol, the following statement: ''EX—Contains up to X% ethanol.'' The term X refers to the maximum volume percent ethanol present in the gasoline-ethanol blend.

(C) For E10, the following statement: ''E10: Contains between 9 and 10 vol % ethanol.''

(D) For E15, the following statement: ''E15: Contains up to 15 vol % ethanol.''

(E) For gasoline-ethanol blends containing more than 15 volume percent ethanol, the following statement: ''EXX: Contains up to XX vol % ethanol.'' The term XX refers to the maximum volume percent ethanol present in the gasoline-ethanol blend.

(ii) No person may designate a fuel as E10 if the fuel is produced by blending ethanol and gasoline in a manner designed to contain less than 9.0 or more than 10.0 volume percent ethanol.

(iii) No person may designate a fuel as E15 if the fuel is produced by blending ethanol and gasoline in a manner designed to contain less than 10.0 or more than 15.0 volume percent ethanol.

(d) *Oxygenate language requirements.* In addition to any other PTD requirements of this subpart, on each occasion when any person transfers custody or title to any oxygenate upstream of any oxygenate blending facility, the transferor must provide to the transferee PTDs that include the following information, as applicable:

(1) For DFE: ''Denatured fuel ethanol, maximum 10 ppm sulfur.''

(2) For other oxygenates, the name of the specific oxygenate must be identified on the PTD, followed by ''maximum 10 ppm sulfur.'' For example, for isobutanol, the following statement on the PTD would be required, ''Isobutanol, maximum 10 ppm sulfur.''

(e) *Gasoline detergent language requirements.* In addition to any other PTD requirements of this subpart, on each occasion when any person transfers custody or title to any gasoline detergent, the transferor must provide to the transferee PTDs that include the following information:

(1) The identity of the product being transferred as detergent, detergent-additized gasoline, or non-additized detergent gasoline.

(2) The name of the registered detergent must be used to identify the detergent additive package on its PTD and the LAC on the PTD must be consistent with the requirements in § 1090.240.

(f) *Gasoline additives language requirements.* In addition to any other PTD requirements of this subpart, on each occasion when any person transfers custody or title to any gasoline additive that meets the requirements of

§ 1090.255(a), the transferor must provide to the transferee PTDs that include all the following information:

(1) The maximum allowed treatment rate of the additive so that the additive will contribute no more than 3 ppm sulfur to the finished gasoline.

(2) [Reserved].

(g) *Certified ethanol denaturant language requirements.* In addition to any other PTD requirements of this subpart, on each occasion when any person transfers custody or title to any certified ethanol denaturant that meets the requirements of § 1090.235(b), the transferor must provide to the transferee PTDs that include all the following information:

(1) The following statement: ''Certified Ethanol Denaturant suitable for use in the manufacture of denatured fuel ethanol meeting EPA standards.''

(2) The PTD must state that the sulfur content is 330 ppm or less. If the certified ethanol denaturant manufacturer represents a batch of denaturant as having a maximum sulfur content lower than 330 ppm, the PTD must instead state that lower sulfur maximum (*e.g.,* has a sulfur content of 120 ppm or less).

(h) *Butane and pentane language requirements.* (1) In addition to any other PTD requirements of this subpart, on each occasion when any person transfers custody or title to any certified butane or certified pentane, the transferor must provide to the transferee PTDs that include the following information:

(i) The certified butane or certified pentane producer company name and facility registration number issued by EPA.

(ii) One of the following statements, as applicable:

(A) ''Certified pentane for use by certified pentane blenders''.

(B) ''Certified butane for use by certified butane blenders''.

(2) PTDs that are compliant with the requirements of paragraph (h)(1) of this section must be transferred from each party transferring certified butane or certified pentane for use by certified butane or certified pentane blenders to each party that receives the certified butane or certified pentane through to the certified butane or certified pentane blender, respectively.

§ 1090.1165 PTD requirements for distillate and residual fuels.

(a) *General requirements.* For each occasion that any person transfers custody of any distillate or residual fuel, the transferor must provide the transferee PTDs that include the following information:

(1) The sulfur per-gallon standard that the transferor represents the fuel to meet under subpart D of this part (*e.g.,* 15 ppm sulfur for ULSD or 1,000 ppm sulfur for ECA marine fuel).

(2) An accurate and clear statement of the applicable designation(s) of the fuel under § 1090.1115 (*e.g.,* ''ULSD'', ''500 ppm LM diesel fuel'', or ''ECA marine fuel'').

(3) If the fuel does not meet the ULSD sulfur standard in § 1090.305(b), the following statement: ''Not for use in highway vehicles or engines or nonroad, locomotive, or marine engines.''

(b) *500 ppm LM diesel fuel language requirements.* For batches of 500 ppm LM diesel fuel, in addition to the information required under paragraph (a) of this section, the following information must be included on the PTD:

(1) The following statement: ''500 ppm sulfur (maximum) LM diesel fuel. For use only in accordance with a compliance plan under 40 CFR 1090.520(g). Not for use in highway vehicles or other nonroad vehicles and engines.''

(2) [Reserved]

(c) *ECA marine fuel language requirements.* For batches of ECA marine fuel, in addition to the information required under paragraph (a) of this section, the following information must be included on the PTD:

(1) The following statement: ''1,000 ppm sulfur (maximum) ECA marine fuel. For use in Category 3 marine vessels only. Not for use in Category 1 or Category 2 marine vessels.''

(2) Parties may replace the required statement in paragraph (c)(1) of this section with the following statement for qualifying vessels under 40 CFR part 1043: ''High sulfur fuel. For use only in ships as allowed by MARPOL Annex VI, Regulation 3 or Regulation 4.''

(3) Under 40 CFR 1043.80, fuel suppliers (*i.e.,* ECA marine fuel distributors, retailers, and WPCs) must provide bunker delivery notes to vessel operators in addition to any applicable PTD requirements under this subpart.

(d) *Distillate global marine fuel language requirements.* For batches of distillate global marine fuel, in addition to the information required under paragraph (a) of this section, the following information must be included on the PTD:

(1) The following statement: ''For use only in steamships or Category 3 marine vessels outside of an Emission Control Area (ECA), consistent with MARPOL Annex VI.''

(2) [Reserved]

§ 1090.1170 Diesel fuel additives language requirements.

In addition to any other PTD requirements in this subpart, on each occasion that any person transfers custody or title to a diesel fuel additive that is subject to the provisions of § 1090.310 to a party in the additive distribution system or in the diesel fuel distribution system for use downstream of the diesel fuel manufacturing facility, the transferor must provide to the transferee PTDs that include the following information:

(a) For diesel fuel additives that comply with the sulfur standard in § 1090.310(a), include the following statement: ''The sulfur content of this diesel fuel additive does not exceed 15 ppm.''

(b) For diesel fuel additives that meet the requirements of § 1090.310(b), the transferor must provide to the transferee documents that identify the additive as such, and do all the following:

(1) Indicate the high sulfur potential of the diesel fuel additive by including the following statement: ''This diesel fuel additive may exceed the federal 15 ppm sulfur standard. Improper use of this additive may result in non-compliant diesel fuel.''

(2) If the diesel fuel additive package contains a static dissipater additive or red dye having a sulfur content greater than 15 ppm, one of the following statements must be included that accurately describes the contents of the additive package:

(i) ''This diesel fuel additive contains a static dissipater additive having a sulfur content greater than 15 ppm.''

(ii) ''This diesel fuel additive contains red dye having a sulfur content greater than 15 ppm.''

(iii) ''This diesel fuel additive contains a static dissipater additive and red dye having a sulfur content greater than 15 ppm.''

(3) Include the following information:

(i) The diesel fuel additive package's maximum sulfur concentration.

(ii) The maximum recommended concentration for use of the diesel fuel additive package in diesel fuel, in volume percent.

(iii) The contribution to the sulfur level of the fuel (in ppm) that would result if the diesel fuel additive package is used at the maximum recommended concentration.

(c) For diesel fuel additives that are sold in containers for use by the ultimate consumer of diesel fuel, each transferor must display on the additive container, in a legible and conspicuous manner, one of the following statements, as applicable:

(1) For diesel fuel additives that comply with the sulfur standard in § 1090.310(a), ''This diesel fuel additive complies with the federal low sulfur content requirements for use in diesel motor vehicles and nonroad engines.''

(2) For diesel fuel additives that do not comply with the sulfur standard in § 1090.310(a), the following statement: ''This diesel fuel additive does not comply with federal ultra-low sulfur content requirements.''

§ 1090.1175 Alternative PTD language provisions.

(a) Alternative PTD language to the language specified in this subpart may be used if approved by EPA in advance. Such language must contain all the applicable informational elements specified in this subpart.

(b) Requests for alternative PTD language must be submitted as specified in § 1090.10.

Subpart L—Recordkeeping

§ 1090.1200 General recordkeeping requirements.

(a) *Length of time records must be kept.* Records required by this part must be kept for 5 years from the date they were created, except that records relating to credit transfers must be kept by the transferor for 5 years from the date the credits were transferred and must be kept by the transferee for 5 years from the date the credits were transferred, used, or terminated, whichever is later.

(b) *Make records available to EPA.* On request by EPA, the records specified in this part must be provided to EPA. For records that are electronically generated or maintained, the equipment and software necessary to read the records must be made available, or upon approval by EPA, electronic records must be converted to paper documents that must be provided to EPA.

§ 1090.1205 Recordkeeping requirements for all regulated parties.

(a) *Overview.* Any party subject to the requirements and provisions of this part must keep records containing the information specified in this section.

(b) *Records related to PTDs.* Any party that transfers title or custody of any fuel, fuel additive, or regulated blendstock must maintain the PTDs for which the party is the transferor or transferee.

(c) *Records related to sampling and testing.* Any party required to perform any sampling and testing on any fuel, fuel additive, or regulated blendstock must keep records of the following:

(1) The location, date, time, and storage tank or truck, rail car, or vessel identification for each sample collected.

(2) The identification of the person(s) who collected the sample and the person(s) who performed the testing.

(3) The results of all tests as originally printed by the testing apparatus, or where no printed result is produced, the results as originally recorded by the person or apparatus that performed the test. Where more than one test is performed, keep all the results.

(4) The methodology used to test any parameter under this part.

(5) Records related to performance-based measurement and statistical quality control under §§ 1090.1360 through 1090.1375.

(6) Records related to gasoline deposit control testing under § 1090.1395.

(7) The actions taken to stop the sale of any fuel, fuel additive, or regulated blendstock found not to be in compliance with applicable standards under this part, and the actions taken to identify the cause of any noncompliance and prevent future instances of noncompliance.

(d) *Records related to registration.* For parties required to register under subpart I of this part, the party must maintain records supporting the information required to complete and maintain the registration for the party's company and each registered facility. The party must also maintain copies of any confirmation received from the submission of such registration information to EPA.

(e) *Records related to reporting.* For parties required to submit reports under subpart J of this part, the party must maintain copies of all reports submitted to EPA. The party must also maintain copies of any confirmation received from the submission of such reports to EPA.

(f) *Records related to exemptions.* Anyone that produces or distributes exempt fuel, fuel additive, or regulated blendstock under subpart G of this part must keep the following records:

(1) Designation of the fuel, fuel additive, or regulated blendstock under subparts G and K of this part.

(2) Copies of PTDs generated or accompanying the exempted fuel, fuel additive, or regulated blendstock.

(3) Records demonstrating that the exempt fuel, fuel additive, or regulated blendstock was actually used in accordance with the requirements of the applicable exemption(s) under subpart G of this part.

§ 1090.1210 Recordkeeping requirements for gasoline manufacturers.

(a) *Overview.* In addition to the requirements in § 1090.1205, gasoline manufacturers must keep records for each of their facilities that include the information in this section.

(b) *Batch records.* For each batch of gasoline, gasoline manufacturers must keep records of the following information:

(1) The results of tests, including any calculations necessary to transcribe or correlate test results into reported values under subpart J of this part, performed to determine gasoline properties and characteristics as specified in subpart M of this part.

(2) The batch volume.

(3) The batch number.

(4) The date the batch was produced or imported.

(5) The designation of the batch under § 1090.1110.

(6) The PTDs for any gasoline produced or imported.

(7) The PTDs for any gasoline received.

(c) *Downstream oxygenate accounting records.* For BOB certified for including in downstream oxygenate accounting under § 1090.710, gasoline manufacturers must keep records of the following information:

(1) The test results for hand blends prepared under § 1090.1340.

(2) Records that demonstrate that the gasoline manufacturer participates in the national fuels survey program under subpart N of this part.

(3) Records that demonstrate that the gasoline manufacturer participates in the national sampling oversight program under § 1090.1440.

(4) Compliance calculations specified in § 1090.700 based on an assumed addition of oxygenate.

(d) *Records for PCG.* For new batches of gasoline produced by adding blendstock to PCG, gasoline manufacturers must keep records of the following information:

(1) Records that reflect the storage and movement of the PCG and blendstock within the fuel manufacturing facility to the point such PCG is used to produce gasoline or BOB.

(2) For new batches of gasoline produced by adding blendstock to PCG under § 1090.1320(a)(1), keep records of the following additional information:

(i) The results of tests to determine the sulfur content, benzene content, RVP in the summer, and oxygenate(s) content for the PCG and volume of the PCG when received at the fuel manufacturing facility.

(ii) Records demonstrating which batches of PCG were used in each new batch of gasoline.

(iii) Records demonstrating which, if any, blendstocks were used in each new batch of gasoline.

(iv) Records of the test results for sulfur content, benzene content, RVP in the summer, oxygenate(s) content, and distillation parameters for each new batch of gasoline.

(3) For new batches of gasoline produced by adding blendstock to PCG under § 1090.1320(a)(2), keep records of the following additional information:

(i) Records of the test results for sulfur content, benzene content, RVP in the summer, and oxygenate(s) content of each blendstock used to produce the new batch of gasoline.

(ii) Records of the test results for sulfur content and RVP in the summer of each new batch of gasoline.

(iii) Records demonstrating which, if any, blendstocks were used in each new batch of gasoline.

(e) *Records for certified butane and certified pentane blenders.* For certified butane or certified pentane blended into gasoline or BOB under § 1090.1320, certified butane and certified pentane blenders must keep records of the following information:

(1) The volume of certified butane or certified pentane added.

(2) The volume of gasoline prior to and after the certified butane or certified pentane blending.

(3) The purity and properties of the certified butane or certified pentane specified in § 1090.220 or § 1090.225, respectively.

(f) *Records for the importation of gasoline treated as blendstock.* For any imported GTAB, importers must keep records of documents that reflect the storage and physical movement of the GTAB from the point of importation to the point of blending to produce gasoline.

(g) *Records related to ABT.* Gasoline manufacturers must keep records of the following information related to their ABT activities under subpart H of this part, as applicable:

(1) Compliance sulfur values and compliance benzene values under § 1090.700, and the calculations used to determine those values.

(2) The number of valid credits in possession of the gasoline manufacturer at the beginning of each compliance period, separately by facility and compliance period of generation.

(3) The number of credits generated by the gasoline manufacturer under § 1090.725, separately by facility and compliance period of generation.

(4) If any credits were obtained from or transferred to other parties, all the following for each other party:

(i) The party's name.

(ii) The party's EPA company and facility registration numbers.

(iii) The number of credits obtained from or transferred to the party.

(5) The number of credits that expired at the end of each compliance period, separately by facility and compliance period of generation.

(6) The number of credits that will be carried over into the next compliance period, separately by facility and compliance period of generation.

(7) The number of credits used, separately by facility and compliance period of generation.

(8) Contracts or other commercial documents that establish each transfer of credits from the transferor to the transferee.

(9) Documentation that supports the number of credits transferred between facilities within the same company (*i.e.,* intracompany transfers).

§ 1090.1215 Recordkeeping requirements for diesel fuel and ECA marine fuel manufacturers.

(a) *Overview.* In addition to the requirements in § 1090.1205, diesel fuel and ECA marine fuel manufacturers must keep records for each of their facilities that include the information in this section.

(b) *Batch records.* For each batch of ULSD, 500 ppm LM diesel fuel, or ECA marine fuel, diesel fuel and ECA marine fuel manufacturers must keep records of the following information:

(1) The batch volume.

(2) The batch number.

(3) The date the batch was produced or imported.

(4) The designation of the batch under § 1090.1115.

(5) All documents and information created or used for the purpose of batch designation under § 1090.1115, including PTDs for the batch.

(c) *Distillate global marine fuel.* For each batch of distillate global marine fuel, distillate global marine fuel manufacturers must keep records of the following information:

(1) The designation of the batch as distillate global marine fuel.

(2) The PTD for the batch.

§ 1090.1220 Recordkeeping requirements for oxygenate blenders.

(a) In addition to the requirements in § 1090.1205, oxygenate blenders that blend oxygenate into gasoline must keep records that include the information in this section.

(b) For each occasion that an oxygenate blender blends oxygenate into gasoline, oxygenate blenders must keep records of the following information:

(1) The date, time, location, and identification of the blending tank or truck in which the blending occurred.

(2) The volume and oxygenate requirement of the gasoline to which oxygenate was added.

(3) The volume, type, and purity of the oxygenate that was added, and documents that show the supplier(s) of the oxygenate used.

§ 1090.1225 Recordkeeping requirements for gasoline additives.

(a) *Gasoline additive producers and importers.* In addition to the requirements in § 1090.1205, gasoline additive manufacturers must keep records of the following information for each batch of additive produced or imported:

(1) The batch volume.

(2) The date the batch was produced or imported.

(3) The PTD for the batch.

(4) The maximum recommended treatment rate.

(5) The gasoline additive manufacturer's control practices that demonstrate that the additive will contribute no more than 3 ppm on a per-gallon basis to the sulfur content of gasoline when used at the maximum recommended treatment rate.

(b) *Records that parties that take custody of gasoline additives in the gasoline additive distribution system must keep.* Except for gasoline additives packaged for addition to gasoline in the vehicle fuel tank, all parties that take custody of gasoline additives for bulk addition to gasoline—from the producer through to the party that adds the additive to gasoline—must keep records of the following information:

(1) The PTD for each batch of gasoline additive.

(2) The treatment rate at which the additive was added to gasoline, as applicable.

(3) The volume of gasoline that was treated with the additive, as applicable. A new record must be initiated in cases where a new batch of additive is mixed into a storage tank from which the additive is drawn to be injected into gasoline.

§ 1090.1230 Recordkeeping requirements for oxygenate producers.

(a) *Oxygenate producers.* In addition to the requirements in § 1090.1205, oxygenate producers must keep records of the following information for each batch of oxygenate:

(1) The batch volume.

(2) The batch number.

(3) The date the batch was produced or imported.

(4) The PTD for the batch.

(5) The sulfur content of the batch.

(6) The sampling and testing records specified in § 1090.1205(c), if the sulfur

content of the batch was determined by analytical testing.

(b) *DFE producers.* In addition to the requirements in paragraph (a) of this section, DFE producers must keep records of the following information for each batch of DFE if the sulfur content of the batch was determined under § 1090.1330:

(1) The name and title of the person who calculated the sulfur content of the batch.

(2) The date the calculation was performed.

(3) The calculated sulfur content.

(4) The sulfur content of the neat (un-denatured) ethanol.

(5) The date each batch of neat ethanol was produced.

(6) The neat ethanol batch number.

(7) The neat ethanol batch volume.

(8) As applicable, the neat ethanol production quality control records, or the test results on the neat ethanol, including all the following:

(i) The location, date, time, and storage tank or truck identification for each sample collected.

(ii) The name and title of the person who collected the sample and the person who performed the test.

(iii) The results of the test as originally printed by the testing apparatus, or where no printed result is produced, the results as originally recorded by the person who performed the test.

(iv) Any record that contains a test result for the sample that is not identical to the result recorded in paragraph (b)(8)(iii) of this section.

(v) The test methodology used.

(9) The sulfur content of each batch of denaturant used, and the volume percent at which the denaturant was added to neat (un-denatured) ethanol to produce DFE.

(10) The PTD for each batch of denaturant used.

(c) *Records that parties that take custody of oxygenate in the oxygenate distribution system must keep.* All parties that take custody of oxygenate—from the oxygenate producer through to the oxygenate blender—must keep records of the PTD for each batch of oxygenate.

§ 1090.1235 Recordkeeping requirements for ethanol denaturant.

(a) *Certified ethanol denaturant producers.* In addition to the requirements in § 1090.1205, certified ethanol denaturant producers must keep records of the following information for each batch of certified ethanol denaturant:

(1) The batch volume.

(2) The batch number.

(3) The date the batch was produced or imported.

(4) The PTD for the batch.

(5) The sulfur content of the batch.

(b) *Parties that take custody of ethanol denaturants.* All parties that take custody of denaturant designated as suitable for use in the production of DFE under § 1090.230(b) must keep records of the following information:

(1) The PTD for each batch of denaturant.

(2) The volume percent at which the denaturant was added to ethanol, as applicable.

§ 1090.1240 Recordkeeping requirements for gasoline detergent blenders.

(a) *Overview.* In addition to the requirements in § 1090.1205, gasoline detergent blenders must keep records that include the information in this section.

(b) *Gasoline detergent blenders.* Gasoline detergent blenders must keep records of the following information:

(1) The PTD for each detergent used.

(2) For automated detergent blending facilities, keep records of the following information:

(i) The dates of the VAR Period.

(ii) The total volume of detergent blended into gasoline, as determined using one of the following methods, as applicable:

(A) For facilities that use in-line meters to measure the amount of detergent blended, the total volume of detergent measured, together with supporting data that includes one of the following:

(*1*) The beginning and ending meter readings for each meter being measured.

(*2*) Other comparable metered measurements.

(B) For facilities that use a gauge to measure the inventory of the detergent storage tank, the total volume of detergent must be calculated as follows:

$$V_D = DI_i - DI_f + DI_a - DI_w$$

Where:

V_D = Volume of detergent.

DI_i = Initial detergent inventory of the tank.

DI_f = Final detergent inventory of the tank.

DI_a = Sum of any additions to detergent inventory.

DI_w = Sum of any withdrawals from detergent inventory for purposes other than the additization of gasoline.

(C) The value of each variable in the equation in paragraph (b)(2)(ii)(B) of this section must be separately recorded. Recorded volumes of detergent must be expressed to the nearest gallon (or smaller units), except that detergent volumes of five gallons or less must be expressed to the nearest tenth of a gallon (or smaller units). However, if the blender's equipment is unable to accurately measure to the nearest tenth of a gallon, then such volumes must be rounded downward to the next lower gallon.

(iii) The total volume of gasoline to which detergent has been added, together with supporting data that includes one of the following:

(A) The beginning and ending meter measurements for each meter being measured.

(B) The metered batch volume measurements for each meter being measured.

(C) Other comparable metered measurements.

(iv) The actual detergent concentration, calculated as the total volume of the detergent added (as determined under paragraph (b)(2)(ii) of this section) divided by the total volume of gasoline (as determined under paragraph (b)(2)(iii) of this section). The concentration must be calculated and recorded to four digits and rounded as specified in § 1090.50.

(v) The initial detergent concentration rate, together with the date and description of each adjustment to any initially set concentration.

(vi) If the detergent injector is set below the applicable LAC, or adjusted by more than 10 percent above the concentration initially set in the VAR Period, documentation establishing that the purpose of the change is to correct a batch misadditization prior to the end of the VAR Period and prior to the transfer of the batch to another party or to correct an equipment malfunction and the date and adjustments of the correction.

(vii) Documentation reflecting the performance and results of the calibration of detergent equipment under § 1090.1390.

(3) For non-automated detergent blending facilities, keep records of the following information:

(i) The date of additization.

(ii) The volume of added detergent.

(iii) The volume of gasoline to which the detergent was added.

(iv) The actual detergent concentration, calculated as the volume of added detergent (as determined under paragraph (b)(3)(ii) of this section) divided by the volume of gasoline (as determined under paragraph (b)(3)(iii) of this section). The concentration must be calculated and recorded to four digits and rounded as specified in § 1090.50.

§ 1090.1245 Recordkeeping requirements for independent surveyors.

(a) In addition to the requirements in § 1090.1205, independent surveyors must keep records that include the information in this section.

(b) Independent surveyors must keep records of the following information, as applicable:

(1) Records related to the national fuels survey program under § 1090.1405.

(2) Records related to a geographically-focused E15 survey program under § 1090.1420(b).

(3) Records related to the national sampling oversight program under § 1090.1440.

§ 1090.1250 Recordkeeping requirements for auditors.

(a) In addition to the requirements in § 1090.1205, auditors must keep records that include the information in this section.

(b) Auditors must keep records of the following information:

(1) Documents pertaining to the performance of each audit performed under subpart R of this part.

(2) Copies of each attestation report prepared and all related records developed to prepare the attestation report.

(c) Auditors must keep the records specified in paragraph (b) of this section for 5 years after issuing each attestation report.

§ 1090.1255 Recordkeeping requirements for transmix processors, transmix blenders, transmix distributors, and pipeline operators.

(a) In addition to the requirements in § 1090.1205, transmix processors, transmix blenders, transmix distributors, and pipeline operators must keep records that include the information in this section.

(b) Transmix processors and transmix distributors must keep records that reflect the results of any sampling and testing required under subpart F or M of this part.

(c) Pipeline operators must keep records that demonstrate compliance with the interface handling practices in § 1090.525.

(d) Transmix processors must keep records showing the volumes of TGP recovered from transmix and the type and amount of any blendstock or PCG added to make gasoline from TGP under § 1090.510.

(e) Transmix blenders must keep records showing compliance with the quality assurance program and/or sampling and testing requirements in § 1090.505, and for each batch of gasoline with which transmix is blended, the volume of the batch, and the volume of transmix blended into the batch.

(f) Manufacturers and distributors of 500 ppm LM diesel fuel using transmix must keep records of the following information, as applicable:

(1) Copies of the compliance plan required under § 1090.520(g).

(2) Documents demonstrating how the party complies with each applicable element of the compliance plan under § 1090.520(g).

(3) Documents and copies of calculations used to determine compliance with the 500 ppm LM diesel fuel volume requirements under § 1090.520(c).

(4) Documents or information that demonstrates that the 500 ppm LM diesel fuel was only used in locomotive and marine engines that are not required to use ULSD under 40 CFR 1033.815 and 40 CFR 1042.660, respectively.

Subpart M—Sampling, Testing, and Retention

§ 1090.1300 General provisions.

(a) This subpart is organized as follows:

(1) Sections 1090.1310 through 1090.1330 specify the scope of required testing, including special provisions that apply in several unique circumstances.

(2) Sections 1090.1335 through 1090.1345 specify handling procedures for collecting and retaining samples. Sections 1090.1350 through 1090.1375 specify the procedures for measuring the specified parameters. These procedures apply to anyone who performs testing under this subpart.

(3) Section 1090.1390 specifies the requirements for calibrating automated detergent blending equipment.

(4) Section 1090.1395 specifies the procedures for testing related to gasoline deposit control test procedure.

(b) If you need to meet requirements for a quality assurance program at some minimum frequency, your first batch of product triggers the testing requirement. The specified frequency serves as a deadline for performing the required testing, and as a starting point for the next testing period. The following examples illustrate the requirements for testing based on sampling the more frequent of every 90 days or 500,000 gallons of certified butane you received from a supplier:

(1) If your testing period starts on March 1 and you use less than 500,000 gallons of butane from March 1 through May 29 (90 days), you must perform testing under a quality assurance program sometime between March 1 and May 29. Your next test period starts with the use of butane on May 30 and again ends after 90 days or after you use 500,000 gallons of butane, whichever occurs first.

(2) If your testing period starts on March 1 and you use 500,000 gallons of butane for the testing period on April 29 (60 days), you must perform testing under a quality assurance program sometime between March 1 and April 29. Your next testing period starts with the use of butane on April 30 and again ends after 90 days or after you use 500,000 gallons of butane, whichever occurs first.

(c) Anyone performing tests on behalf of a manufacturer to demonstrate compliance with standards or other requirements under this part must meet the requirements of this subpart in the same way that the manufacturer needs to meet requirements for its own testing.

(d) Anyone performing tests under this subpart must apply good laboratory practices for all sampling, measurement, and calculations related to testing required under this part. This requires performing these procedures in a way that is consistent with generally accepted scientific and engineering principles and properly accounting for all available relevant information.

(e) Subpart P of this part has provisions related to importation, including provisions that describe how to meet the sampling and testing requirements of this subpart.

(f) The following general provisions apply:

(1) A crosscheck program is an arrangement for laboratories to perform measurements from test samples prepared from a single homogeneous fuel batch to establish an accepted reference value for evaluating precision and accuracy. This subpart relies on inter-laboratory crosscheck programs sponsored by ASTM International or another voluntary consensus standards body, or on crosscheck programs conducted separately by one or more companies.

(2) A voluntary consensus standards body (VCSB) is an organization that follows consistent protocols to adopt standards reflecting a wide range of input from interested parties. ASTM International and the International Organization for Standardization are examples of VCSB organizations.

Scope of Testing

§ 1090.1310 Testing to demonstrate compliance with standards.

(a) Perform testing as needed to submit the reports specified in subpart J of this part. This section specifies additional test requirements.

(b) Fuel manufacturers must perform the following measurements before the fuel, fuel additive, or regulated blendstock from a given batch leaves the fuel manufacturing facility, except as specified in § 1090.1315:

(1) *Diesel fuel.* Perform testing for each batch of ULSD, 500 ppm LM diesel fuel, and ECA marine fuel to demonstrate compliance with sulfur standards.

(2) *Gasoline.* Perform testing for each batch of gasoline to demonstrate compliance with sulfur and benzene standards and perform testing for each batch of summer gasoline to demonstrate compliance with RVP standards.

(c) The following testing provisions apply for gasoline and gasoline regulated blendstock:

(1) Gasoline manufacturers producing BOB must prepare a hand blend as specified in § 1090.1340 and perform the following measurements:

(i) For Summer CG, measure RVP in the BOB.

(ii) For Summer RFG, measure RVP in the hand blend.

(iii) Measure the sulfur content of both the BOB and the hand blend.

(iv) Measure the benzene content of the hand blend.

(2) Oxygenate producers must measure the sulfur content of each batch of oxygenate, except that DFE producers may meet the alternative requirements in § 1090.1330.

(3) Ethanol denaturant producers that certify denaturant under § 1090.1330 must measure the sulfur content of each batch of denaturant.

(4) Certified butane and certified pentane producers must perform sampling and testing to demonstrate compliance with purity specifications and sulfur and benzene standards as specified in § 1090.1320.

(5) Transmix processors producing gasoline from TGP must test each batch of gasoline for parameters required to demonstrate compliance with § 1090.510 as specified in § 1090.1325.

(d) Blending manufacturers producing gasoline by adding blendstock to PCG must comply with § 1090.1320.

(e) For gasoline produced at a fuel blending facility or a transmix processing facility, gasoline manufacturers must measure such gasoline for oxygenate and for distillation parameters (*i.e.,* T10, T50, T90, final boiling point, and percent residue) in addition to other measurements to demonstrate compliance with applicable standards.

§ 1090.1315 In-line blending.

Fuel manufacturers using in-line blending equipment may qualify for a waiver from the requirement in § 1090.1310(b) to test every batch of fuel before the fuel leaves the fuel manufacturing facility as follows:

(a) The waiver in this section applies if you use or intend to use in-line blending equipment to supply fuel directly into a pipeline, marine vessel, or other type of distribution that does not involve collecting fuel in a tank or other type of storage for creating a batch of fuel. It also applies for fuel manufacturers that produce batches of fuel that are too large to contain in available storage tanks.

(b) Waivers granted under 40 CFR part 80 are no longer valid. Any party who received an in-line blending waiver granted under 40 CFR part 80 may continue to operate under the waiver until January 1, 2022. To obtain a waiver under this part, submit a request signed by the RCO to EPA with the following information:

(1) Describe the location of your in-line blending operation, how long it has been in operation, and how much of each type and grade of fuel you have blended over the preceding 3 years (or since starting the in-line blending operation if that is less than 3 years). Describe the physical layout of the blending operation and how you move the blended fuel into distribution. Also describe how your automated system monitors and controls blending proportions and the properties of the blended fuel. For new installations, describe these as a planned operation with projected volumes by type and grade.

(2) Describe how you collect and test composite fuel samples in a way that is equivalent to measuring the fuel properties of a batch of blended fuel as specified in this subpart. Your procedures need to conform to the sampling specifications in ASTM D4177 and the composite calculations in ASTM D5854 (both incorporated by reference in § 1090.95).

(3) Describe any expectation or plan for you or another party to perform additional downstream testing for the same fuel parameters.

(4) Describe your quality assurance procedures. Describe any experiences from the previous 3 years where these quality assurance procedures led you to make corrections to your in-line blending operation.

(5) Describe any times from the previous 3 years that you modified fuel after it came out of your blending operation. Describe how you modified the fuel and why that was necessary.

(6) Describe how you will meet the auditing requirements of paragraph (c) of this section.

(c) You must arrange for an audit of your blending operation each calendar year that reviews procedures and documents to determine whether measured and calculated values properly represent the aggregate fuel properties for the blended fuel.

(d) You must update your in-line blending waiver request 60 days prior to making any material change to your in-line blending process.

(e) If EPA approves your request for a waiver under this section, you may need to update your procedures for more effective control and documentation of measured fuel parameters based on audit results, development of improved practices, or other information.

§ 1090.1320 Adding blendstock to PCG.

The requirements of this section apply for refiners and blending manufacturers that add blendstock to PCG to produce a new batch of gasoline. Paragraph (c) of this section specifies an alternative approach for certified butane and certified pentane blenders. Section 1090.1325 describes additional provisions that apply to transmix processors.

(a) Sample and test using one of the following methods to exclude PCG from the compliance demonstration for sulfur and benzene:

(1) *Compliance by subtraction.* (i) Sample and test the sulfur and benzene content of each batch of PCG before blending blendstocks to produce a new batch of gasoline.

(ii) Determine the volume of PCG that was blended with blendstock to produce a new batch of gasoline. Report the PCG as a negative batch as specified in § 1090.905(c)(3)(i).

(iii) After adding blendstock to PCG, sample and test the sulfur and benzene content of the new batch of gasoline.

(iv) Determine the volume of the new batch of gasoline. Report the new batch of gasoline as a positive batch as specified in § 1090.905(c)(3)(ii).

(v) Include the PCG batch and the new batch of gasoline in compliance calculations as specified in § 1090.700(d)(4)(i).

(vi) The sample retention requirements in § 1090.1345 apply for both the new batch of gasoline and the associated PCG.

(2) *Compliance by addition.* (i) Sample and test the sulfur and benzene content of each batch of blendstock used to produce a new batch of gasoline from PCG.

(ii) Determine the volume of each batch of blendstock used to produce the new batch of gasoline.

(iii) Report each batch of blendstock as specified in § 1090.905(c)(4).

(iv) Include each batch of blendstock in compliance calculations as specified in § 1090.700(d)(4)(ii).

(v) The sample retention requirements in § 1090.1345 apply for the new batch of gasoline and for each blendstock.

(b) Regardless of the approach used under paragraph (a) of this section, fuel manufacturers must determine the volume of each blended batch of gasoline, and perform the following measurements for each blended batch of gasoline using the procedures specified in § 1090.1350:

(1) Measure the sulfur content, benzene content, oxygenate content, and for summer gasoline, RVP.

(2) Determine the following distillation parameters: T10, T50, T90, final boiling point, and distillation residue.

(c) Certified butane or certified pentane blenders that blend certified butane or certified pentane into PCG to make a new batch of gasoline may comply with the following requirements instead of the requirements of paragraphs (a) and (b) of this section:

(1) For summer gasoline, measure RVP of the blended fuel. The fuel manufacturer may rely on sulfur and benzene test results from the certified butane or certified pentane producer. Note that § 1090.245(e) disallows adding certified butane and certified pentane to RFG.

(2) Before blending the certified butane or certified pentane with PCG, obtain a copy of the producer's test results indicating that the certified butane or certified pentane meets the standards in § 1090.220 or § 1090.225, respectively.

(3) The certified pentane blender must enter into a contract with the certified pentane producer to verify that the certified pentane producer has an adequate quality assurance program to ensure that the certified pentane received will not be contaminated in transit.

(4) The certified butane or certified pentane blender must conduct a quality assurance program to demonstrate that the certified butane or certified pentane meets the standards specified in § 1090.220 or § 1090.225, respectively. The quality assurance program must be based on sampling the more frequent of every 90 days or 500,000 gallons of certified butane or certified pentane received from each producer. The certified butane or certified pentane blender may rely on a third party to perform the testing.

§ 1090.1325 Adding blendstock to TGP.

The following provisions apply to transmix processors producing gasoline by adding blendstock to TGP:

(a) Perform testing for each batch of summer gasoline to demonstrate compliance with the applicable RVP standard in § 1090.215.

(b) Measure the distillation endpoint for gasoline produced from TGP as specified in § 1090.1350.

(c) Determine the volume, sulfur content, and benzene content of each blendstock batch used to produce gasoline for reporting and compliance calculations by following the sampling and testing requirements in § 1090.1320 and treating the TGP used to produce the gasoline as PCG.

(d) Sample and test the gasoline made from TGP and blendstock to demonstrate compliance with the sulfur per-gallon standard in § 1090.205(b) and the applicable RVP standard in § 1090.215.

(e) Transmix processors producing gasoline by only adding TGP to PCG do not have to measure the benzene content of the finished gasoline. Such transmix processors also do not have to measure the oxygenate content of the finished gasoline if the records for each blendstock show no oxygenate content.

§ 1090.1330 Preparing denatured fuel ethanol.

Instead of measuring every batch, DFE producers and importers may calculate the sulfur content of a batch of DFE as follows:

(a) Determine the sulfur content of ethanol before adding denaturant by measuring it as specified in § 1090.1310 or by estimating it based on your production quality control procedures.

(b) Use the ppm sulfur content of certified ethanol denaturant specified on the PTD for the batch. If the sulfur content is specified as a range, use the maximum specified value.

(c) Calculate the weighted sulfur content of the DFE using the values determined under paragraphs (a) and (b) of this section.

Handling and Preparing Samples

§ 1090.1335 Collecting and preparing samples for testing.

(a) *General provisions.* Use good laboratory practice to collect samples to represent the batch you are testing. For example, take steps to ensure that a batch is always well mixed before sampling. Also, always take steps to prevent sample contamination, such as completely flushing sampling taps and piping and pre-rinsing sample containers with the product being sampled. Follow the procedures in paragraph (b) of this section for manual sampling. Follow the procedures paragraph (c) of this section for automatic sampling. Additional requirements for measuring RVP are specified in paragraph (d) of this section.

(b) *Manual sampling.* Perform manual sampling using one of the methods specified in ASTM D4057 (incorporated by reference in § 1090.95) as follows:

(1) Use tap sampling or spot sampling to collect upper, middle, and lower samples. Adjust spot sampling for partially filled tanks as shown in Table 1 or Table 5 of ASTM D4057 as applicable. For tap sampling, collect samples that most closely match the recommendations in Table 5 of ASTM D4057. If you test more than one sample for a given fuel parameter, calculate the arithmetic average of the test results to represent the batch and use the average result for determining compliance with the standards under this part. Each measured sample must meet all applicable per-gallon standards. If you test only one sample for a given parameter, you must use that test result to represent the batch. You may not use the results from a composite sample to determine compliance with the standards under this part.

(2) Collect a ''running'' or ''all-levels'' sample from the top of the tank. Drawing a sample from a standpipe is acceptable only if it is slotted or perforated to ensure that the drawn sample properly represents the whole batch of fuel.

(3) If the procedures in paragraphs (b)(1) and (2) of this section are impractical for a given storage configuration, you may use alternative sampling procedures as specified in ASTM D4057. This applies primarily for sampling with trucks, railcars, retail stations, and other downstream locations.

(4) Test results with manual sampling are valid only after you demonstrate homogeneity as specified in § 1090.1337, except that the homogeneity testing requirement does not apply in the following cases:

(i) There is only a single sample using the procedures specified in paragraph (b)(1) of this section.

(ii) Upright cylindrical tanks that have a liquid depth (from the tank outlet) less than 10 feet.

(iii) You draw spot or tap samples as specified in paragraph (b)(1) of this section and test each sample for every parameter subject to a testing requirement and use the worst-case test result for each parameter for purposes of reporting, meeting per-gallon and average standards, and all other aspects of compliance.

(iv) Sampling at a downstream location where it is not possible to collect separate samples and you take

steps to ensure that the batch is well mixed.

(c) *Automatic sampling.* Perform automatic sampling as specified in ASTM D4177 (incorporated by reference in § 1090.95). Configure the system to ensure a well-mixed stream at the sampling point. The default sampling frequency should follow the recommended approach of at least 9,604 samples to represent a batch. EPA may approve a less frequent sampling strategy under § 1090.1315(b)(2) if it is appropriate for a given facility or for a small-volume batch. Take steps to align the start and end of sampling with the start and end of creating the batch.

(d) *Sampling provisions related to measuring RVP of summer gasoline.* The following additional provisions apply for preparing samples to measure RVP of summer gasoline:

(1) Meet the additional specifications for manual and automatic sampling in ASTM D5842 (incorporated by reference in § 1090.95).

(2) If you measure RVP for multiple test samples to demonstrate compliance, do not calculate an average result. Rather, each tested sample must meet the applicable RVP standard.

(3) If you measure other fuel parameters for a given sample in addition to RVP testing, always measure RVP first.

§ 1090.1337 Demonstrating homogeneity.

(a) Use the procedures in this section as specified in § 1090.1335 to determine whether a batch is homogeneous and suitable for parameter measurements under this subpart. If the batch is not homogeneous, increase mixing or take other appropriate steps and repeat the procedure.

(b) Draw a sample representing different levels of stored fuel, fuel additive, or regulated blendstock in the tank as specified in § 1090.1335(b)(1).

(c) For testing to meet the gasoline standards in subpart C of this part, demonstrate homogeneity using two of the procedures specified in paragraph (c)(1) through (4) of this section. For summer gasoline, the homogeneity demonstration must include RVP measurements.

(1) Measure API gravity from each sample using ASTM D287, ASTM D1298, or ASTM D4052 (incorporated by reference in § 1090.95).

(2) Measure the sulfur content of each sample as specified in this subpart.

(3) Measure the benzene content of each sample as specified in this subpart.

(4) Measure the RVP of each sample as specified in this subpart.

(d) For testing to meet the diesel fuel standards in subpart D of this part, demonstrate homogeneity using one of the procedures specified in paragraph (c)(1) or (2) of this section.

(e) Consider the batch to be homogeneous for a given parameter if the measured values for all tested samples vary by less than the published repeatability of the test method. If repeatability is a function of measured values, calculate repeatability using the average value of the measured parameter representing all tested samples. Calculate using all meaningful significant figures as specified for the test method, even if § 1090.1350(c) describes a different precision. For cases that do not require a homogeneity demonstration under § 1090.1335(b)(4), the lack of homogeneity demonstration does not prevent a quantity of fuel, fuel additive, or regulated blendstock from being considered a batch for demonstrating compliance with the requirements of this part.

§ 1090.1340 Preparing a hand blend from BOB.

(a) If you produce or import BOB and instruct downstream blenders to add oxygenate, you must meet the sampling requirements of this subpart by blending oxygenate into a BOB sample to represent the final blended fuel. To do this, prepare each fuel sample by adding oxygenate to the BOB sample in a way that corresponds to your instructions to downstream blenders for the sampled batch of fuel. Prepare a hand blend representing a worst case for oxygenate as follows:

(1) Take steps to avoid introducing high or low bias in sulfur content when selecting from available samples to create the hand blend. For example, if there are three samples with discrete sulfur measurements, select the sample with the mid-range sulfur content. In other cases, randomly select the sample.

(2) If your instructions allow for downstream blenders to add more than one type or concentration of oxygenate, prepare a hand blend for summer gasoline intended for blending with ethanol using the lowest specified ethanol blend. For summer gasoline intended for blending only with oxygenate other than ethanol, and for all winter gasoline, blend at the lowest specified oxygenate concentration, regardless of the type of oxygenate. For example, if you give instructions for a given batch of BOB to perform downstream blending to make E10, E15, and an 8 percent blend with butanol, prepare a hand blend for testing winter gasoline with 8 percent butanol, and prepare an E10 hand blend for testing summer gasoline.

(b) Blend the fuel using the procedures specified in ASTM D7717 (incorporated by reference in § 1090.95). The blended fuel must have an amount of oxygenate that does not exceed the oxygenate concentration specified on the PTD for the BOB under § 1090.1160(b)(1).

(c) If you produce or import BOB and you blend in oxygenate before selling or transporting the fuel, you must instead draw samples from your blended fuel.

§ 1090.1345 Retaining samples.

(a) Fuel manufacturers, regulated blendstock producers, and independent surveyors must retain samples of fuel and oxygenate tested under this subpart as follows:

(1) If you test gasoline, diesel fuel, or oxygenate to measure any parameter as required under this subpart, you must keep a representative fuel sample for at least 30 days after testing is complete, except that a longer sample retention of 120 days applies for blending manufacturers that produce gasoline.

(2) The nominal volume of retained samples must be at least 330 ml. If you have only a single sample for testing, keep that sample after testing is complete. If you collect multiple samples from a single batch or you create a hand blend, select a representative sample as follows:

(i) If you test a hand blend under § 1090.1340, keep a sample of the BOB.

(ii) For summer gasoline, keep an untested (or less tested) sample that is most like the tested sample, as applicable. In all other cases, keep the tested (or most tested) sample.

(b) Oxygenate producers and importers must keep oxygenate samples as follows:

(1) Keep a representative sample of any tested oxygenate. Also keep a representative sample of DFE if you used the provisions of § 1090.1330 to calculate its sulfur content. The nominal volume of retained samples must be at least 330 ml.

(2) Keep all the samples you collect over the previous 21 days. If you have fewer than 20 samples from the previous 21 days, continue keeping the most recent 20 samples collected up to a maximum of 90 days for any given sample.

(c) Keep records of all calculations, test results, and test methods for the batch associated with each stored sample.

(d) If EPA requests a test sample, you must follow EPA's instructions and send it to EPA by a courier service (or equivalent). The instructions will describe where and when to send the sample. For each test sample, you must

identify the test results and test methods used.

(e) You are responsible for meeting the requirements of this section even if a third party performs testing and stores the fuel samples for you.

Measurement Procedures

§ 1090.1350 Overview of test procedures.

Fuel manufacturers meet the requirements of this subpart based on laboratory measurements of the specified fuel parameters. Test procedures for these measurements apply as follows:

(a) Except as specified in paragraph (b) of this section, the Performance-based Measurement System specified in §§ 1090.1360 through 1090.1375 applies for all testing specified in this subpart for the following fuels and fuel parameters:

(1) Sulfur content of diesel fuel.

(2) Sulfur content of ECA marine fuel.

(3) RVP, sulfur content, benzene content, and oxygenate content of gasoline. The procedures for measuring sulfur in gasoline in this subpart also apply for testing sulfur in certified ethanol denaturant; however, demonstrating compliance for alternative procedures in § 1090.1365 and statistical quality control in § 1090.1375 do not apply for sulfur concentration above 80 ppm.

(4) Sulfur content of butane.

(b) Specific test procedures apply for measuring other fuel parameters, as follows:

(1) Determine the cetane index of diesel fuel as specified in ASTM D976 or ASTM D4737 (incorporated by reference in § 1090.95). There is no cetane-related test requirement for biodiesel.

(2) Measure aromatic content of diesel fuel as specified in ASTM D1319 or ASTM D5186 (incorporated by reference in § 1090.95). You may use an alternative procedure if you correlate your test results with ASTM D1319 or ASTM D5186.

(3) Measure the purity of butane and pentane as specified in ASTM D2163 (incorporated by reference in § 1090.95).

(4) Measure the benzene content of butane and pentane as specified in ASTM D5134 (incorporated by reference in § 1090.95).

(5) Measure the sulfur content of pentane as specified in ASTM D6667 (incorporated by reference in § 1090.95).

(6) Measure distillation parameters of gasoline as specified in ASTM D86 (incorporated by reference in § 1090.95). You may use an alternative procedure if you correlate your test results with ASTM D86.

(7) Measure the sulfur content of neat ethanol as specified in ASTM D5453 (incorporated by reference in § 1090.95). You may use an alternative procedure if you correlate your test results with ASTM D5453.

(8) Measure the phosphorus content of gasoline as specified in ASTM D3231 (incorporated by reference in § 1090.95).

(9) Measure the lead content of gasoline as specified in ASTM D3237 (incorporated by reference in § 1090.95).

(10) Measure the sulfur content of gasoline additives and diesel fuel additives as specified in ASTM D2622 (incorporated by reference in § 1090.95).

(11) Use referee procedures specified in § 1090.1360(d) and the following additional methods to measure gasoline fuel parameters to meet the survey requirements of subpart N of this part:

TABLE 1 TO PARAGRAPH (b)(11)

Fuel parameter	Units	Test method [1]
Distillation (T50 and T90)	°C	ASTM D86.
Aromatic content	volume percent	ASTM D5769.
Olefin content	volume percent	ASTM D6550.

[1] ASTM specifications are incorporated by reference in § 1090.95.

(12) Updated versions of the test procedures specified in this section are acceptable as alternative procedures if both repeatability and reproducibility are at least as precise as the values specified in the earlier version.

(c) Record measured values with the following precision, with rounding in accordance with § 1090.50:

(1) Record sulfur content to the nearest whole ppm.

(2) Record benzene to the nearest 0.01 volume percent.

(3) Record RVP to the nearest 0.01 psi.

(4) Record oxygenate content to the nearest 0.01 mass percent for each calibrated oxygenate.

(5) Record diesel aromatic content to the nearest 0.1 volume percent, or record cetane index to the nearest whole number.

(6) Record gasoline aromatic and olefin content to the nearest 0.1 volume percent.

(7) Record distillation parameters to the nearest whole degree.

(d) For any measurement or calculation that depends on the volume of the test sample, correct the volume of the sample to a reference temperature of 15.5 °C (288.65 K). Use a correction equation that is appropriate for each tested compound. This applies for all fuels, blendstocks, and additives, except butane.

§ 1090.1355 Calculation adjustments and corrections.

Adjust measured values for special circumstances as follows:

(a) Adjust measured values for total vapor pressure as follows:

$$RVP\ (psi) = 0.956 \bullet P_{total} - 0.347$$

Where:

P_{total} = Measured total vapor pressure, in psi.

(b) For measuring the sulfur and benzene content of gasoline, adjust a given test result upward in certain circumstances, as follows:

(1) If your measurement method involves a published procedure with a Pooled Limit of Quantitation (PLOQ), treat the PLOQ as your final result if your measured result is below the PLOQ.

(2) If your measurement method involves a published procedure with a limited scope but no PLOQ, treat the lower bound of the scope as your final result if your measured result is less than that value.

(3) If you establish a Laboratory Limit of Quantitation (LLOQ) below the lower bound of the scope of the procedure as specified in ASTM D6259 (incorporated by reference in § 1090.95), treat the LLOQ as your final result if your measured result is less than the LLOQ. Note that this option is meaningful only if the LLOQ is less than a published PLOQ, or if there is no published PLOQ.

(c) For measuring the benzene content of butane and pentane, report a zero value if the test result is at or below the PLOQ or Limit of Detection (LOD) that applies for the test method.

(d) If measured content of any oxygenate compound is less than 0.1 percent by mass, record the result as ''None detected.''

§ 1090.1360 Performance-based Measurement System.

(a) The Performance-based Measurement System (PBMS) is an approach that allows for laboratory testing with any procedure that meets specified performance criteria. This subpart specifies the performance criteria for measuring certain fuel parameters to demonstrate compliance with the standards and other specifications of this part. These provisions do not apply to process stream analyzers used with in-line blending.

(b) Different requirements apply for absolute fuel parameters and method-defined fuel parameters.

(1) Absolute fuel parameters are those for which it is possible to evaluate measurement accuracy by comparing measured values of a test sample to a reference sample with a known value for the measured parameter. The following are absolute fuel parameters:

(i) Sulfur. This applies for measuring sulfur in any fuel, fuel additive, or regulated blendstock.

(ii) [Reserved]

(2) Method-defined fuel parameters are all those that are not absolute fuel parameters. Additional test provisions apply for method-defined fuel parameters under this section because there is no reference sample for evaluating measurement accuracy.

(c) The performance criteria of this section apply as follows:

(1) Section 1090.1365 specifies the initial qualifying criteria for all measurement procedures. You may use an alternative procedure only if testing shows that you meet the initial qualifying criteria

(2) Section 1090.1375 specifies ongoing quality testing requirements that apply for laboratories that use either referee procedures or alternative procedures.

(3) Streamlined requirements for alternative procedures apply for procedures adopted by a voluntary consensus standards body (VCSB). Compliance testing with non-VCSB procedures requires advance approval by EPA. Procedures are considered non-VCSB testing as follows:

(i) Procedures developed by individual companies or other parties are considered non-VCSB procedures.

(ii) Draft procedures under development by a VCSB organization are considered non-VCSB procedures until they are approved for publication.

(iii) A published procedure is considered non-VCSB for testing with fuel parameters that fall outside the range of values covered in the research report of the ASTM D6708 (incorporated by reference in § 1090.95) assessment comparing candidate alternative procedures to the referee procedure specified in paragraph (d) of this section.

(4) You may qualify updated versions of the referee procedures as alternative procedures under § 1090.1365. You may ask EPA for approval to use an updated version of the referee procedure for qualifying other alternative procedures if the updated referee procedure has the same or better accuracy and precision compared to the version specified in § 1090.95. If the updated procedure has worse accuracy and precision compared to the earlier version, you must complete the required testing specified in § 1090.1365 using the older, referenced version of the referee procedure.

(5) Any laboratory may use the specified referee procedure without qualification testing. To use alternative procedures at a given facility, you must perform the specified testing to demonstrate compliance with precision and accuracy requirements, with the following exceptions:

(i) Testing you performed to qualify alternative procedures under 40 CFR part 80 continues to be valid for making the demonstrations required in this part.

(ii) Qualification testing is not required for laboratories that measure the benzene content of gasoline using Procedure B of ASTM D3606 (incorporated by reference in § 1090.95). However, qualification testing may be necessary for updated versions of this procedure as specified in § 1090.1365(a)(2).

(d) Referee procedures are presumed to meet the initial qualifying criteria in this section. You may use alternative procedures if you qualify them using the referee procedures as a benchmark as specified in § 1090.1365. The following are the referee procedures:

TABLE 1 TO PARAGRAPH (d)

Tested product	Parameter	Referee procedure [1]
ULSD, 500 ppm diesel fuel, ECA marine fuel, gasoline.	Sulfur	ASTM D2622.
Butane	Sulfur	ASTM D6667.
Gasoline	oxygenate content	ASTM D5599.
Gasoline	RVP	ASTM D5191, except as specified in § 1090.1355(a).
Gasoline	benzene	ASTM D5769.

[1] ASTM specifications are incorporated by reference in § 1090.95.

§ 1090.1365 Qualifying criteria for alternative measurement procedures.

This section specifies how to qualify alternative procedures for measuring absolute and method-defined fuel parameters under the Performance-based Analytical Test Method specified in § 1090.1360.

(a) The following general provisions apply for qualifying alternative procedures:

(1) Alternative procedures must have appropriate precision to allow for reporting to the number of decimal places specified in § 1090.1350(c).

(2) Testing to qualify an alternative procedure applies for the specified version of the procedure you use for making the necessary measurements. Once an alternative procedure for a method-defined fuel parameter is qualified for your laboratory, updated versions of that same procedure are qualified without further testing, as long as the procedure's specified reproducibility is the same as or better than the values specified in the earlier version. For absolute fuel parameters, updated versions are qualified without testing if both repeatability and reproducibility are the same as or better than the values specified in the earlier version.

(3) Except as specified in paragraph (d) of this section, testing to demonstrate compliance with the precision and accuracy specifications in this section apply only for the test facility where the testing occurred.

(4) If a procedure for measuring benzene or sulfur in gasoline has no specified PLOQ and no specified scope with a lower bound, you must establish a LLOQ for your facility.

(5) Testing for method-defined fuel parameters must take place at a reference installation as specified in § 1090.1370.

(b) All alternative procedures must meet precision criteria based on a calculated maximum allowable standard deviation for a given fuel parameter as specified in this paragraph. The precision criteria apply for measuring the parameters and fuels specified in paragraph (b)(3) of this section. Take the following steps to qualify the measurement procedure for measuring a given fuel parameter:

(1) The fuel must meet the parameter specifications in Table 1 to paragraph (b)(3) of this section. This may require that you modify the fuel you typically produce to be within the specified range. Absent a specification (maximum or minimum), select a fuel representing values that are typical for your testing. Store and mix the fuel to maintain a homogenous mixture throughout the measurement period to ensure that each fuel sample drawn from the batch has the same properties.

(2) Measure the fuel parameter from a homogeneous fuel batch at least 20 times. Record each result in sequence. Do not omit any valid results unless you use good engineering judgment to determine that the omission is necessary and you document those results and the reason for excluding them. Perform this analysis over a 20-day period. You may make up to 4 separate measurements in a 24-hour period, as long as the interval between measurements is at least 4 hours. Do not measure RVP more than once from a single sample.

(3) Calculate the maximum allowable standard deviation as follows:

$$\sigma_{max} = x_1 \cdot \frac{x_2}{x_3}$$

Where:

σ_{max} = Maximum allowable standard deviation.

x_1, x_2, and x_3 have the values from the following table:

TABLE 1 TO PARAGRAPH (b)(3)—PRECISION CRITERIA FOR QUALIFYING ALTERNATIVE PROCEDURES

Fuel, fuel additive, or regulated blendstock	Fuel parameter	Range	x_1	x_2 = Repeatability (r) or reproducibility (R) [1]	x_3	Fixed values of σ_{max}	Source [2]
ULSD	Sulfur	5 ppm minimum	1.5	r=1.33	2.77	0.72	ASTM D3120–08 (2019).
500 ppm LM diesel fuel.	Sulfur	350 ppm minimum	1.5	r=21.3	2.77	11.5	ASTM D2622–16.
ECA marine fuel	Sulfur	700 ppm minimum	1.5	37.1	2.77	20.1	ASTM D2622–16.
Butane	Sulfur		1.5	$r = 0.1152 \cdot x$	2.77		ASTM D6667–14 (2019).
Gasoline	Sulfur		1.5	$r = 0.4998 \cdot x^{0.54}$	2.77		ASTM D7039–15a.
Gasoline	oxygenate		0.3	$R = 0.13 \cdot x^{0.83}$	1		ASTM D5599–18.
Gasoline	RVP [3]		0.3	R=0.40	1	0.12	ASTM D5191–19.
Gasoline	Benzene		0.15	$R=0.221 \cdot x^{0.67}$	1		ASTM D5769–15.

[1] Calculate repeatability and reproducibility using the average value determined from testing. Use units as specified in § 1090.1350(c).

[2] ASTM publications are incorporated by reference in § 1090.95. Note that the listed procedure may be different than the referee procedure identified in § 1090.1360(d), or it may be an older version of the referee procedure.

[3] Use only 1-liter containers for testing to qualify alternative methods.

(c) Alternative VCSB procedures for measuring absolute fuel parameters (sulfur) must meet accuracy criteria based on the following measurement procedure:

(1) Obtain gravimetric sulfur standards to serve as representative reference samples. The samples must have known sulfur content within the ranges specified in paragraph (c)(3) of this section. The known sulfur content is the accepted reference value (ARV) for the fuel sample.

(2) Measure the sulfur content of the fuel sample at your laboratory at least 10 times, without interruption. Use good laboratory practice to compensate for any known chemical interferences; however, you must apply that same compensation for all tests to measure the sulfur content of a test fuel. Calculate the arithmetic average of all the measured values, including any compensation.

(3) The measurement procedure meets the accuracy requirement as follows:

(i) Demonstrate accuracy for measuring sulfur in gasoline, gasoline regulated blendstock, and gasoline additive using test fuels to represent sulfur values from 1 to 10 ppm, 11 to 20 ppm, and 21 to 95 ppm. You may omit any of these ranges if you do not perform testing with fuel in that range. Calculate the maximum allowable difference between the average measured value and ARV for each applicable range as follows:

$$\Delta_{max} = 0.75 \cdot \sigma_{max}$$

Where:

Δ_{max} = Maximum allowable difference.

σ_{max} = the maximum allowable standard deviation from paragraph (b)(3) of this section using the sulfur content represented by ARV.

(ii) Demonstrate accuracy for measuring sulfur in diesel fuel using test fuels meeting the specifications in Table 2 to this section. For testing diesel-related blendstocks and additives, use representative test samples meeting the appropriate sulfur specification. Table 2 to paragraph (c)(3)(ii) of this section also identifies the maximum allowable difference between average measured values and ARV corresponding to ARV at the upper end of the specified ranges. These values are based on calculations with the equation in paragraph (c)(3)(i) of this section, with parameter values set to be equal to the standard.

TABLE 2 TO PARAGRAPH (c)(3)(ii)—ACCURACY CRITERIA FOR QUALIFYING ALTERNATIVE PROCEDURES WITH DIESEL FUEL AND DIESEL-RELATED BLENDSTOCKS AND ADDITIVES

Fuel	Sulfur content (ppm)	Illustrated maximum allowable differences
ULSD	10–20	0.54
500 ppm LM diesel fuel	450–500	8.65
ECA marine fuel	900–1,000	15.1

(d) Alternative VCSB procedures for measuring method-defined fuel parameters must meet accuracy criteria as follows:

(1) You may use the alternative procedure only if you follow all the statistical protocols and meet all the criteria specified in Section 6 of ASTM D6708 (incorporated by reference in § 1090.95) when comparing your measurements using the alternative procedure to measurements at a reference installation using the appropriate referee test method identified in § 1090.1360(d).

(2) For qualifying alternative procedures, determine whether the alternative procedure needs a correlation equation to correct bias relative to the reference test method. Create such a correlation equation as specified in Section 7 of ASTM D6708. For all testing, apply the correlation equation to adjust measured values to be statistically consistent to measuring with the reference test method.

(3) If an alternative VCSB procedure states that the procedure has a successful assessment relative to the referee procedures in this section under ASTM D6708, that finding applies for all test facilities using that procedure.

(e) Alternative non-VCSB procedures for measuring absolute fuel parameters (sulfur) must meet accuracy criteria as follows:

(1) Demonstrate whether the procedure meets statistical criteria and whether it needs a correlation equation as specified in paragraphs (d)(1) and (2) of this section. Apply the correlation equation for all testing with the alternative procedure.

(2) Demonstrate at your laboratory that the alternative procedure meets the accuracy criteria specified in paragraph (c) of this section.

(3) Send EPA a written request to use the alternative procedure. In your request, fully describe the procedure to show how it functions for achieving accurate measurements and include detailed information related to your assessment under paragraph (d)(1) and (2) of this section.

(f) Alternative non-VCSB procedures for measuring method-defined fuel parameters must meet accuracy and precision criteria as follows:

(1) Demonstrate whether the procedure meets statistical criteria and whether it needs a correlation equation as specified in paragraphs (d)(1) and (2) of this section. Apply the correlation equation for all testing with the alternative procedure.

(2) Test with a range of fuels that are typical of those you will analyze at your laboratory. Use either consensus-named fuels or locally-named reference materials. Consensus-named fuels are homogeneous fuel quantities sent around to different laboratories for analysis, which results in a ''consensus name'' representing the average value of the parameter for all participating laboratories. Locally named reference materials are fuel samples analyzed using the reference test method, either at your laboratory or at a reference installation, to establish an estimated value for the fuel parameter; locally named reference materials usually come from the fuel you produce.

(3) You may qualify your procedure as meeting the variability requirements of paragraph (f)(1) of this section only for a narrower, defined range of fuels. If this is the case, identify the appropriate range of fuels in your request for approval and describe how you will screen fuel samples accordingly.

(4) Qualify the precision of the alternative procedure by comparing results to testing with the referee procedure based on ''between methods reproducibility,'' Rxy, as specified in ASTM D6708. The Rxy must be at or below 75 percent of the reproducibility of the referee procedure from § 1090.1360(d).

(5) Perform testing at your laboratory as specified in paragraph (b) of this section to establish the repeatability of the alternative procedure. The repeatability must be as good as or better than that specified in paragraph (b)(3) of this section.

(6) Fully describe the procedure to show how it functions for achieving accurate measurements. Describe the technology, test instruments, and testing method so a competent person lacking experience with the procedure and test instruments would be able to replicate the results.

(7) Engage a third-party auditor to review and verify your information as follows:

(i) The auditor must qualify as an independent third party and meet the specifications for technical ability as specified in § 1090.55.

(ii) The auditor must send you a report describing their inspection of your facilities and their review of the information supporting your request to use the alternative procedure. The report must describe how the auditor performed the review, identify any errors or discrepancies, and state whether the information supports a conclusion that the alternative procedure should be approved.

(iii) The auditor must keep records related to the review for at least 5 years after sending you the report and provide those records to EPA upon request.

(8) Send EPA a written request to use the alternative procedure. Include the specified information and any additional information EPA needs to evaluate your request.

(g) Keep fuel samples from any qualification testing under this section for at least 180 days after you have taken all steps to qualify an alternative procedure under this section. This applies for testing at your laboratory and at any reference installation you use for demonstrating the accuracy of an alternative procedure.

§ 1090.1370 Qualifying criteria for reference installations.

(a) A reference installation refers to a test facility that uses the referee test method specified in § 1090.1360(d) to evaluate the accuracy of alternative procedures for method-defined parameters, by comparing measured values to companion tests using one of the referee procedures in § 1090.1360(d). This evaluation may result in an equation to correlate results between the two procedures. Once a facility qualifies as a reference installation, that qualification is valid for five years from the qualifying date, consistent with good laboratory practices.

(b) Qualify a reference installation for VCSB procedures by participating in an interlaboratory crosscheck program with at least 16 separate measurements that are not identified as outliers. This presumes that the results for the candidate reference installation are not outliers.

(c) Qualify a reference installation for non-VCSB procedures based on the following measurement protocol:

(1) Use the precision testing procedure specified in § 1090.1365(b) to show that your standard deviation for tests using the reference test method is at or below 0.3 times the reproducibility for a given fuel parameter.

(2) You must correlate your test results for a given fuel parameter against the accepted reference values from a monthly crosscheck program based on Section 6.2.2.1 and Note 7 of ASTM D6299 (incorporated by reference in § 1090.95) as follows:

(i) If there are multiple fuels available from the crosscheck program, select the fuel that has the closest value to the standard. If there is no standard for a given fuel parameter, select the fuel with values for the fuel parameter that best represent typical values for fuels you test.

(ii) Measure the fuel parameter for the crosscheck fuel at your facility using the appropriate referee procedure. Calculate

a mean value that includes all your repeat measurements.

(iii) Determine the mean value from the crosscheck program and calculate the difference between this value and the mean value from your testing. Express this difference as a certain number of standard deviations relative to the data set from the crosscheck program.

(iv) The calculated monthly difference between the mean values from § 1090.1365(c)(3)(ii) for 5 consecutive months must fall within the central 50 percent of the distribution of data at least 3 times. The central 50 percent of the distribution corresponds to 0.68 standard deviations.

(v) Calculate the mean value of the differences from § 1090.1365(c)(3)(ii) for all 5 months. This mean value must fall within the central 50 percent of the distribution of data from the crosscheck program. For example, if the difference was 0.5 standard deviations for two months, 0.6 for one month, and 0.7 for two months, the mean value of the difference is 0.6 standards deviations, and the reference installation meets the requirements of this paragraph.

(3) You must demonstrate that the reference installation is in statistical quality control for at least 5 months with the designated procedure as specified in ASTM D6299 (incorporated by reference in § 1090.95). If at any point the reference installation is not in statistical quality control, you must make any necessary changes and restart testing toward meeting the requirement to achieve statistical quality control for at least 5 months, except as follows:

(i) Do not consider measurements you perform as part of regular maintenance or recalibration for evaluating statistical quality control.

(ii) If you find that the reference installation is not in statistical quality control during an initial 5-month period and you are able to identify the problem and make the necessary changes to again achieve statistical quality control before the end of the 5-month demonstration period, you may consider the reference installation as meeting the requirement to be in statistical quality control for at least 5 months.

§ 1090.1375 Quality control procedures.

This section specifies ongoing quality testing requirements as part of the Performance-based Measurement System specified in § 1090.1360.

(a) *General provisions.* You must perform testing to show that your test facility meets specified precision and accuracy criteria as follows:

(1) The testing requirement applies for the referee procedures in § 1090.1360(d) and for alternate procedures that are qualified or approved under § 1090.1365. The testing requirements apply separately for each test instrument at each test facility.

(2) If you fail to conduct specified testing, your test facility is not qualified for measuring fuel parameters to demonstrate compliance with the standards and other specifications of this part until you perform this testing. Similarly, if your test facility fails to meet the specified criteria, it is not qualified for measuring fuel parameters to demonstrate compliance with the standards and other specifications of this part until you make the necessary changes to your test facility and perform testing to show that the test facility again meets the specified criteria.

(3) If you perform major maintenance such as overhauling an instrument, confirm that the instrument still meets precision and accuracy criteria before you start testing again based on the procedures specified in ASTM D6299 (incorporated by reference in § 1090.95).

(4) Keep records to document your testing under this section for 5 years.

(b) *Precision demonstration.* Show that you meet precision criteria as follows:

(1) Meeting the precision criteria of this paragraph (b) qualifies your test facility for performing up to 20 production tests or 7 days, whichever is less.

(2) Perform precision testing using the control-chart procedures in ASTM D6299. If you opt to use the Q-procedure, validate the first run on the new QC batch by either an overlap in-control result of the old batch, or by a single execution of an accompanying standard reference material. The new QC material result would be considered validated if the single result of the standard reference material is within the established site precision (R') of the ARV of the standard reference material, as determined by ASTM D6792 (incorporated by reference in § 1090.95).

(3) Use I charts and MR charts as specified in ASTM D6299 to show that the long-term standard deviation for the test facility meets the precision criteria specified in § 1090.1365(b).

(c) *Accuracy demonstration.* For absolute fuel parameters (VCSB and non-VCSB) and for method-defined fuel parameters using non-VCSB methods, you must show that you meet accuracy criteria as specified in this paragraph. For method-defined VCSB procedures, you may meet accuracy requirements as specified in this paragraph or by comparing your results to the accepted reference value in an inter-laboratory crosscheck program sponsored by ASTM International or another VCSB at least 3 times per year.

(1) Meeting the accuracy criteria of this paragraph (c) qualifies your test facility for 130 days.

(2) Except as specified in paragraph (c)(3) of this section, test every instrument using a check standard meeting the specifications of ASTM D6299. Select a fuel sample with an ARV that is at or slightly below the standard that applies. If there are both average and batch standards, use the average standard. If there is no standard, select a fuel sample representing fuel that is typical for your testing.

(3) The following provisions apply for method-defined non-VCSB alternative procedures with high sensitivity to sample-specific bias:

(i) Procedures have high sensitivity if the closeness sum of squares (CSS) statistic exceeds the 95th percentile value, as specified in ASTM D6708 (incorporated by reference in § 1090.95).

(ii) Create a check standard from production fuel representing the fuel you will routinely analyze. Determine the ARV of your check standard using the protocol in ASTM D6299 at a reference installation as specified in § 1090.1370.

(iii) You must send EPA a fuel sample from every twentieth batch of gasoline or diesel fuel and identify the procedures and corresponding test results from your testing. EPA may return one of your samples to you for further testing; if this occurs, you must repeat your measurement and report your results within 180 days of receiving the fuel sample.

(4) You meet accuracy requirements under this section if the difference between your measured value for the check standard and the ARV is less than the value from the following equation:

$$\Delta_{max} = 0.75 \cdot \mathrm{R} \cdot \sqrt{1 + \frac{1}{\mathrm{L}}}$$

Where:

Δ_{max} = Maximum allowable difference.

R = Reproducibility of the referee procedure identified in § 1090.1360(d), as noted in Table 1 to paragraph (b)(3) of § 1090.1365 or in the following table:

TABLE 1 TO PARAGRAPH (c)(3)

Tested product	Referee procedure [1]	Reproducibility (R) [2]
ULSD, 500 ppm diesel fuel, ECA marine fuel, diesel fuel additive, gasoline, gasoline regulated blendstock, and gasoline additive.	ASTM D2622	$R = 0.4273 \cdot x^{0.8015}$
Butane	ASTM D6667	$R = 0.3130 \cdot x$

[1] ASTM specifications are incorporated by reference in § 1090.95.
[2] Calculate reproducibility using the average value determined from testing. Use units as specified in § 1090.1350(c).

L = the total number of test results used to determine the ARV of a consensus-named fuel. For testing locally named fuels for which no consensus-based ARV applies, use L = ∞.

Testing Related to Gasoline Deposit Control

§ 1090.1390 Requirement for Automated Detergent Blending Equipment Calibration.

(a) Automated detergent blending facilities must calibrate their automated detergent blending equipment once in each calendar half-year, with the acceptable calibrations being no less than 120 days apart.

(b) Equipment recalibration is also required each time the detergent package is changed, unless written documentation indicates that the new detergent package has the same viscosity as the previous detergent package. Calibrating after changing the detergent package may be used to satisfy the semiannual recalibration requirement in paragraph (a) of this section, provided that the calibrations occur in the appropriate calendar half-year and are no less than 120 days apart.

§ 1090.1395 Gasoline deposit control test procedures.

Gasoline detergent manufacturers must perform testing as specified in paragraph (a), (b), or (c) of this section to establish the lowest additive concentration (LAC) for the detergent.

(a) *Top Tier-Based Test Method.* Use the procedures specified in ASTM D6201 (incorporated by reference in § 1090.95), as follows:

(1) Use a base fuel that conforms to the specifications for gasoline-alcohol blends in ASTM D4814 (incorporated by reference in § 1090.95). Blendstocks used to formulate the test fuel must be derived from conversion units downstream of distillation, with all processes representing normal fuel manufacturing facility operations. Blendstocks may not come from chemical grade streams. Butane and pentane may be added to adjust vapor pressure. The base fuel should include any nondetergent additives typical of commercially available fuel if they may positively or negatively affect deposit formation. In addition, the base fuel must have the following properties:

(i) 8.0–10.0 Volume percent DFE that meets the requirements in § 1090.230 and conforms to the specifications of ASTM D4806 (incorporated by reference in § 1090.95).

(ii) At least 8.0 volume percent olefins.

(iii) At least 15 volume percent aromatics.

(iv) No more than 80 ppm sulfur.

(v) T90 distillation temperature at or above 143 °C.

(vi) No detergent-active substance. A base fuel with typical nondetergent additives, such as antioxidants, corrosion inhibitors, and metal deactivators, may be used.

(2) Perform the 100-hour test for intake valve deposits with the base fuel to demonstrate that the intake valves accumulate at least 500 mg on average. If the test engine fails to accumulate enough deposits, make any necessary adjustments and repeat the test. This demonstration is valid for any further detergent testing with the same base fuel.

(3) Repeat the test on the same engine with a specific concentration of detergent added to the base fuel. If the test results in less than 50 mg average per intake valve, the tested detergent concentration is the LAC for the detergent.

(b) *CARB-Based Test Method.* Use the procedures specified by CARB in Title 13, California Code of Regulations, section 2257.

(1) A detergent tested under this option or certified under 40 CFR 80.163(d) prior to January 21, 2021, may be used at the LAC specified for use in the state of California in any gasoline in the United States.

(2) The gasoline detergent manufacturer must cease selling a detergent immediately upon being notified by CARB that the CARB certification for this detergent has been invalidated and must notify EPA under 40 CFR 79.21.

(c) *Alternative test methods.* (1) An EPA-approved alternative test method may be used if the alternative test method can be correlated to any one of the following methods.

(i) The Top Tier-Based Test Method specified in paragraph (a) of this section.

(ii) The CARB-Based Test Method in paragraph (b) of this section.

(iii) The retired EPA BMW Test Method as follows:

(A) Prepare the test fuel with the following specification:

(*1*) Sulfur—minimum 340 ppm.

(*2*) T–90—minimum 339 degrees Fahrenheit.

(*3*) Olefins—minimum 11.4 volume percent.

(*4*) Aromatics—minimum 31.1 volume percent.

(*5*) Ethanol—minimum 10 volume percent.

(*6*) Sulfur, T–90, olefins, and aromatics specifications must be met prior to the addition of ethanol.

(*7*) Di-tert-butyl disulfide may be added to the test fuel to help meet the sulfur specification.

(B) Using the test fuel meeting the requirements of paragraphs (c)(1)(iii)(A) of this section, test the test fuel with and without detergent in accordance with ASTM D5500 (incorporated by reference in § 1090.95) and under the following conditions:

(*1*) The unadditized fuel's test results must meet or exceed 290 mg per valve on average.

(*2*) The required test fuel, including detergent additives, must produce the accumulation of less than 100 mg of intake valve deposits on average.

(*3*) The duration of the demonstration tests under ASTM D5500 may be less than the specified 10,000 miles, provided the results satisfy the standards of this paragraph.

(C) If the demonstration test results do not meet the criteria in paragraph (c)(1)(iii)(B) of this section, then the formulated fuel may not be used for detergent deposit control testing.

(2) Alternative test methods for detergent additives must be correlated to one of the methods specified in paragraph (c)(1) of this section in the submission.

(3) Information describing the alternative test method and analysis demonstrating correlation must be submitted for EPA approval as specified in § 1090.10.

Subpart N—Survey Provisions

§ 1090.1400 National fuels survey program participation.

(a) Gasoline manufacturers that elect to account for the addition of oxygenate added downstream under § 1090.710 must participate in the national fuel survey program specified in this subpart.

(b) Parties required to participate in an E15 survey under § 1090.1420(a) must participate in the national fuels survey specified in this subpart or a survey approved by EPA under § 1090.1420(b) or (c).

(c) Other parties may elect to participate in the national fuel survey program for purposes of establishing an affirmative defense against violations of requirements and provisions under this part as specified in § 1090.1720.

§ 1090.1405 National fuels survey program requirements.

The national fuels survey program must meet all the following requirements:

(a) The survey program must be planned and conducted by an independent surveyor that meets the independence requirements in § 1090.55 and the requirements specified in § 1090.1410.

(b) The survey program must be conducted at a representative sample of gasoline and diesel retail outlets in the United States as specified in § 1090.1415.

§ 1090.1410 Independent surveyor requirements.

The independent surveyor conducting the national fuels survey program must meet all the following requirements:

(a) Submit a proposed survey program plan under § 1090.1415 to EPA for approval for each calendar year.

(b)(1) Obtain samples representative of the gasoline and diesel fuel (including diesel fuel made available at retail to nonroad vehicles, engines, and equipment) offered for sale separately from all gasoline and diesel retail outlets in accordance with the survey program plan approved by EPA, or immediately notify EPA of any refusal of a retailer to allow samples to be taken.

(2) Obtain the number of samples representative of the number of gasoline retail outlets offering E15.

(3) Collect samples of gasoline produced at blender pump using ''method 1'' specified in NIST Handbook 158 (incorporated by reference, see § 1090.95). All other samples of gasoline and diesel fuel must be collected using the methods specified in subpart M of this part.

(4) Samples must be shipped via ground service to an EPA-approved laboratory within 2 business days of being collected.

(c) Test, or arrange to be tested, the collected samples, as follows:

(1) Gasoline samples must be analyzed for oxygenate content, sulfur content, and benzene content. Gasoline samples collected from June 1 through September 15 must also be analyzed for RVP.

(2) A subset of gasoline samples, as determined by § 1090.1415(e)(3), must also be analyzed for aromatics content, olefins content, and distillation parameters (*i.e.,* T50 and T90).

(3) Diesel samples must be analyzed for sulfur content.

(4) All samples must be tested by an EPA-approved laboratory using the test methods specified in subpart M of this part.

(5) All testing must be completed by the EPA-approved laboratory within 10 business days after receipt of the sample.

(d) Verify E15 labeling requirements at gasoline retail outlets that offer E15 for sale.

(e) Using procedures specified in an EPA-approved plan under § 1090.1415, notify EPA, the retailer, and the branded fuel manufacturer (if applicable) within 24 hours after the EPA-approved laboratory has completed analysis when any of the following occur:

(1) A test result for a gasoline sample yields a sulfur content result that exceeds the sulfur standard in § 1090.205(c).

(2) A test result for a gasoline sample yields an RVP result that exceeds the applicable RVP standard in § 1090.215.

(3) A test result for a diesel sample yields a sulfur content result that exceeds the sulfur standard in § 1090.305(b).

(4) A test result for a gasoline sample identified as ''E15'' yields an ethanol content result that exceeds 15 volume percent.

(5) A test result for a gasoline sample not identified as ''E15'' yields an ethanol content of more than 10 volume percent ethanol.

(f) Provide to EPA quarterly and annual summary reports that include the information specified in § 1090.925.

(g) Keep records related to the national fuels survey program as specified in § 1090.1245(b)(1).

(h) Submit contracts to EPA as specified in § 1090.1430.

(i) Permit any representative of EPA to monitor at any time the conducting of the survey, including sample collection, transportation, storage, and analysis.

§ 1090.1415 Survey plan design requirements.

The national fuels survey program plan must include all the following:

(a) *Number of surveys.* The survey program plan must include 4 surveys each calendar year that occur during the following time periods:

(1) One survey during the period of January 1 through March 31.

(2) One survey during the period of April 1 through June 30.

(3) One survey during the period of July 1 through September 30.

(4) One survey during the period of October 1 through December 31.

(b) *Sampling areas.* The survey program plan must include sampling in all sampling strata during each survey. These sampling strata must be further divided into discrete sampling areas or clusters. Each survey must include sampling in at least 40 sampling areas in each stratum that are randomly selected.

(c) *No advance notice of surveys.* The survey program plan must include procedures to keep the identification of the sampling areas that are included in the plan confidential from any participating party prior to the beginning of a survey in an area. However, this information must not be kept confidential from EPA.

(d) *Gasoline and diesel retail outlet selection.* (1) Gasoline and diesel retail outlets to be sampled in a sampling area must be selected from among all gasoline retail outlets in the United States that sell gasoline with the probability of selection proportionate to the volume of gasoline sold at the retail outlet. The sample of retail outlets must also include gasoline retail outlets with different brand names as well as those gasoline retail outlets that are unbranded.

(2) For any gasoline or diesel retail outlet from which a sample of gasoline or diesel was collected during a survey was reported to EPA under § 1090.1410(e), that gasoline or diesel retail outlet must be included in the subsequent survey.

(3) At least one sample of a product dispensed as E15 must be collected at each gasoline retail outlet when E15 is present, and separate samples must be taken that represent the gasoline contained in each storage tank at the gasoline retail outlet unless collection of separate samples is not practicable.

(4) At least one sample of a product dispensed as diesel fuel must be collected at each diesel fuel retail outlet when diesel fuel is present. Samples of diesel fuel may be collected at retail outlets that sell gasoline.

(e) *Number of samples.* (1) The number of retail outlets to be sampled must be independently calculated for the total number of gasoline retail outlets and the total number of diesel fuel retail outlets. The same retail outlet may represent both a gasoline retail outlet and a diesel fuel retail outlet for purposes of determining the number of samples.

(2) The minimum number of samples to be included in the survey plan for each calendar year is calculated as follows:

$$n = \left\{ \frac{\left(Z_\alpha + Z_\beta\right)^2}{4 \cdot \left(\arcsin\left(\sqrt{\varphi_1}\right) - \arcsin\left(\sqrt{\varphi_0}\right)\right)^2} \right\} \cdot F_a \cdot F_b \cdot Su_n \cdot St_n$$

Where:

n = Minimum number of samples in a year-long survey series. However, n must be greater than or equal to 2,000 for the number of diesel samples or 5,000 for the number of gasoline samples.

$Z\alpha$ = Upper percentile point from the normal distribution to achieve a one-tailed 95% confidence level (5% α-level). For purposes of this survey program, $Z\alpha$ equals 1.645.

$Z\beta$ = Upper percentile point to achieve 95% power. For purposes of this survey program, $Z\beta$ equals 1.645.

ϕ_1 = The maximum proportion of non-compliant outlets for a region to be deemed compliant. This parameter needs to be 5% or greater (*i.e.,* 5% or more of the outlets, within a stratum such that the region is considered non-compliant).

ϕ_0 = The underlying proportion of non-compliant outlets in a sample. For the first survey plan, ϕ_0 will be 2.3%. For subsequent survey plans, ϕ_0 will be the average of the proportion of outlets found to be non-compliant over the previous 4 surveys.

F_a = Adjustment factor for the number of extra samples required to compensate for samples that could not be included in the survey (*e.g.,* due to technical or logistical considerations), based on the number of additional samples required during the previous 4 surveys. F_a must be greater than or equal to 1.1.

F_b = Adjustment factor for the number of samples required to resample each retail outlet with test results reported to EPA under § 1090.1410(e), based on the rate of resampling required during the previous 4 surveys. F_b must be greater than or equal to 1.1.

Su_n = Number of surveys per year. For purposes of this survey program, Su_n equals 4.

St_n = Number of sampling strata. For purposes of this survey program, St_n equals 3.

(3) The number of gasoline samples that also need to be tested for aromatics, olefins, and distillation parameters under § 1090.1410(c)(2) must be calculated using the methodology specified in paragraph (e)(2) of this section without the F_a, F_b, and Su_n parameters.

(4) The number of samples determined under paragraphs (e)(2) and (3) of this section must be distributed approximately equally among the 4 surveys conducted during the calendar year.

(f) *Laboratory designation.* Any laboratory that the independent surveyor intends to use to test samples collected as part of the national fuels survey program must be approved annually as part of the national fuels survey program plan approval process in § 1090.1425. In the survey program plan submitted to EPA, the independent surveyor must include the following information regarding any laboratory they intend to use to test samples:

(1) The name of the laboratory.

(2) The address of the laboratory.

(3) The test methods for each fuel parameter measured at the laboratory.

(4) Reports demonstrating the laboratory's performance in a laboratory cross-check program for the most recent 12 months prior to submission of the plan.

(g) *Submission.* Plans submitted under this section must be approved annually under § 1090.1425.

§ 1090.1420 Additional requirements for E15 misfueling mitigation surveying.

(a) *E15 misfueling mitigation survey requirement.* (1) Any gasoline manufacturer, oxygenate blender, or oxygenate producer that produces, introduces into commerce, sells, or offers for sale E15, gasoline, BOB, DFE, or gasoline-ethanol blended fuel that is intended for use in or as E15 must comply with either survey program Option 1 (as specified in paragraph (b) of this section) or Option 2 (as specified in paragraph (c) of this section).

(2) For oxygenate producers that produce or import DFE, the DFE is deemed as intended for use in E15 unless an oxygenate producer demonstrates that it was not intended for such use. Oxygenate producers may demonstrate, at a minimum, that DFE is not intended for use in E15 by including language on PTDs stating that the DFE is not intended for use in E15, entering into contracts with oxygenate blenders to limit the use of their DFE to gasoline-ethanol blended fuels of no more than 10 volume percent, and limiting the concentration of their DFE to no more than 10 volume percent in their fuel additive registration under 40 CFR part 79.

(b) *Survey Option 1.* To comply with the E15 misfueling mitigation survey requirement specified in paragraph (a) of this section, the gasoline manufacturer, oxygenate blender, or oxygenate producer must properly conduct a survey program in accordance with a survey program plan that has been approved by EPA in all areas that may be reasonably expected to be supplied with their gasoline, BOB, DFE, or gasoline-ethanol blended fuel. Such approval must be based on a survey program plan meeting all the following requirements:

(1) The survey program must consist of at least quarterly surveys that occur during the following time periods in every year during which the gasoline manufacturer, oxygenate blender, or oxygenate producer introduces E15 into commerce:

(i) One survey during the period of January 1 through March 31.

(ii) One survey during the period of April 1 through June 30.

(iii) One survey during the period of July 1 through September 30.

(iv) One survey during the period of October 1 through December 31.

(2) The survey program plan must meet all the requirements of this subpart, except for §§ 1090.1400, 1090.1405(b), 1090.1410(c)(2) and (3), and 1090.1415(b), (d)(1), (2), and (4), and (e). In lieu of meeting these exempted sections, the survey program plan must specify the sampling strata, clusters, and area(s) to be surveyed, and the number of samples to be included in the survey.

(c) *Survey Option 2.* To comply with the E15 misfueling mitigation survey requirement specified in paragraph (a) of this section, the gasoline manufacturer, oxygenate blender, or oxygenate producer must participate in the survey program specified in § 1090.1405.

§ 1090.1425 Program plan approval process.

(a) A program plan that complies with the requirements in § 1090.1415 or § 1090.1440 must be submitted to EPA no later than October 15 of the year preceding the calendar year in which the program will be conducted.

(b) The program plan must be signed by an RCO of the independent surveyor conducting the program.

(c) The program plan must be submitted as specified in § 1090.10.

(d) EPA will send a letter to the party submitting the program plan that indicates whether EPA approves or disapproves the plan.

§ 1090.1430 Independent surveyor contract.

(a) No later than December 15 of the year preceding the year in which the survey will be conducted, the contract with the independent surveyor must be in effect, and the amount of compensation necessary to carry out the entire survey plan must either be paid to the independent surveyor or placed into an escrow account with instructions to the escrow agent to remit the compensation to the independent surveyor during the course of the survey plan.

(b) No later than December 31 of the year preceding the year in which the survey will be conducted, EPA must receive a copy of the contract with the independent surveyor and proof that the compensation necessary to carry out the survey plan has either been paid to the independent surveyor or placed into an escrow account. If placed into an escrow account, a copy of the escrow agreement must be sent to EPA.

§ 1090.1440 National sampling oversight program requirements.

(a) *National sampling oversight program participation.* (1) Except for gasoline manufacturers that have an approved in-line blending waiver under § 1090.1315, any gasoline manufacturer that elects to account for the addition of oxygenate added downstream under § 1090.710 must participate in the national sampling oversight program in this section.

(2) Other gasoline manufacturers may elect to participate in the national sampling oversight program for purposes of establishing an affirmative defense to a violation under § 1090.1720.

(3) Gasoline manufacturers that elect to participate in the national sampling oversight program must test, or arrange to be tested, samples collected from their gasoline manufacturing facilities as specified in paragraph (c)(2) of this section and report results to the independent surveyor within 10 business days of the date the sample was collected.

(b) *National sampling oversight program requirements.* The national oversight sampling program must meet all the following requirements:

(1) The national oversight sampling program must be planned and conducted by an independent surveyor that meets the independence requirements in § 1090.55 and the requirements of paragraph (c) of this section.

(2) The national sampling oversight program must be conducted at each gasoline manufacturing facility from all participating gasoline manufacturers.

(c) *Independent surveyor requirements.* The independent surveyor conducting the national sampling oversight program must meet all the following requirements:

(1) Submit a proposed national sampling oversight program plan that meets the requirements of paragraph (d) of this section to EPA for approval each calendar year.

(2)(i) Obtain at least one sample representing summer gasoline and one sample representing winter gasoline for each participating gasoline manufacturing facility.

(ii) Observe the gasoline manufacturer collect at least one sample representing summer gasoline and one sample representing winter gasoline for each participating gasoline manufacturing facility. The independent surveyor must also obtain a portion of the sample collected by the gasoline manufacturer and ship the sample as specified in paragraph (c)(2)(v) of this section. The observed sample does not need to represent a batch of certified gasoline (*i.e.,* the independent surveyor may observe the collection of a simulated sample if the gasoline manufacturer does not have a batch of certified gasoline available).

(iii) The independent surveyor must immediately notify EPA of any refusal of a gasoline manufacturer to allow samples to be taken. Gasoline manufacturers that refuse to allow the independent surveyor to take portions of collected samples are no longer considered by EPA to participate in the national sampling oversight program and may not account for the addition of oxygenate added downstream under § 1090.710.

(iv) Samples must be retained by the independent surveyor as specified in § 1090.1345(a).

(v) Samples collected must be shipped via ground service within 2 business days from when the samples are collected to an EPA-approved laboratory as established in an approved plan under this section. A random subset of collected samples must also be shipped to the EPA National Vehicle and Fuel Emissions Laboratory as established in an approved plan under this section.

(3) Test, or arrange to be tested, samples collected under paragraph (c)(2) of this section as follows:

(i) Winter gasoline samples must be analyzed for oxygenate content, sulfur content, benzene content, distillation parameters, aromatics, and olefins.

(ii) Summer gasoline samples must be analyzed for oxygenate content, sulfur content, benzene content, distillation parameters, aromatics, olefins, and RVP.

(iii) All samples must be tested by an EPA-approved laboratory using test methods specified in subpart M of this part.

(iv) All analyses must be completed by the EPA-approved laboratory within 10 business days after receipt of the sample.

(v) Gasoline manufacturers must analyze gasoline samples for sulfur and benzene content, and for summer gasoline, RVP.

(4) Using procedures specified in the EPA-approved plan under this section, notify EPA and the gasoline manufacturer within 24 hours after the EPA-approved laboratory has completed analysis when any of the following occur:

(i) A test result for a gasoline sample yields a sulfur content result that exceeds the sulfur standard in § 1090.205(b).

(ii) A test result for a gasoline sample yields an RVP result that exceeds the applicable RVP standard in § 1090.215.

(5) Make the test results available to EPA and the gasoline manufacturer for all analyses specified in paragraph (c)(3) of this section within 5 business days of completion of the analysis.

(6) Compare test results of all samples collected under paragraph (c)(2) of this section and all test results obtained from the gasoline manufacturer from the same samples as specified in paragraph (a)(3) of this section and inform EPA and the gasoline manufacturer if the test result for any parameter tested under paragraph (c)(3) of this section is greater than the reproducibility of the applicable method specified in subpart M of this part.

(7) Provide to EPA quarterly and annual summary reports that include the information specified in subpart J of this part.

(8) Keep records related to the national sampling oversight program as specified in § 1090.1245(b)(3).

(9) Submit contracts to EPA as specified in § 1090.1430.

(10) Review the test performance index and precision ratio for each method and instrument the laboratory used to test the gasoline samples collected under this section as follows:

(i) For each test method and instrument, the surveyor must obtain the relevant records from the gasoline manufacturer to determine the site precision, either from an inter-laboratory crosscheck program or from ASTM D6299 (incorporated by reference in § 1090.95).

(ii) Using relevant information obtained from the gasoline manufacturers, the surveyor must determine the appropriate Test Performance Index (TPI) and Precision Ration (PR) from ASTM D6792 Table 2 Guidelines for Action Based on TPI (incorporated by reference in § 1090.95).

(iii) Report as part of the quarterly and annual reporting requirements in § 1090.925 the determined site precision under paragraph (c)(10)(i) of this section and the test performance index under paragraph (c)(10)(ii) of this section.

(iv) Gasoline manufacturers must supply copies of the necessary information to the independent surveyor to review the TPI and PR for each method and instrument used to test the gasoline samples collected under this section.

(11) Permit any representative of EPA to monitor at any time the conducting of the national sampling oversight program, including sample collection, transportation, storage, and analysis.

(d) *National sampling oversight program plan requirements.* The national sampling oversight program plan specified in paragraph (c)(1) of this section must include, at a minimum, all the following:

(1) *Advance notice of sampling.* The program plan must include procedures on how to keep the identification of the gasoline manufacturing facilities included in the program plan confidential with minimal advanced notification from any participating gasoline manufacturer prior to collecting a sample. However, this information must not be kept confidential from EPA.

(2) *Gasoline manufacturing facility selection.* (i) Each participating gasoline manufacturing facility must be sampled at least once during the summer season and once during the winter season. The plan must demonstrate how these facilities will be randomly selected within the summer and winter seasons.

(ii) In addition to the summer and winter sample collected at each participating gasoline manufacturing facility, additional oversight samples are required under paragraph (d)(3)(ii) of this section. The independent surveyor must identify how these samples will be randomly distributed among participating gasoline manufacturing facilities.

(3) *Number of samples.* (i) The number of gasoline manufacturing facilities to be sampled must be calculated for the total number of samples to be collected for the next calendar year as part of the program plan.

(ii) The minimum number of samples to be included in the program plan for each calendar year is calculated as follows:

$$n = R * F_a * F_b * Su_n$$

Where:

n = Minimum number of samples in a year.

R = The number of participating gasoline manufacturing facilities.

F_a = Adjustment factor for the number of extra samples required to compensate for samples that could not be included in the national sampling oversight program (*e.g.,* due to technical or logistical considerations), based on the number of additional samples required during the previous 2 calendar years. F_a must be greater than or equal to 1.1.

F_b = Adjustment factor for the number of samples required to ensure oversight. For purposes of this program, F_b equals 1.25.

Su_n = Number of samples required per participating facility per year. For purposes of this program, Su_n equals 2.

(4) *Laboratory designation.* Any laboratory that the independent surveyor intends to use to test samples collected as part of the national sampling oversight program specified in this subpart must be approved annually as part of the sampling oversight program plan approval process in § 1090.1425. The independent surveyor must include the following information regarding any laboratory it intends to use to test samples:

(i) The name of the laboratory.

(ii) The address of the laboratory.

(iii) The test methods for each fuel parameter measured at the laboratory.

(iv) Reports demonstrating the laboratory's performance in a laboratory cross-check program for the most recent 12 months prior to submission of the plan.

(5) *Sampling procedure.* The plan must include a detailed description of the sampling procedures used to collect samples at participating gasoline manufacturing facilities.

(6) *Notification of test results.* The plan must include a description of how the independent surveyor will notify EPA and gasoline manufacturers of test results under paragraph (c)(4) of this section.

(7) *Submission.* Plans submitted under this section must be approved annually under § 1090.1425.

Subpart O—Retailer and Wholesale Purchaser-Consumer Provisions

§ 1090.1500 Overview.

(a) Retailers and WPCs must meet the labeling requirements in §§ 1090.1510 and 1090.1515, as applicable, and the refueling hardware requirements in §§ 1090.1550 through 1090.1565, as applicable.

(b) An alternative label design to those specified in this subpart may be used if the design is approved by EPA prior to use and meets all the following requirements:

(1) The alternative label must be similar in substance and appearance to the EPA-required label.

(2) The alternative label must contain the same informational elements.

(3) The alternative label must be submitted as specified in § 1090.10.

Labeling

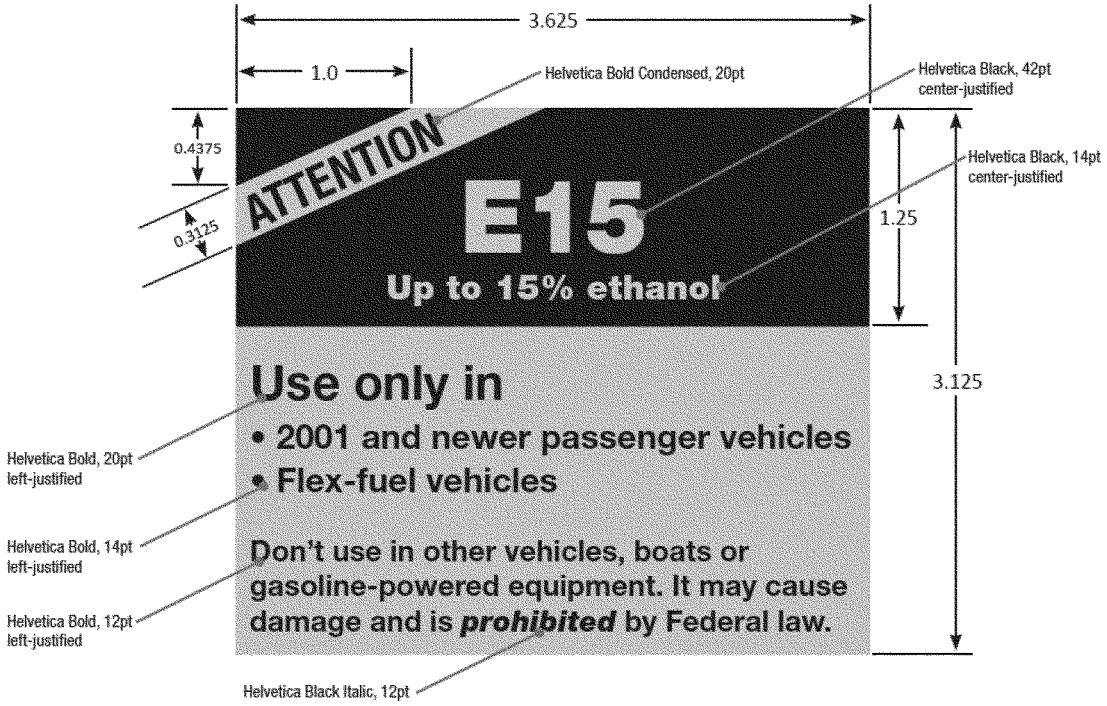
§ 1090.1510 E15 labeling provisions.

Any retailer or WPC dispensing E15 must apply a label to the fuel dispenser as follows:

(a) Position the label to clearly identify which control the consumer will use to select E15. If the dispenser is set up to dispense E15 without the consumer taking action to select the fuel, position the label on a vertical surface in a prominent place, approximately at eye level.

(b) Figure 1 of this section shows the required content and formatting. Use black letters on an orange background for the lower portion and the diagonal ''Attention'' field and use orange letters on a black background for the rest of the upper portion. Font size is shown in Figure 1. Set vertical position and line spacing as appropriate for each field. Dimensions are nominal values.

Figure 1 of §1090.1510—E15 Label



§ 1090.1515 Diesel sulfur labeling provisions.

Any retailer or WPC dispensing heating oil, 500 ppm LM diesel fuel, or ECA marine fuel must apply labels to fuel dispensers as follows:

(a) Labels must be in a prominent location where the consumer will select or dispense either the corresponding fuel or heating oil. The label content must be in block letters of no less than 24-point bold type, printed in a color contrasting with the background.

(b) Labels must include the following statements, or equivalent alternative statements approved by EPA:

(1) For dispensing heating oil along with any kind of diesel fuel for any kind of engine, vehicle, or equipment, apply the following label:

HEATING OIL

WARNING

Federal law prohibits use in highway vehicles or engines, or in nonroad, locomotive, or marine diesel engines.

Its use may damage these diesel engines.

(2) For dispensing 500 ppm LM diesel fuel, apply the following label:

LOCOMOTIVE AND MARINE DIESEL FUEL (500 ppm Sulfur Maximum)

WARNING

Federal law prohibits use in nonroad engines or in highway vehicles or engines.

(3) For dispensing ECA marine fuel, apply the following label:

ECA MARINE FUEL (1,000 ppm Sulfur Maximum).

For use in Category 3 (C3) marine vessels only.

WARNING

Federal law prohibits use in any engine that is not installed in a C3 marine vessel; use of fuel oil with a sulfur content greater than 1,000 ppm in an ECA is prohibited except as allowed by 40 CFR part 1043.

Note: If a pump dispensing 500 ppm LM diesel fuel is labeled with the ''LOW SULFUR LOCOMOTIVE AND MARINE DIESEL FUEL (500 ppm Sulfur Maximum)'' label, the retailer or WPC does not need to replace this label.

Refueling Hardware

§ 1090.1550 Requirements for gasoline dispensing nozzles used with motor vehicles.

(a) The following refueling hardware specifications apply for any nozzle installation used for dispensing gasoline into motor vehicles:

(1) The outside diameter of the terminal end must not be greater than 21.3 mm.

(2) The terminal end must have a straight section of at least 63 mm.

(3) The retaining spring must terminate at least 76 mm from the terminal end.

(b) For nozzles that dispense gasoline into motor vehicles, the dispensing flow rate may not exceed a maximum value of 10 gallons per minute. The flow rate may be controlled through any means in the pump/dispenser system, as long as it does not exceed the specified maximum value. Any dispensing pump dedicated to heavy-duty vehicles or airplanes is exempt from this flow-rate requirement. Dispensing pumps primarily used with marine vessels must instead meet the requirements in § 1090.1555.

§ 1090.1555 Requirements for gasoline dispensing nozzles used primarily with marine vessels.

The refueling hardware specifications of this section apply for any nozzle installation used primarily for dispensing gasoline into marine vessels. Note that nozzles meeting these specifications also meet the specifications of § 1090.1550(a).

(a) The outside diameter of the terminal end must have a diameter of 20.93 ± 00.43 mm.

(b) The spout must include an aspirator hole for automatic shutoff positioned with a center that is 17.0 ± 01.3 mm from the terminal end of the spout.

(c) The terminal end must have a straight section of at least 63.4 mm with no holes or grooves other than the aspirator hole.

(d) The retaining spring (if applicable) must terminate at least 76 mm from the terminal end.

§ 1090.1560 Requirements related to dispensing natural gas.

(a) Except for pumps dedicated to heavy-duty vehicles, any pump installation used for dispensing natural gas into motor vehicles must have a nozzle and hose configuration that vents no more than 1.2 grams of natural gas during a complete refueling event for a vehicle meeting the requirements of 40 CFR 86.1813–17(f)(1).

(b) Determine the vented volume using calculations based on the geometric shape of the nozzle and hose.

§ 1090.1565 Requirements related to dispensing liquefied petroleum gas.

(a) Except for pumps dedicated to heavy-duty vehicles, any pump installation used for dispensing liquefied petroleum gas into motor vehicles must have a nozzle that has no greater than 2.0 cm^3 dead space from which liquefied petroleum gas will be released when the nozzle disconnects from the vehicle.

(b) Determine the volume of the nozzle cavity using calculations based on the geometric shape of the nozzle, with an assumed flat surface where the nozzle face seals against the vehicle.

Subpart P—Importer and Exporter Provisions

§ 1090.1600 General provisions for importers.

(a) This subpart contains provisions that apply to any person who imports fuel, fuel additive, or regulated blendstock.

(b) Importers that import fuel at multiple import facilities must comply with the gasoline average standards as specified in § 1090.705(b) unless the importer elects to comply with the alternative per-gallon standards for rail and truck imports specified in §§ 1090.205(d) and 1090.210(c).

(c) Importers must separately comply with any applicable certification or other requirements for U.S. Customs.

(d) Alternative testing requirements for importers that import gasoline or diesel fuel by rail or truck are specified in § 1090.1610.

§ 1090.1605 Importation by marine vessel.

Importers that import fuel, fuel additive, or regulated blendstock using a marine vessel must comply with the requirements of this section.

(a) Importers must certify each fuel, fuel additive, or regulated blendstock imported at each port, even if it is transported by the same vessel making multiple stops.

(b)(1) Except as specified in paragraph (d) of this section, importers must certify each fuel, fuel additive, or regulated blendstock while it is onboard the vessel used to transport it to the United States, and certification sampling must be performed after the vessel's arrival at the port where the fuel, fuel additive, or regulated blendstock will be offloaded.

(2) Importers must sample each compartment of the vessel and treat each compartment as a separate batch unless the importer collects and combines samples from separate compartments into a single, volume-weight composite sample using ASTM D4057 (incorporated by reference in § 1090.95) and demonstrates that the fuel, fuel additive, or regulated blendstock is homogeneous across the compartments under § 1090.1337.

(3) Importers must ensure that all applicable per-gallon standards are met before offloading the fuel, fuel additive, or regulated blendstock.

(4) Importers must not rely on testing conducted by a foreign supplier.

(c) Once the fuel, fuel additive, or regulated blendstock on a vessel has been certified under paragraph (b) of this section, it may be transferred to shore tanks using smaller vessels or barges (lightered) as a certified fuel, fuel additive, or regulated blendstock. These lightering transfers may be to terminals located in any harbor and are not restricted to terminals located in the harbor where the vessel is anchored. For example, certified gasoline could be transferred from an import vessel anchored in New York harbor to a lightering vessel and transported to Albany, New York or Providence, Rhode Island without separately certifying the gasoline upon arrival in Albany or Providence. In this lightering scenario, transfers of certified gasoline to a lightering vessel must be accompanied by PTDs that meet the PTD requirements of subpart K of this part.

(d) As an alternative to paragraphs (b) and (c) of this section, importers may offload fuel, fuel additive, or regulated blendstock into shore tanks containing the same fuel, fuel additive, or regulated blendstock if the importer meets the following requirements:

(1) For gasoline, importers must offload gasoline into one or more empty shore tanks or tanks containing PCG that the importer owns.

(i) If importers offload gasoline into one or more empty shore tanks, they must sample and test the sulfur and benzene content, and for summer gasoline, RVP, of each shore tank into which the gasoline was offloaded.

(ii) If importers offload gasoline into one or more shore tanks containing PCG, they must sample the PCG already in the shore tank prior to offloading gasoline from the marine vessel, test the sulfur and benzene content, and report this PCG as a batch with a negative volume. After offloading the gasoline into the shore tanks, the importer must sample and test the sulfur and benzene content, and RVP for summer gasoline, of each shore tank into which the gasoline was offloaded and report the volume and sulfur and benzene content as a positive batch.

(2) For all other fuel, fuel additive, or regulated blendstock, importers must sample and test the fuel, fuel additive, or regulated blendstock in each shore tank into which it was offloaded. Importers must ensure that all applicable per-gallon standards are met before the fuel, fuel additive, or regulated blendstock is shipped from the shore tank.

§ 1090.1610 Importation by rail or truck.

Importers that import fuel, fuel additive, or regulated blendstock by rail or truck may meet the sampling and testing requirements of subpart M of this part based on test results from the supplier if they meet all the following requirements:

(a) The importer must get documentation of test results from the supplier for each batch of fuel, fuel additive, or regulated blendstock in accordance with the following requirements:

(1) The testing must include measurements for all the fuel parameters specified in § 1090.1310 using the measurement procedures specified in § 1090.1350.

(2) Testing for a given batch must occur after the most recent delivery into the supplier's storage tank and before transferring the fuel, fuel additive, or regulated blendstock to the railcar or truck.

(b) The importer must conduct testing to verify test results from each supplier as follows:

(1) Collect a sample at least once every 30 days or every 50 rail or truckloads from a given supplier, whichever is more frequent. Test such samples as specified in paragraphs (a)(1) and (2) of this section.

(2) Treat importation of each fuel, fuel additive, or regulated blendstock separately, but treat railcars and truckloads together if the fuel, fuel additive, or regulated blendstock is imported from a given supplier by rail and truck.

(c) If the importer fails to meet the requirements of paragraphs (a) and (b) of this section, they must perform testing as specified in § 1090.1310 until EPA determines that the importer has adequately addressed the cause of the failure.

§ 1090.1615 Gasoline treated as a blendstock.

(a) Importers may exclude GTAB from their compliance calculations if they meet all the following requirements:

(1) The importer reports such GTAB to EPA under § 1090.905(c)(7).

(2) Such GTAB is treated as blendstock at a related gasoline manufacturing facility that produces gasoline using the GTAB.

(3) The related gasoline manufacturing facility must report the gasoline produced using such GTAB and must include the gasoline produced using such GTAB in their compliance calculations.

(b) After importation, the title of the GTAB may not be transferred to another party until the GTAB has been blended to produce gasoline and all applicable standards and requirements have been met for the gasoline produced.

(c) The facility at which the GTAB is used to produce gasoline must be physically located at either the same terminal at which the GTAB first arrives in the United States, the import facility, or at a facility to which the GTAB is directly transported from the import facility.

(d)(1) The importer must treat the GTAB as if were imported gasoline and complete all requirements for gasoline manufacturers under § 1090.105(a) (except for the sampling, testing, and sample retention requirements in § 1090.105(a)(5)) for the GTAB at the time it is imported.

(2) Any GTAB that ultimately is not used to produce gasoline (*e.g.,* a tank bottom of GTAB) must be treated as newly imported gasoline and must meet all applicable requirements for imported gasoline.

§ 1090.1650 General provisions for exporters.

Except as specified in this section and in subpart G of this part, gasoline and diesel fuel produced, imported, distributed, or offered for sale in the United States is subject to the standards and requirements of this part.

(a) Fuels designated for export by a fuel manufacturer are not subject to the standards in this part, provided they are ultimately exported to a foreign country. However, such fuels must be designated at the fuel manufacturing facility and must be accompanied by PTDs stating that the fuel is for ''export only'' under subpart K of this part. Fuel manufacturers must keep records to demonstrate that the fuel was exported. Fuel designated for export must be segregated from all fuel intended for use in the United States.

(b) Fuel not designated for export may be exported without restriction. However, the fuel remains subject to the provisions of this part while in the United States. For example, fuel designated as ULSD must meet the applicable sulfur standards under this part even if it will later be exported.

(c) Fuel that has been classified as American Goods Returned to the U.S. by the U.S. Customs Service is not considered to be imported for purposes of this part, provided all the following requirements are met:

(1) Such fuel was produced at a fuel manufacturing facility located within the United States and has not been mixed with fuel produced at a fuel manufacturing facility located outside the United States.

(2) Such fuel must be included in compliance calculations by the producing fuel manufacturer.

(3) All the fuel that was exported must ultimately be classified as American Goods Returned to the U.S. and none may be used in a foreign country.

(4) No fuel classified as American Goods Returned to the U.S. may be combined with any fuel produced at a foreign fuel manufacturing facility prior to importation into the United States.

Subpart Q—Compliance and Enforcement Provisions

§ 1090.1700 Prohibited acts.

(a) No person may violate any prohibited act in this part or fail to meet a requirement that applies to that person under this part.

(b) No person may cause another person to commit an act in violation of this part.

§ 1090.1705 Evidence related to violations.

(a)(1) EPA may use results from any testing required by this part to determine whether a given fuel, fuel additive, or regulated blendstock meets any applicable standard. However, EPA may also use any other evidence or information to make this determination if the evidence or information supports the conclusion that the fuel, fuel additive, or regulated blendstock would fail to meet one or more of the parameter specifications in this part if the appropriate sampling and testing methodology had been correctly performed. Examples of other relevant information include business records, commercial documents, and measurements with alternative procedures.

(2) Testing to determine noncompliance with this part may occur at any location and be performed by any party.

(b) Determinations of compliance with the requirements of this part other than the fuel, fuel additive, or regulated blendstock standards, and determinations of liability for any violation of this part, may be based on information from any source or location. Such information may include, but is not limited to, business records and commercial documents.

§ 1090.1710 Penalties.

(a) Any person liable for a violation under this part is subject to civil penalties as specified in 42 U.S.C. 7524 and 7545 for every day of such violation and the amount of economic benefit or savings resulting from each violation.

(b)(1) Any person liable for the violation of an average standard under this part is subject to a separate day of violation for each and every day in the compliance period.

(2) Any person liable under this part for a failure to fulfill any requirement for credit generation, transfer, use, banking, or deficit correction is subject to a separate day of violation for each and every day in the compliance period in which invalid credits are generated or used.

(c)(1) Any person liable under this part for a violation of a per-gallon standard, or of causing another party to violate a per-gallon standard, is subject to a separate day of violation for each and every day the non-complying fuel, fuel additive, or regulated blendstock remains any place in the distribution system.

(2) For the purposes of paragraph (c)(1) of this section, the length of time the fuel, fuel additive, or regulated blendstock that violates a per-gallon standard remained in the distribution system is deemed to be 25 days, unless a person subject to liability or EPA demonstrates by reasonably specific showings, by direct or circumstantial evidence, that the non-complying fuel, fuel additive, or regulated blendstock remained in the distribution system for fewer than or more than 25 days.

(d) Any person liable for failure to meet, or causing a failure to meet, any other provision of this part is liable for a separate day of violation for each and every day such provision remains unfulfilled.

(e) For any person that fails to meet separate parameter requirements of this part, these count as separate violations.

(f) Violation of any misfueling prohibition under this part counts as a separate violation for each and every day the noncompliant fuel, fuel additive, or regulated blendstock remains in any engine, vehicle, or equipment.

(g) The presumed values of fuel parameters in paragraphs (g)(1) through (6) of this section apply for cases in which any person fails to perform required testing and must be reported, unless EPA, in its sole discretion, approves a different value in writing. EPA may consider any relevant information to determine whether a different value is appropriate.

(1) For gasoline: 970 ppm sulfur, 5 volume percent benzene, and 11 psi RVP.

(2) For diesel fuel: 1,000 ppm sulfur.

(3) For ECA marine fuel: 5,000 ppm sulfur.

(4) For the PCG portion for PCG by subtraction under § 1090.1320(a)(1): 0 ppm sulfur and 0 volume percent benzene.

(5) For fuel additives: 970 ppm sulfur.

(6) For regulated blendstocks: 970 ppm sulfur and 5 volume percent benzene.

§ 1090.1715 Liability provisions.

(a) Any person who violates any requirement in this part is liable for the violation.

(b) Any person who causes someone to commit a prohibited act under this subpart is liable for violating that prohibition.

(c) Any parent corporation is liable for any violation committed by any of its wholly-owned subsidiaries.

(d) Each partner to a joint venture, or each owner of a facility owned by two or more owners, is jointly and severally liable for any violation of this subpart that occurs at the joint venture facility or facility owned by the joint owners, or is committed by the joint venture operation or any of the joint owners of the facility.

(e)(1) Any person that produced, imported, sold, offered for sale, dispensed, supplied, offered for supply, stored, transported, caused the transportation or storage of, or introduced into commerce fuel, fuel additive, or regulated blendstock that is in the storage tank containing fuel, fuel additive, or regulated blendstock that is found to be in violation of a per-gallon standard is liable for the violation.

(2) In order for a carrier to be liable under paragraph (e)(1) of this section, EPA must demonstrate by reasonably specific showing, by direct or circumstantial evidence, that the carrier caused the violation.

(f) If a fuel manufacturer's corporate, trade, or brand name is displayed at a facility where a violation occurs, the fuel manufacturer is liable for the violation. This also applies where the displayed corporate, trade, or brand name is from the fuel manufacturer's marketing subsidiary.

§ 1090.1720 Affirmative defense provisions related to noncompliant fuel, fuel additive, or regulated blendstock.

(a) Any person liable for a violation under § 1090.1715(e) or (f) will not be deemed in violation if the person demonstrates all the following:

(1) The violation was not caused by the person or the person's employee or agent.

(2) In cases where PTD requirements of this part apply, the PTDs account for the fuel, fuel additive, or regulated blendstock found to be in violation and indicate that the violating fuel, fuel additive, or regulated blendstock was in compliance with the applicable requirements while in that person's control.

(3) The person conducted a quality assurance program, as specified in paragraph (d) of this section.

(i) A carrier may rely on the quality assurance program carried out by another party, including the party that owns the fuel in question, provided that the quality assurance program is carried out properly.

(ii) Retailers and WPCs are not required to conduct sampling and testing of fuel as part of their quality assurance program.

(b) For a violation found at a facility operating under the corporate, trade, or brand name of a fuel manufacturer, or a fuel manufacturer's marketing subsidiary, the fuel manufacturer must show, in addition to the defense elements required under paragraph (a) of this section, that the violation was caused by one of the following:

(1) An act in violation of law (other than the Clean Air Act or this part), or an act of sabotage or vandalism.

(2) The action of any retailer, distributor, reseller, oxygenate blender, carrier, retailer, or WPC in violation of a contractual agreement between the branded fuel manufacturer and the person designed to prevent such action, and despite periodic sampling and testing by the branded fuel manufacturer to ensure compliance with such contractual obligation.

(3) The action of any carrier or other distributor not subject to a contract with the fuel manufacturer, but engaged for transportation of fuel, fuel additive, or regulated blendstock despite specifications or inspections of procedures and equipment that are reasonably calculated to prevent such action.

(c) For any person to show under paragraph (a) of this section that a violation was not caused by that person, or to show under paragraph (b) of this section that a violation was caused by any of the specified actions, the person must demonstrate by reasonably specific showings, through direct or circumstantial evidence, that the violation was caused or must have been caused by another person and that the person asserting the defense did not contribute to that other person's causation.

(d) To demonstrate an acceptable quality assurance program under paragraph (a)(3) of this section, a person must present evidence of all the following:

(1)(i) A periodic sampling and testing program adequately designed to ensure the fuel, fuel additive, or regulated blendstock the person sold, dispensed, supplied, stored, or transported meets the applicable per-gallon standard. A person may meet this requirement by participating in a survey program under subpart N of this part that was in effect at the time of the violation.

(ii) In addition to the requirements in paragraph (d)(1)(i) of this section, gasoline manufacturers must also participate in the national sampling oversight program specified in § 1090.1440 at the time of the violation.

(2) On each occasion when a fuel, fuel additive, or regulated blendstock is found to be in noncompliance with the applicable per-gallon standard, the person does all the following:

(i) Immediately ceases selling, offering for sale, dispensing, supplying, offering for supply, storing, or transporting the non-complying fuel, fuel additive, or regulated blendstock.

(ii) Promptly remedies the violation and the factors that caused the violation (*e.g.,* by removing the non-complying fuel, fuel additive, or regulated blendstock from the distribution system until the applicable standard is achieved and taking steps to prevent future violations of a similar nature from occurring).

(3) For any carrier that transports a fuel, fuel additive, or regulated blendstock in a tank truck, the quality assurance program required under paragraph (d)(1) of this section does not need to include periodic sampling and testing of gasoline in the tank truck. In lieu of such tank truck sampling and testing, the carrier must demonstrate

evidence of an oversight program for monitoring compliance with the requirements of this part relating to the transport or storage of fuel, fuel additive, or regulated blendstock by tank truck, such as appropriate guidance to drivers regarding compliance with the applicable per-gallon standards and PTD requirements, and the periodic review of records received in the ordinary course of business concerning gasoline quality and delivery.

(e) In addition to the defenses provided in paragraphs (a) through (d) of this section, in any case in which an ethanol blender, distributor, reseller, carrier, retailer, or WPC would be in violation under § 1090.1715 as a result of gasoline that contains between 9 and 15 percent ethanol (by volume) but exceeds the applicable standard by more than 1.0 psi, the ethanol blender, distributor, reseller, carrier, retailer or wholesale purchaser-consumer will not be deemed in violation if such person can demonstrate, by showing receipt of a certification from the facility from which the gasoline was received or other evidence acceptable to EPA, all the following:

(1) The gasoline portion of the blend complies with the applicable RVP standard in § 1090.215.

(2) The ethanol portion of the blend does not exceed 15 percent (by volume).

(3) No additional alcohol or other additive has been added to increase the RVP of the ethanol portion of the blend.

(4) In the case of a violation alleged against an ethanol blender, distributor, reseller, or carrier, if the demonstration required by paragraphs (e)(1) through (3) of this section is made by a certification, it must be supported by evidence that the criteria in paragraphs (e)(1) through (3) of this section have been met, such as an oversight program conducted by or on behalf of the ethanol blender, distributor, reseller, or carrier alleged to be in violation, which includes periodic sampling and testing of the gasoline or monitoring the volatility and ethanol content of the gasoline. Such certification will be deemed sufficient evidence of compliance provided it is not contradicted by specific evidence, such as testing results, and provided that the party has no other reasonable basis to believe that the facts stated in the certification are inaccurate. In the case of a violation alleged against a retail outlet or WPC facility, such certification will be deemed an adequate defense for the retailer or WPC, provided that the retailer or WPC is able to show certificates for all the gasoline contained in the storage tank found in violation, and, provided that the retailer or WPC has no reasonable basis to believe that the facts stated in the certifications are inaccurate.

Subpart R—Attestation Engagements

§ 1090.1800 General provisions.

(a) The following parties must arrange for attestation engagement using agreed-upon procedures as specified in this subpart:

(1) Gasoline manufacturers that produce or import gasoline subject to the requirements of subpart C of this part.

(2) Gasoline manufacturers that perform testing as specified in subpart M of this part, and gasoline manufacturers that rely on testing from independent laboratories.

(b) Auditors performing attestation engagements must meet the following requirements:

(1) Auditors must meet one of the following professional qualifications:

(i) The auditor may be an internal auditor that is employed by the fuel manufacturer and certified by the Institute of Internal Auditors. Internal auditors must perform the attestation engagement in accordance with the *International Standards for the Professional Practice of Internal Auditing (Standards)* (incorporated by reference in § 1090.95).

(ii) The auditor may be a certified public accountant, or firm of such accountants, that is independent of the gasoline manufacturer. Such auditors must comply with the AICPA Code of Professional Conduct, including its independence requirements, the AICPA Statements on Quality Control Standards (both incorporated by reference in § 1090.95), and applicable rules of state boards of public accountancy. Such auditors must also perform the attestation engagement in accordance with the AICPA *Statements on Standards for Attestation Engagements (SSAE) No. 18, Attestation Standards: Clarification and Recodification,* especially as noted in sections AT–C 105, 215, and 315 (incorporated by reference in § 1090.95).

(2) The auditor must meet the independence requirements in § 1090.55.

(3) The auditor must be registered with EPA under subpart I of this part.

(4) Any auditor suspended or debarred under 2 CFR part 1532 or 48 CFR part 9, subpart 9.4, is not qualified to perform attestation engagements under this subpart.

(c) Auditors must perform attestation engagements separately for each gasoline manufacturing facility for which the gasoline manufacturer submitted reports to EPA under subpart J of this part for the compliance period.

(d) The following provisions apply to each attestation engagement performed under this subpart:

(1) The auditor must prepare a report identifying the applicable procedures specified in this subpart along with the auditor's corresponding findings for each procedure. The auditor must submit the report electronically to EPA by June 1 of the year following the compliance period.

(2) The auditor must identify any instances where compared values do not agree or where specified values do not meet applicable requirements under this part.

(3) Laboratory analysis refers to the original test result for each analysis of a product's properties. The following provisions apply in special cases:

(i) For laboratories using test methods that must be correlated to the standard test method, the laboratory analysis must include the correlation factors along with the corresponding test results.

(ii) For gasoline manufacturers that rely on third-party laboratories for all testing, the laboratory analysis consists of the results provided by the third-party laboratory.

§ 1090.1805 Representative samples.

(a) If the specified procedures require evaluation of a representative sample from the overall population for a given data set, determine the number of results for evaluation using one of the following methods:

(1) Determine sample size using the following table:

TABLE 1 TO PARAGRAPH (a)(1)

Population	Sample size
1–25	The smaller of the population or 19.
26–40	20.
41–65	25.
66 or more	29.

(2) Determine sample size corresponding to a confidence level of 95 percent, an expected error rate of 0 percent, and a maximum tolerable error rate of 10 percent, using conventional statistical principles and methods.

(3) Determine sample size using an alternate method that is equivalent to or better than the methods specified in paragraphs (a)(1) and (2) of this section with respect to strength of inference and freedom from bias. Auditors that determine a sample size using an alternate method must describe and justify the alternate method in the attestation report.

(b) Select specific data points for evaluation over the course of the

compliance period in a way that leads to a simple random sample that properly represents the overall population for the data set.

§ 1090.1810 General procedures—gasoline manufacturers.

The procedures specified in this section apply to refiners, blending manufacturers, and transmix processers that produce gasoline.

(a) *Registration and EPA reports.* Auditors must review registration and EPA reports as follows:

(1) Obtain copies of the gasoline manufacturer's registration information submitted under subpart I of this part and all reports (except batch reports) submitted to EPA under subpart J of this part.

(2) For each gasoline manufacturing facility, confirm that the facility's registration is accurate based on the activities reported during the compliance period, including that the registration for the facility and any related updates were completed prior to conducting regulated activities at the facility, reporting any discrepancies.

(3) Confirm that the gasoline manufacturer submitted all the reports required under subpart J of this part for activities they performed during the compliance period, reporting any exceptions.

(4) Obtain a written statement from the gasoline manufacturer's RCO that the submitted reports are complete and accurate.

(5) Report in the attestation report the name of any commercial computer program used to track the data required under this part, if any.

(b) *Inventory reconciliation analysis.* Auditors must perform an inventory reconciliation analysis as follows:

(1) Obtain an inventory reconciliation analysis from the gasoline manufacturer for each product type produced at each facility (*e.g.,* RFG, CG, RBOB, CBOB), including the inventory at the beginning and end of the compliance period, receipts, production, shipments, transfers, and gain/loss.

(2) Foot and cross-foot the volumes.

(3) Compare the beginning and ending inventory to the manufacturer's inventory records for each product type, reporting any variances.

(4) Report in the attestation report the volume totals for each product type on the basis of which gasoline batches are reported.

(c) *Listing of tenders.* Auditors must review a listing of tenders as follows:

(1) Obtain detailed listings of gasoline tenders from the gasoline manufacturer, by product type.

(2) Foot the listings of gasoline tenders.

(3) Compare the total volume from the gasoline tenders to the total volume shipped in the inventory reconciliation analysis for each product type, reporting any variances.

(d) *Listing of batches.* Auditors must review listings of batches as follows:

(1) Obtain the batch reports submitted under subpart J of this part.

(2) Foot the batch volumes by product type.

(3) Compare the total volume from the batch reports to the total production or shipment volume from the inventory reconciliation analysis specified in paragraph (b)(4) of this section for each product type, reporting any variances.

(4) Report as a finding in the attestation report any gasoline batch with reported values that do not meet a per-gallon standard in subpart C of this part.

(e) *Test methods.* Auditors must follow the procedures specified in § 1090.1845 to determine whether the gasoline manufacturer complies with the applicable quality control requirements specified in § 1090.1375.

(f) *Review of BOB tenders.* Auditors must review a detailed listing of BOB tenders as follows:

(1) Select a representative sample of PTDs from the listing of BOB tenders.

(2) For each sample, obtain the associated PTDs.

(3) Using a unique identifier, confirm that the correct PTDs are obtained for the samples and compare the volume on the listing of each selected BOB tender to the associated PTD, reporting any exceptions.

(4) Confirm that the PTD associated with each selected BOB tender contains all the applicable language requirements under subpart K of this part, reporting any exceptions.

(g) *Detailed testing of BOB batches.* Auditors must review a detailed listing of BOB batches as follows:

(1) Select a representative sample from the BOB batch reports submitted to EPA under subpart J of this part and obtain the volume documentation and laboratory analysis for each sample.

(2) Compare the reported volume for each selected sample to the volume documentation, reporting any exceptions.

(3) Compare the reported properties for each selected sample BOB batch to the laboratory analysis, reporting any exceptions.

(4) Compare the reported test methods used for each selected BOB batch to the laboratory analysis, reporting any exceptions.

(5) Determine each oxygenate type and amount that is required for blending with the BOB.

(6) Confirm that each oxygenate type and amount included in the BOB hand blend agrees within an acceptable range to each selected BOB batch, reporting any exceptions.

(7) Confirm that the manufacturer participates in the national fuels survey program under subpart N of this part, if applicable.

(8) For blending manufacturers, confirm that the laboratory analysis includes test results for oxygenate and distillation parameters (*i.e.,* T10, T50, T90, final boiling point, and percent residue).

(h) *Detailed testing of finished gasoline tenders.* Auditors must review a detailed listing of finished gasoline tenders as follows:

(1) Select a representative sample from the listing of finished gasoline tenders and obtain the associated PTD for each selected tender.

(2) Using a unique identifier, confirm that the correct PTDs are obtained for the samples and compare the volume on the listing for each finished gasoline tender to the associated PTD.

(3) Confirm that the PTD associated with each selected finished gasoline tender contains all the applicable language requirements under subpart K of this part, reporting any exceptions.

(4) Report as a finding in the attestation report any tenders where the PTD did not contain all applicable PTD language requirements under subpart K of this part, reporting any exceptions.

(i) *Detailed testing of finished gasoline batches.* Auditors must review a detailed listing of finished gasoline batches as follows:

(1) Select a representative sample of finished gasoline batches from the batch reports submitted to EPA under subpart J of this part and obtain the volume documentation and laboratory analysis for each selected finished gasoline batch.

(2) Compare the reported volume for each selected finished gasoline batch to the volume documentation, reporting any exceptions.

(3) Compare the reported properties for each selected finished gasoline batch to the laboratory analysis, reporting any exceptions.

(4) Compare the reported test methods used for each selected finished gasoline batch to the laboratory analysis, reporting any exceptions.

(5) For blending manufacturers, confirm that the laboratory analysis includes test results for oxygenate and distillation parameters (*i.e.,* T10, T50, T90, final boiling point, and percent residue).

§ 1090.1815 General procedures—gasoline importers.

The procedures of this section apply to gasoline manufacturers that import gasoline:

(a) *Registration and EPA reports.* Auditors must review registration and EPA reports for gasoline importers as specified in § 1090.1810(a).

(b) *Listing of imports.* Auditors must review a listing of imports as follows:

(1) Obtain detailed listings of gasoline imports from the importer, by product type.

(2) Foot the listings of gasoline imports from the importer.

(3) Obtain listings of gasoline imports directly from the third-party customs broker, by product type.

(4) Foot the listings of gasoline imports from the third-party customs broker.

(5) Compare the total volume from the importer's listings of gasoline imports to the listings from the third-party customs broker for each product type, reporting any variances.

(6) Report in the attestation report the total imported volume for each product type.

(c) *Listing of batches.* Auditors must review listings of batches as follows:

(1) Obtain the batch reports submitted under subpart J of this part.

(2) Foot the batch volumes by product type.

(3) Compare the total volume from the batch reports to the total volume per the listings of gasoline imports from the importer specified in paragraph (b)(1) of this section for each product type, reporting any variances.

(4) Report as a finding in the attestation report any gasoline batches with parameter results that do not meet the per-gallon standards in subpart C of this part.

(d) *Test methods.* Auditors must follow the procedures specified in § 1090.1845 to determine whether the importer complies with the quality control requirements specified in § 1090.1375 for gasoline, gasoline additives, and gasoline regulated blendstocks.

(e) *Detailed testing of BOB imports.* Auditors must review a detailed listing of BOB imports as follows:

(1) Select a representative sample from the listing of BOB imports from the importer and obtain the associated U.S. Customs Entry Summary and PTD for each selected BOB import.

(2) Using a unique identifier, confirm that the correct U.S. Customs Entry Summaries are obtained for the samples and compare the location that each selected BOB import arrived in the United States and volume on the listing of BOB imports from the importer to the U.S. Customs Entry Summary, reporting any exceptions.

(3) Using a unique identifier, confirm that the correct PTDs are obtained for the samples. Confirm that the PTD contains all the applicable language requirements under subpart K of this part, reporting any exceptions.

(f) *Detailed testing of BOB batches.* Auditors must review a detailed listing of BOB batches as follows:

(1) Select a representative sample of BOB batches from the batch reports submitted under subpart J of this part and obtain the volume inspection report and laboratory analysis for each selected BOB batch.

(2) Compare the reported volume for each selected BOB batch to the volume inspection report, reporting any exceptions.

(3) Compare the reported properties for each selected BOB batch to the laboratory analysis, reporting any exceptions.

(4) Compare the reported test methods used for each selected BOB batch to the laboratory analysis, reporting any exceptions.

(5) Determine each oxygenate type and amount that is required for blending with each selected BOB batch.

(6) Confirm that each oxygenate type and amount included in the BOB hand blend agrees within an acceptable range to each selected BOB batch, reporting any exceptions.

(7) Confirm that the importer participates in the national fuels survey program under subpart N of this part, if applicable.

(g) *Detailed testing of finished gasoline imports.* Auditors must review a detailed listing of finished gasoline imports as follows:

(1) Select a representative sample from the listing of finished gasoline imports from the importer and obtain the associated U.S. Customs Entry Summary and PTD for each selected finished gasoline import.

(2) Using a unique identifier, confirm that the correct U.S. Customs Entry Summaries are obtained for the samples and compare the location that each selected finished gasoline import arrived in the United States and volume on the listing of finished gasoline imports from the importer to the U.S. Customs Entry Summary, reporting any exceptions.

(3) Using a unique identifier, confirm that the correct PTDs are obtained for the samples. Confirm that the PTD contain all the applicable language requirements under subpart K of this part, reporting any exceptions.

(h) *Detailed testing of finished gasoline batches.* Auditors must review a detailed listing of finished gasoline batches as follows:

(1) Select a representative sample of finished gasoline batches from the batch reports submitted under subpart J of this part and obtain the volume inspection report and laboratory analysis for each selected finished gasoline batch.

(2) Compare the reported volume for each selected finished gasoline batch to the volume inspection report, reporting any exceptions.

(3) Compare the reported properties for each selected finished gasoline batch to the laboratory analysis, reporting any exceptions.

(4) Compare the reported test methods used for each selected finished gasoline batch to the laboratory analysis, reporting any exceptions.

(i) *Additional procedures for certain gasoline imported by rail or truck.* Auditors must perform the following additional procedures for importers that import gasoline into the United States by rail or truck under § 1090.1610:

(1) Select a representative sample from the listing of batches obtained under paragraph (c) of this section and perform the following for each selected batch:

(i) Identify the point of sampling and testing associated with each selected batch in the tank activity records from the supplier.

(ii) Confirm that the sampling and testing occurred after the most recent delivery into the supplier's storage tank and before transferring product to the railcar or truck.

(2)(i) Obtain a detailed listing of the importer's quality assurance program sampling and testing results.

(ii) Determine whether the frequency of the sampling and testing meets the requirements in § 1090.1610(b).

(iii) Select a representative sample from the importer's sampling and testing records under the quality assurance program and perform the following for each selected batch:

(A) Obtain the corresponding laboratory analysis.

(B) Determine whether the importer analyzed the test sample, and whether they performed the analysis using the methods specified in subpart M of this part.

(C) Review the terminal test results corresponding to the time of collecting the quality assurance test samples. Compare the terminal test results with the test results from the quality assurance program, noting any parameters with differences that are greater than the reproducibility of the

applicable method specified in subpart M of this part.

§ 1090.1820 Additional procedures for gasoline treated as blendstock.

In addition to any applicable procedures required under §§ 1090.1810 and 1090.1815, auditors must perform the procedures in this section for gasoline manufacturers that import GTAB under § 1090.1615.

(a) *Listing of GTAB imports.* Auditors must review a listing of GTAB imports as follows:

(1) Obtain a detailed listing of GTAB imports from the GTAB importer.

(2) Foot the listing of GTAB imports from the GTAB importer.

(3) Obtain a listing of GTAB imports directly from the third-party customs broker.

(4) Foot the listing of GTAB imports from the third-party customs broker, reporting any variances.

(5) Compare the total volume from the GTAB importer's listing of GTAB imports to the listing from the third-party customs broker.

(6) Report in the attestation report the total imported volume of GTAB and the corresponding facilities at which the GTAB was blended.

(b) *Listing of GTAB batches.* Auditors must review a listing of GTAB batches as follows:

(1) Obtain the GTAB batch reports submitted under subpart J of this part.

(2) Foot the batch volumes.

(3) Compare the total volume from the GTAB batch reports to the total volume from the importer's listing of GTAB imports in paragraph (a)(1) of this section, reporting any variances.

(c) *Detailed testing of GTAB imports.* Auditors must review a detailed listing of GTAB imports as follows:

(1) Select a representative sample from the listing of GTAB imports obtained in paragraph (a)(1) of this section.

(2) For each selected GTAB batch, obtain the U.S. Customs Entry Summaries.

(3) Using a unique identifier, confirm that the correct U.S. Customs Entry Summaries are obtained for the samples. Compare the volumes and locations that each selected GTAB batch arrived in the United States to the U.S. Customs Entry Summary, reporting any exceptions.

(d) *Detailed testing of GTAB batches.* Auditors must review a detailed listing of GTAB batches as follows:

(1) Select a representative sample from the batch reports obtained under paragraph (b)(1) of this section.

(2) For each selected GTAB batch sample, obtain the volume inspection report.

(3) Compare the reported volume for each selected GTAB batch to the volume inspection report, reporting any exceptions.

(4) Compare the reported properties for the selected GTAB batches to the laboratory analysis, reporting any exceptions.

(5) Compare the reported test methods used for the selected GTAB batches to the laboratory analysis, reporting any exceptions.

(e) *GTAB tracing.* Auditors must trace and review the movement of GTAB from importation to use to produce gasoline as follows:

(1) Compare the volume total on each GTAB batch report obtained under paragraph (b)(1) of this section to the GTAB volume total in the gasoline manufacturer's inventory reconciliation analysis under § 1090.1810(b).

(2) For each selected GTAB batch under paragraph (d)(1) of this section:

(i) Obtain tank activity records that describe the movement of the selected GTAB batch from importation to use to produce gasoline.

(ii) Identify each selected GTAB batch in the tank activity records and trace each selected GTAB batch to subsequent reported batches of BOB or finished gasoline.

(iii) Agree the location of the facility where gasoline was produced from each selected GTAB batch to the location that the GTAB batch arrived in the United States, or to the facility directly receiving the GTAB batch from the import facility.

(iv) Determine the status of the tank(s) before receiving each selected GTAB batch (*e.g.,* empty tank, tank containing blendstock, tank containing GTAB, tank containing PCG).

(v) If the tank(s) contained PCG before receiving the selected GTAB batch, take the following additional steps:

(A) Obtain and review a copy of the documented tank mixing procedures.

(B) Determine the volume and properties of the tank bottom that was PCG before adding GTAB.

(C) Confirm that the gasoline manufacturer determined the volume and properties of the BOB or finished gasoline produced using GTAB by excluding the volume and properties of any PCG, and that the gasoline manufacturer separately reported the PCG volume and properties under subpart J of this part, reporting any discrepancies.

§ 1090.1825 Additional procedures for PCG used to produce gasoline.

In addition to any applicable procedures required under § 1090.1810, auditors must perform the procedures in this section for gasoline manufacturers that produce gasoline from PCG under § 1090.1320.

(a) *Listing of PCG batches.* Auditors must review a listing of PCG batches as follows:

(1) Obtain the PCG batch reports submitted under subpart J of this part.

(2) Foot the batch volumes.

(3) Compare the volume total for each PCG batch report to the receipt volume total in the inventory reconciliation analysis specified in § 1090.1810(b), reporting any variances.

(b) *Detailed testing of PCG batches.* Auditors must review a detailed listing of PCG batches as follows:

(1) Select a representative sample from the PCG batch reports obtained under paragraph (a) of this section.

(2) Obtain the volume documentation, laboratory analysis, associated PTDs, and tank activity records for each selected PCG batch.

(3) Identify each selected PCG batch in the tank activity records and trace each selected PCG batch to subsequent reported batches of BOB or finished gasoline, reporting any exceptions.

(4) Report as a finding in the attestation report any instances where the reported PCG batch volume was adjusted from the original receipt volume, such as for exported PCG.

(5) Compare the volume for each selected PCG batch to the volume documentation, reporting any exceptions.

(6) Compare the product type and grade for each selected PCG batch to the associated PTDs, reporting any exceptions.

(7) Compare the reported properties for each selected PCG batch to the laboratory analysis, reporting any exceptions.

(8) Compare the reported test methods used for each selected PCG batch to the laboratory analysis, reporting any exceptions.

§ 1090.1830 Alternative procedures for certified butane blenders.

Auditors must use the procedures of this section instead of or in addition to the procedures in § 1090.1810 for certified butane blenders that blend certified butane into PCG under the provisions of § 1090.1320.

(a) *Registration and EPA reports.* Auditors must review registration and EPA reports as follows:

(1) Obtain copies of the certified butane blender's registration information submitted under subpart I of this part and all reports submitted under subpart J of this part, including the batch reports for the butane received and blended.

(2) For each certified butane blending facility, confirm that the facility's registration is accurate based on activities reported during the compliance period, including that the registration for the facility and any related updates were completed prior to conducting regulated activities at the facility, reporting any discrepancies.

(3) Confirm that the certified butane blender submitted the reports required under subpart J of this part for activities they performed during the compliance period, reporting any exceptions.

(4) Obtain a written statement from the certified butane blender's RCO that the submitted reports are complete and accurate.

(5) Report in the attestation report the name of any commercial computer program used to track the data required under this part, if any.

(b) *Inventory reconciliation analysis.* Auditors must complete an inventory reconciliation analysis review as follows:

(1) Obtain an inventory reconciliation analysis from the certified butane blender for each blending facility related to all certified butane movements, including the inventory at the beginning and end of the compliance period, receipts, blending/production volumes, shipments, transfers, and gain/loss.

(2) Foot and cross-foot the volumes.

(3) Compare the beginning and ending inventory to the certified butane blender's inventory records, reporting any variances.

(4) Compare the total volume of certified butane received from the batch reports obtained under paragraph (a) of this section to the inventory reconciliation analysis, reporting any variances.

(5) Compare the total volume of certified butane blended from the batch reports to the inventory reconciliation analysis, reporting any variances.

(6) Report in the attestation report the total volume of certified butane received and blended.

(c) *Listing of certified butane receipts.* Auditors must review a listing of certified butane receipts as follows:

(1) Obtain a detailed listing of all certified butane batches received at the blending facility from the certified butane blender.

(2) Foot the listing of certified butane batches received.

(3) Compare the total volume from batch reports for certified butane received at the butane blending facility to the certified butane blender's listing of certified butane batches received, reporting any variances.

(d) *Detailed testing of certified butane batches.* Auditors must review a detailed listing of certified butane batches as follows:

(1) Select a representative sample from the certified butane batch reports submitted under subpart J of this part.

(2) Obtain the volume documentation and laboratory analysis for each selected certified butane batch.

(3) Compare the reported volume for each selected certified butane batch to the volume documentation, reporting any exceptions.

(4) Compare the reported properties for each selected certified butane batch to the laboratory analysis, reporting any exceptions.

(5) Compare the reported test methods used for each selected certified butane batch to the laboratory analysis, reporting any exceptions.

(6) Confirm that the butane meets the standards for certified butane under subpart C of this part, reporting any exceptions.

(e) *Quality control review.* Auditors must obtain the certified butane blender's sampling and testing results for certified butane received and determine if the frequency of the sampling and testing meets the requirements in § 1090.1320(c)(4), reporting any discrepancies.

§ 1090.1835 Alternative procedures for certified pentane blenders.

(a) Auditors must use the procedures of this section instead of or in addition to the procedures in §§ 1090.1810 and 1090.1815, as applicable, for certified pentane blenders that blend certified pentane into PCG under the provisions of § 1090.1320.

(b) Auditors must apply the procedures in § 1090.1830 by substituting ''pentane'' for ''butane'' in all cases.

§ 1090.1840 Additional procedures related to compliance with gasoline average standards.

Auditors must perform the procedures of this section for gasoline manufacturers that comply with the standards in subpart C of this part using the procedures specified in subpart H of this part.

(a) *Annual compliance demonstration review.* Auditors must review annual compliance demonstrations as follows:

(1) Obtain the annual compliance reports for sulfur and benzene and associated batch reports submitted under subpart J of this part.

(2)(i) For gasoline refiners and blending manufacturers, compare the gasoline production volume from the annual compliance report to the inventory reconciliation analysis under § 1090.1810(b), reporting any variances.

(ii) For gasoline importers, compare the gasoline import volume from the annual compliance report to the corresponding volume from the listing of imports under § 1090.1815(b), reporting any variances.

(3) For each facility, recalculate the following and report in the attestation report the recalculated values:

(i) Compliance sulfur value, per § 1090.700(a)(1), and compliance benzene value, per § 1090.700(b)(1).

(ii) Average benzene concentration, per § 1090.700(b)(3).

(iii) Number of credits generated during the compliance period, or number of banked or traded credits needed to meet standards for the compliance period.

(iv) Number of credits from the preceding compliance period that are expired or otherwise no longer available for the compliance period being reviewed.

(4) Compare the recalculated values in paragraph (a)(3) of this section to the reported values in the annual compliance reports, reporting any exceptions.

(5) Report in the attestation report whether the gasoline manufacturer had a deficit for both the compliance period being reviewed and the preceding compliance period.

(b) *Credit transaction review.* Auditors must review credit transactions as follows:

(1) Obtain the gasoline manufacturer's credit transaction reports submitted under subpart J of this part and contracts or other information that documents all credit transfers. Also obtain records that support intracompany transfers.

(2) For each reported transaction, compare the supporting documentation with the credit transaction reports for the following elements, reporting any exceptions:

(i) Compliance period of creation.

(ii) Credit type (*i.e.,* sulfur or benzene) and number of times traded.

(iii) Quantity.

(iv) The name of the other company participating in the credit transfer.

(v) Transaction type.

(c) *Facility-level credit reconciliation.* Auditors must perform a facility-level credit reconciliation separately for each gasoline manufacturing facility as follows:

(1) Obtain the credits remaining or the credit deficit from the previous compliance period from the gasoline manufacturer's credit transaction information for the previous compliance period.

(2) Compute and report as a finding the net credits remaining at the end of the compliance period.

(3) Compare the ending balance of credits or credit deficit recalculated in paragraph (c)(2) of this section to the corresponding value from the annual compliance report, reporting any variances.

(4) For importers, the procedures of this paragraph (c) apply at the company level.

(d) *Company-level credit reconciliation.* Auditors must perform a company-level credit reconciliation as follows:

(1) Obtain a credit reconciliation listing company-wide credits aggregated by facility for the compliance period.

(2) Foot and cross-foot the credit quantities.

(3) Compare and report the beginning balance of credits, the ending balance of credits, the associated credit activity at the company level in accordance with the credit reconciliation listing, and the corresponding credit balances and activity submitted under subpart J of this part.

(e) *Procedures for gasoline manufacturers that recertify BOB.* Auditors must perform the following procedures for any gasoline manufacturer that recertifies a BOB under § 1090.740 and incurs a deficit:

(1) Auditors must perform the procedures specified in § 1090.1810(a) to review registration and EPA reports.

(2) Obtain the batch reports for recertified BOB submitted under subpart J of this part.

(3) Select a representative sample of recertified BOB batches from the batch reports.

(4) For each sample, obtain supporting documentation.

(5) Confirm the accuracy of the information reported, reporting any exceptions.

(6) Recalculate the deficits in accordance with the provisions of § 1090.740, reporting any discrepancies.

(7) Confirm that the deficits are included in the annual compliance demonstration calculations, reporting any exceptions.

§ 1090.1845 Procedures related to meeting performance-based measurement and statistical quality control for test methods.

(a) *General provisions.* (1) Auditors must conduct the procedures specified in this section for gasoline manufacturers.

(2) Auditors performing the procedures specified in this section must meet the laboratory experience requirements specified in § 1090.55(b)(2).

(3) In cases where the auditor needs to involve an external specialist, all the requirements of § 1090.55 apply to the external specialist. The auditor is responsible for overseeing the work of the specialist, consistent with applicable professional standards specified in § 1090.1800.

(4) In the case of quality control testing at a third-party laboratory, the auditor may perform a single attestation engagement on the third-party laboratory for multiple gasoline manufacturers if the auditor directly reviewed the information from the third-party laboratory.

(b) *Non-referee method review.* For each test method used to measure a parameter for gasoline as specified in a report submitted under subpart J of this part that is not one of the referee methods listed in § 1090.1360(d), the auditor must:

(1) Obtain supporting documentation showing that the laboratory has qualified the test method by meeting the precision and accuracy criteria specified under § 1090.1365.

(2) Report in the attestation report a list of the alternative methods used.

(3) Report as a finding in the attestation report any of these test methods that have not been qualified by the facility.

(4) If an auditor has previously reviewed supporting documentation under this paragraph for an alternative method at the facility, the auditor does not have to review the supporting document again.

(c) *Reference installation review.* For each reference installation used by the gasoline manufacturer during the compliance period, the auditor must review the following:

(1) Obtain supporting documentation demonstrating that the reference installation followed the qualification procedures specified in § 1090.1370(c)(1) and (2) and the quality control procedures specified in § 1090.1370(c)(3).

(2) Report as a finding in the attestation report any of the qualification procedures that were not completed by the facility.

(d) *Instrument control review.* For each test instrument used to test gasoline parameters for batches selected as part of a representative sample under § 1090.1810, the auditor must review whether test instruments were in control as follows:

(1) Obtain statistical quality assurance data and control charts demonstrating ongoing quality testing to meet the accuracy and precision requirements specified in § 1090.1375.

(2) Report as a finding in the attestation report any instruments for which the facility failed to perform statistical qualtiy assurance monitoring under § 1090.1375.

(3) Report as a finding in the attestation report the instrument list obtained under paragraph (b)(1) of this section and the compliance period when the instrument control review was completed.

§ 1090.1850 Procedures related to in-line blending waivers.

In addition to any other procedure required under this subpart, auditors must perform the procedures specified in this section for gasoline refiners that rely on an in-line blending waiver under § 1090.1315.

(a) Obtain a copy of the refiner's in-line blending waiver submission and EPA's approval letter.

(b) Confirm that the refiner uses the in-line blending waiver only for qualified operations as specified in § 1090.1315(a).

(c) Confirm that the sampling procedures and composite calculations conform to specifications as specified in § 1090.1315(b)(2).

(d) Review the refiner's procedure for defining a batch for compliance purposes. Review available test data demonstrating that the test results from in-line blending correctly characterize the fuel parameters for the designated batch.

(e) Confirm that the refiner corrected their operations because of previous audits, if applicable.

(f) Confirm that the equipment and procedures are not materially changed from the refiner's in-line blending waiver. Report in the attestation report whether the refiner has failed to update their in-line blending waiver based on a material change in equipment or procedure.

(g) Report in the attestation report whether the refiner has complied with all provisions related to their in-line blending waiver.

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Part III

Department of Health and Human Services

45 CFR Parts 146, 149, *et al.*

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Parts 146, 149, 155, 156 and 158

[CMS–9916–F]

RIN 0938–AT98

Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule sets forth payment parameters and provisions related to the risk adjustment and risk adjustment data validation programs; cost-sharing parameters and cost-sharing reductions; and user fees for Federally-facilitated Exchanges and State-based Exchanges on the Federal platform. It also finalizes changes related to essential health benefits and will provide states with additional flexibility in the operation and establishment of Exchanges. The rule includes changes related to cost sharing for prescription drugs; notice requirements for excepted benefit health reimbursement arrangements offered by non-Federal governmental plan sponsors; Exchange eligibility and enrollment; exemptions from the requirement to maintain coverage; quality rating information display standards for Exchanges; and other related topics. This final rule also repeals regulations relating to the Early Retiree Reinsurance Program.

DATES: These regulations are effective July 13, 2020.

FOR FURTHER INFORMATION CONTACT: Usree Bandyopadhyay, (410) 786–6650, Kiahana Brooks, (301) 492–5229, or Evonne Muoneke (301) 492–4402, for general information.

David Mlawsky, (410) 786–6851, for matters related to excepted benefit health reimbursement arrangements (HRAs).

Allison Yadsko, (410) 786–1740 or Krutika Amin, (301) 646–2420, for matters related to risk adjustment.

Aaron Franz, (410) 786–8027, for matters related to Federally-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees and sequestration.

Joshua Paul, (301) 492–4347 or Allison Yadsko, (410) 786–1740, for matters related to risk adjustment data validation (RADV).

Joshua Paul, (301) 492–4347, for matters related to the premium adjustment percentage.

Alper Ozinal, (301) 492–4178, for matters related to timely submission of enrollment reconciliation data and dispute of HHS payment and collections reports.

Rebecca Zimmermann, (301) 492–4396, for matters related to value-based insurance plan design.

Becca Bucchieri, (301) 492–4341, for matters related to essential health benefit (EHB)-benchmark plans and defrayal of state-required benefits.

Jill Gotts, (202) 603–0480, for matters related to eligibility appeals.

Emily Ames, (301) 492–4246, for matters related to coverage effective dates and termination notices.

Marisa Beatley, (301) 492–4307, for matters related to employer-sponsored coverage verification and periodic data matching (PDM).

Carolyn Kraemer, (301) 492–4197, for matters related to special enrollment periods under part 155.

Kendra May, (301) 492–4477, for matters related to terminations.

LeAnn Brodhead, (410) 786–3943, for matters related to cost-sharing requirements.

Christina Whitefield, (301) 492–4172, for matters related to the medical loss ratio (MLR) program.

Kevin Kendrick, (301) 492–4127, for matters related to the Early Retiree Reinsurance Program (ERRP).

Jenny Chen, (301) 492–5156, Shilpa Gogna, (301) 492–4257 or Nidhi Singh Shah, (301) 492–5110), for matters related to quality rating information display standards for Exchanges.

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I. Executive Summary

American Health Benefit Exchanges, or ''Exchanges,'' are entities established under the Patient Protection and Affordable Care Act [1] (PPACA) through which qualified individuals and qualified employers can purchase health insurance coverage in qualified health plans (QHPs). Many individuals who enroll in QHPs through individual market Exchanges are eligible to receive a premium tax credit (PTC) to reduce their costs for health insurance premiums and to receive reductions in required cost-sharing payments to reduce out-of-pocket expenses for health care services. The PPACA also established the risk adjustment program, which is intended to increase the workability of the PPACA regulatory changes in the individual and small group markets, both on and off Exchanges.

On January 20, 2017, the President issued an Executive Order which stated that, to the maximum extent permitted by law, the Secretary of HHS and heads of all other executive departments and agencies with authorities and

[1] The PPACA (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), which amended and revised several provisions of the PPACA, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the ''Patient Protection and Affordable Care Act'' or ''PPACA''.

responsibilities under the PPACA should exercise all authority and discretion available to them to waive, defer, grant exemptions from, or delay the implementation of any provision or requirement of the PPACA that would impose a fiscal burden on any state or a cost, fee, tax, penalty, or regulatory burden on individuals, families, health care providers, health insurers, patients, recipients of health care services, purchasers of health insurance, or makers of medical devices, products, or medications. In this final rule, we are, within the limitations of current law, finalizing provisions to reduce fiscal and regulatory burdens across different program areas and to provide stakeholders with greater flexibility.

In previous rulemakings, we established provisions and parameters to implement many PPACA requirements and programs. In this final rule, we are amending some of these provisions and parameters, with a focus on maintaining a stable regulatory environment. These changes are intended to provide issuers with greater predictability for upcoming plan years, while simultaneously enhancing the role of states in these programs. The provisions will also provide states with additional flexibilities, reduce unnecessary regulatory burdens on stakeholders, empower consumers, ensure program integrity, and improve affordability. In the proposed rule, we solicited comments on modifying the automatic re-enrollment process for enrollees who would be automatically re-enrolled with advance payments of the premium tax credit (APTC) that would cover the enrollee's entire premium. We also announced that, pending such future rulemaking, HHS will not take enforcement action against Exchanges that do not implement a random sampling methodology during plan years 2020 and 2021.

Risk adjustment continues to be a core program in the individual and small group markets both on and off Exchanges, and we are finalizing the proposals to recalibrate the risk adjustment models used in the state payment transfer formula of the HHS-operated risk adjustment methodology, among other updates. As a refinement to the risk adjustment program, we are finalizing changes intended to improve the reliability of risk adjustment data validation (RADV).

As we do every year in the HHS notice of benefit and payment parameters, we are finalizing the user fee rates for issuers offering plans through the Exchanges using the Federal platform. For the 2021 plan year, we are maintaining the Federally-facilitated Exchange (FFE) and State-based Exchange on the Federal platform (SBE–FP) user fees at the current 2020 plan year rates, 3.0 and 2.5 percent of total monthly premiums, respectively, in order to preserve and ensure that the FFE has sufficient funding to cover the cost of all special benefits provided to FFE issuers during the 2021 plan year.

As we do every year, we are updating the maximum annual limitation on cost sharing for the 2021 benefit year, including those for cost-sharing reduction (CSR) plan variations. These updates, which are required by law, will raise the annual limit on cost sharing, thereby increasing cost sharing and out-of-pocket spending for consumers who have out-of-pocket spending close to the annual cost-sharing limit.

We are committed to promoting a consumer-driven health care system in which consumers are empowered to select and maintain health care coverage of their choosing. To this end, we provide information to QHP issuers on ways in which they can implement value-based insurance plan designs that would empower consumers to receive high value services at lower costs. These value-based insurance plan designs will empower consumers and their providers to make evidence-based health decisions.

We also finalize new rules related to special enrollment periods. We will allow Exchange enrollees and their dependents who are enrolled in silver plans and become newly ineligible for CSRs to change to a QHP one metal level higher or lower, if they choose. We will require Exchanges to apply plan category limitations to dependents who are currently enrolled in Exchange coverage and whose non-dependent household member qualifies for a special enrollment period to newly enroll in coverage. We will also shorten the time between the date a consumer selects a plan through certain special enrollment periods and the effective date of that plan. In addition, we will allow all enrollees granted retroactive coverage through a special enrollment period the option to select a later effective date and pay for only prospective coverage. We also finalize the proposals to allow individuals and their dependents who are provided a qualified small employer health reimbursement arrangement (QSEHRA) on a non-calendar year basis to qualify for the existing special enrollment period for individuals enrolled in any non-calendar year group health plan or individual health insurance coverage. We will also allow enrollees whose requests for termination of their coverage were not implemented due to an Exchange technical error to terminate their coverage retroactive to the date they attempted the termination, at the option of the Exchange.

To increase transparency in terminations of Exchange coverage or enrollment, we will require termination notices be provided in all scenarios where Exchange coverage or enrollment is terminated. We also will require excepted benefit health reimbursement arrangements (HRAs) sponsored by non-Federal governmental entities to provide a notice to participants that contains specified information about the benefits available under the excepted benefit HRA.

In addition, we are finalizing changes to the quality rating information display requirements for Exchanges. To continue providing flexibility for State Exchanges, we are codifying in regulation the option for State Exchanges that operate their own eligibility and enrollment platforms to display the quality rating information provided by HHS or to display quality rating information based upon certain state-specific customizations of the quality rating information provided by HHS.

Stable and affordable Exchanges with healthy risk pools are necessary for ensuring consumers maintain stable access to health insurance options. We are sharing our future plans for rulemaking to allow Exchanges to conduct risk-based employer sponsored coverage verification and to remove the requirement that Exchanges select a statistically random sample of applicants when no electronic data sources are available. In order to make it easier for issuers to offer wellness incentives to enrollees and promote a healthier risk pool, we are finalizing the proposal that explicitly allows issuers to include certain wellness incentives as quality improvement activities (QIA) in the individual market for MLR reporting and calculation purposes.

We are also finalizing annual state reporting of state-required benefits that are in addition to essential health benefits (EHB), for which states are required to defray the costs. This will help to ensure that federal APTC dollars are protected and states are appropriately compensating enrollees or issuers for services that are in addition to EHB.

We are finalizing changes to the policy regarding whether drug manufacturer coupons must be applied towards the annual limitation on cost sharing. Specifically, we are revising § 156.130(h) to state that, to the extent consistent with applicable state law, amounts paid toward reducing the cost

sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing. However, we are not finalizing any change to the definition of cost sharing.

We are finalizing additional steps to ensure the proper execution of PPACA requirements and to safeguard and conserve federal funds. To protect against unnecessary overpayments of APTC funds, we will streamline the process for terminating coverage of enrollees who die while enrolled in Exchange coverage. In order to ensure that MLR reporting and rebate calculations are accurate, we are finalizing the proposal that issuers must report expenses for functions outsourced to or services provided by other entities consistently with issuers' non-outsourced expenses, and require issuers to deduct prescription drug rebates and price concessions from MLR incurred claims, not only when such rebates and price concessions are received by the issuer, but also when they are received and retained by an entity that provides pharmacy benefit management services to the issuer. Further, we are finalizing that where enrollees provide consent for the Exchange to end their QHP coverage if they are found to be dually enrolled in other qualifying coverage during the Exchange's periodic data matching (PDM) process, the Exchange will not be required to redetermine the enrollee's eligibility for financial assistance and may discontinue coverage consistent with the consent given by the enrollee.

Finally, we are repealing regulations currently set forth at 45 CFR part 149, governing the Early Retiree Reinsurance Program (ERRP) program and its implementation. The program sunset by law as of January 1, 2014.

II. Background

A. Legislative and Regulatory Overview

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) added a new title XXVII to the Public Health Service Act (PHS Act) to establish various reforms to the group and individual health insurance markets.

These provisions of the PHS Act were later augmented by other laws, including the PPACA. Subtitles A and C of title I of the PPACA reorganized, amended, and added to the provisions of part A of title XXVII of the PHS Act relating to group health plans and health insurance issuers in the group and individual markets. The term ''group health plan'' includes both insured and self-insured group health plans.[2]

Section 1301(a)(1)(B) of the PPACA directs all issuers of QHPs to cover the EHB package described in section 1302(a) of the PPACA, including coverage of the services described in section 1302(b) of the PPACA, adherence to the cost-sharing limits described in section 1302(c) of the PPACA, and meeting the actuarial value (AV) levels established in section 1302(d) of the PPACA. Section 2707(a) of the PHS Act, which is effective for plan or policy years beginning on or after January 1, 2014, extends the requirement to cover the EHB package to non-grandfathered individual and small group health insurance coverage, irrespective of whether such coverage is offered through an Exchange. In addition, section 2707(b) of the PHS Act directs non-grandfathered group health plans to ensure that cost-sharing under the plan does not exceed the limitations described in sections 1302(c)(1) of the PPACA.

Section 1302 of the PPACA provides for the establishment of an EHB package that includes coverage of EHBs (as defined by the Secretary), cost-sharing limits, and the levels of coverage for plans subject to the EHB requirements, according to their AV. The law directs that EHBs be equal in scope to the benefits provided under a typical employer plan, and that they cover at least the following 10 general categories: ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care. Section 1302(d) of the PPACA describes the various levels of coverage based on their AV. Consistent with section 1302(d)(2)(A) of the PPACA, AV is calculated based on the provision of EHB to a standard population. Section 1302(d)(3) of the PPACA directs the Secretary to develop guidelines that allow for *de minimis* variation in AV calculations.

Section 1311(c) of the PPACA provides the Secretary the authority to issue regulations to establish criteria for the certification of QHPs. Section 1311(e)(1) of the PPACA grants the Exchange the authority to certify a health plan as a QHP if the health plan meets the Secretary's requirements for certification issued under section 1311(c) of the PPACA, and the Exchange determines that making the plan available through the Exchange is in the interests of qualified individuals and qualified employers in the state. Section 1311(c)(6)(C) of the PPACA establishes special enrollment periods and section 1311(c)(6)(D) of the PPACA establishes the monthly enrollment period for Indians, as defined by section 4 of the Indian Health Care Improvement Act.[3]

Section 1311(c)(3) of the PPACA provides the Secretary with authority to develop a system to rate QHPs offered through an Exchange, based on relative quality and price. Section 1311(c)(4) of the PPACA authorizes the Secretary to establish an enrollee satisfaction survey that evaluates the level of enrollee satisfaction of members with QHPs offered through an Exchange, for each QHP with more than 500 enrollees in the prior year. Further, sections 1311(c)(3) and 1311(c)(4) of the PPACA require an Exchange to provide this quality rating information[4] to individuals and employers on the Exchange's website.

Section 1311(d)(3)(B) of the PPACA permits a state, at its option, to require QHPs to cover benefits in addition to the EHB. This section also requires a state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional state-required benefits.

Section 1312(c) of the PPACA generally requires a health insurance issuer to consider all enrollees in all health plans (except grandfathered health plans) offered by such issuer to be members of a single risk pool for each of its individual and small group markets. States have the option to merge the individual and small group market risk pools under section 1312(c)(3) of the PPACA.

Sections 1313 and 1321 of the PPACA provide the Secretary with the authority to oversee the financial integrity of State Exchanges, their compliance with HHS standards, and the efficient and non-

[2] The term ''group health plan'' is used in title XXVII of the PHS Act and is distinct from the term ''health plan'' as used in other provisions of title I of PPACA. The term ''health plan'' does not include self-insured group health plans.

[3] The Indian Health Care Improvement Act (IHCIA), the cornerstone legal authority for the provision of health care to American Indians and Alaska Natives, was made permanent when President Obama signed the bill on March 23, 2010, as part of the Patient Protection and Affordable Care Act.

[4] The term ''quality rating information'' includes the Quality Rating System (QRS) scores and ratings and the results of the enrollee satisfaction survey (which is also known as the ''Qualified Health Plan (QHP) Enrollee Experience Survey'').

discriminatory administration of State Exchange activities. Section 1321 of the PPACA provides for state flexibility in the operation and enforcement of Exchanges and related requirements.

Section 1321(a) of the PPACA provides broad authority for the Secretary to establish standards and regulations to implement the statutory requirements related to Exchanges, QHPs and other components of title I of the PPACA. Section 1321(a)(1) of the PPACA directs the Secretary to issue regulations that set standards for meeting the requirements of title I of the PPACA for, among other things, the establishment and operation of Exchanges. When operating an FFE under section 1321(c)(1) of the PPACA, HHS has the authority under sections 1321(c)(1) and 1311(d)(5)(A) of the PPACA to collect and spend user fees and to allocate and manage those funds in order to support Exchange operations. Office of Management and Budget (OMB) Circular No. A–25 establishes Federal policy regarding user fees and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.

Section 1321(d) of the PPACA provides that nothing in title I of the PPACA must be construed to preempt any state law that does not prevent the application of title I of the PPACA. Section 1311(k) of the PPACA specifies that Exchanges may not establish rules that conflict with or prevent the application of regulations issued by the Secretary.

Section 1343 of the PPACA establishes a permanent risk adjustment program to provide payments to health insurance issuers that attract higher-than-average risk populations, such as those with chronic conditions, funded by payments from those that attract lower-than-average risk populations, thereby reducing incentives for issuers to avoid higher-risk enrollees.

Section 1402 of the PPACA provides for, among other things, reductions in cost sharing for EHB for qualified low- and moderate-income enrollees in silver level health plans offered through the individual market Exchanges. This section also provides for reductions in cost sharing for Indians enrolled in QHPs at any metal level.

Section 1411(c) of the PPACA requires the Secretary to submit certain information provided by applicants under section 1411(b) of the PPACA to other Federal officials for verification, including income and family size information to the Secretary of the Treasury.

Section 1411(d) of the PPACA provides that the Secretary must verify the accuracy of information provided by applicants under section 1411(b) of the PPACA for which section 1411(c) does not prescribe a specific verification procedure, in such manner as the Secretary determines appropriate.

Section 1411(f) of the PPACA requires the Secretary, in consultation with the Treasury and Homeland Security Department Secretaries and the Commissioner of Social Security, to establish procedures for hearing and making decisions governing appeals of Exchange eligibility determinations.

Section 1411(f)(1)(B) of the PPACA requires the Secretary to establish procedures to redetermine eligibility on a periodic basis, in appropriate circumstances, including eligibility to purchase a QHP through the Exchange and for APTC and CSRs.

Section 1411(g) of the PPACA allows the exchange of applicant information only for the limited purposes of, and to the extent necessary to, ensure the efficient operation of the Exchange, including by verifying eligibility to enroll through the Exchange and for APTC and CSRs.

Sections 2722 and 2763 of the PHS Act provide that the requirements of title XXVII of the PHS Act generally do not apply to excepted benefits. Excepted benefits are described in section 2791 of the PHS Act. This provision establishes four categories of excepted benefits. One such category is limited excepted benefits, which may include limited scope vision or dental benefits, and benefits for long-term care, nursing home care, home health care, or community based care. Section 2791(c)(2)(C) of the PHS Act, section 733(c)(2)(C) of the Employee Retirement Income Security Act (ERISA), and section 9832(c)(2)(C) of the Internal Revenue Code (the Code) authorize the Secretary of Health and Human Services, with the Secretaries of Labor and the Treasury (collectively, the Secretaries), to issue regulations establishing other, similar limited benefits as excepted benefits. To be excepted under the category of limited excepted benefits, section 2722(c)(1) of the PHS Act provides that limited benefits must either: (1) Be provided under a separate policy, certificate, or contract of insurance; or (2) otherwise not be an integral part of the plan.

Section 2718 of the PHS Act, as added by the PPACA, generally requires health insurance issuers to submit an annual MLR report to HHS, and provide rebates to enrollees if the issuers do not achieve specified MLR thresholds.

Section 5000A of the Code, as added by section 1501(b) of the PPACA requires individuals to have minimum essential coverage (MEC) for each month, qualify for an exemption, or make an individual shared responsibility payment. Under the Tax Cuts and Jobs Act, which was enacted on December 22, 2017, the individual shared responsibility payment is reduced to $0, effective for months beginning after December 31, 2018.[5] Notwithstanding that reduction, certain exemptions are still relevant to determine whether individuals age 30 and above qualify to enroll in catastrophic coverage under § 155.305(h).

1. Premium Stabilization Programs[6]

In the July 15, 2011 **Federal Register** (76 FR 41929), we published a proposed rule outlining the framework for the premium stabilization programs. We implemented the premium stabilization programs in a final rule, published in the March 23, 2012 **Federal Register** (77 FR 17219) (Premium Stabilization Rule). In the December 7, 2012 **Federal Register** (77 FR 73117), we published a proposed rule outlining the benefit and payment parameters for the 2014 benefit year to expand the provisions related to the premium stabilization programs and set forth payment parameters in those programs (proposed 2014 Payment Notice). We published the 2014 Payment Notice final rule in the March 11, 2013 **Federal Register** (78 FR 15409). In the June 19, 2013 **Federal Register** (78 FR 37032), we proposed a modification to the HHS-operated methodology related to community rating states. In the October 30, 2013 **Federal Register** (78 FR 65046), we finalized the proposed modification to the HHS-operated methodology related to community rating states. We published a correcting amendment to the 2014 Payment Notice final rule in the November 6, 2013 **Federal Register** (78 FR 66653) to address how an enrollee's age for the risk score calculation would be determined under the HHS-operated risk adjustment methodology.

In the December 2, 2013 **Federal Register** (78 FR 72321), we published a proposed rule outlining the benefit and payment parameters for the 2015 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment

[5] Public Law 115–97, 131 Stat. 2054 (2017).

[6] The term ''premium stabilization programs'' refers to the risk adjustment, risk corridors, and reinsurance programs established by the PPACA. See 42 U.S.C. 18061, 18062, and 18063.

parameters in those programs (proposed 2015 Payment Notice). We published the 2015 Payment Notice final rule in the March 11, 2014 **Federal Register** (79 FR 13743). In the May 27, 2014 **Federal Register** (79 FR 30240), the FY 2015 sequestration rate for the risk adjustment program was announced.

In the November 26, 2014 **Federal Register** (79 FR 70673), we published a proposed rule outlining the benefit and payment parameters for the 2016 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2016 Payment Notice). We published the 2016 Payment Notice final rule in the February 27, 2015 **Federal Register** (80 FR 10749).

In the December 2, 2015 **Federal Register** (80 FR 75487), we published a proposed rule outlining the benefit and payment parameters for the 2017 benefit year to expand the provisions related to the premium stabilization programs, setting forth certain oversight provisions and establishing the payment parameters in those programs (proposed 2017 Payment Notice). We published the 2017 Payment Notice final rule in the March 8, 2016 **Federal Register** (81 FR 12203).

In the September 6, 2016 **Federal Register** (81 FR 61455), we published a proposed rule outlining the benefit and payment parameters for the 2018 benefit year and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology, new policies around the use of external data for recalibration of our risk adjustment models, and amendments to the RADV process (proposed 2018 Payment Notice). We published the 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058).

In the November 2, 2017 **Federal Register** (82 FR 51042), we published a proposed rule outlining the benefit and payment parameters for the 2019 benefit year, and to further promote stable premiums in the individual and small group markets. We proposed updates to the risk adjustment methodology and amendments to the RADV process (proposed 2019 Payment Notice). We published the 2019 Payment Notice final rule in the April 17, 2018 **Federal Register** (83 FR 16930). We published a correction to the 2019 risk adjustment coefficients in the 2019 Payment Notice final rule in the May 11, 2018 **Federal Register** (83 FR 21925). On July 27, 2018, consistent with 45 CFR 153.320(b)(1)(i), we updated the 2019 benefit year final risk adjustment model coefficients to reflect an additional recalibration related to an update to the 2016 enrollee-level External Data Gathering Environment (EDGE) dataset.[7]

In the July 30, 2018 **Federal Register** (83 FR 36456), we published a final rule that adopted the 2017 benefit year risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17220 through 17252) and in the March 8, 2016 editions of the **Federal Register** (81 FR 12204 through 12352). This final rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2017 benefit year, including the reasons why the program is operated in a budget-neutral manner. This final rule permitted HHS to resume 2017 benefit year risk adjustment payments and charges. HHS also provided guidance as to the operation of the HHS-operated risk adjustment program for the 2017 benefit year in light of publication of this final rule.[8]

In the August 10, 2018 **Federal Register** (83 FR 39644), we published a proposed rule seeking comment on adopting the 2018 benefit year risk adjustment methodology in the final rules published in the March 23, 2012 (77 FR 17219) and in the December 22, 2016 editions of the **Federal Register** (81 FR 94058). The proposed rule set forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner. In the December 10, 2018 **Federal Register** (83 FR 63419), we issued a final rule adopting the 2018 benefit year HHS-operated risk adjustment methodology as established in the final rules published in the March 23, 2012 (77 FR 17219) and the December 22, 2016 (81 FR 94058) editions of the **Federal Register**. This final rule sets forth additional explanation of the rationale supporting use of statewide average premium in the HHS-operated risk adjustment state payment transfer formula for the 2018 benefit year, including the reasons why the program is operated in a budget-neutral manner.

In the January 24, 2019 **Federal Register** (84 FR 227), we published a proposed rule outlining updates to the calibration of the risk adjustment methodology, the use of EDGE data for research purposes, and updates to RADV audits. We published the 2020 Payment Notice final rule in the April 25, 2019, **Federal Register** (84 FR 17454).

On December 6, 2019, we published the HHS Risk Adjustment Data Validation (HHS–RADV) White Paper (2019 RADV White Paper).[9]

2. Program Integrity

In the June 19, 2013 **Federal Register** (78 FR 37031), we published a proposed rule that proposed certain program integrity standards related to Exchanges and the premium stabilization programs (proposed Program Integrity Rule). The provisions of that proposed rule were finalized in two rules, the ''first Program Integrity Rule'' published in the August 30, 2013 **Federal Register** (78 FR 54069) and the ''second Program Integrity Rule'' published in the October 30, 2013 **Federal Register** (78 FR 65045). In the November 9, 2018 **Federal Register** (83 FR 56015), we published a proposed rule that proposed to amend standards relating to oversight of Exchanges established by states, periodic data matching frequency and authority, the length of a consumer's authorization for the Exchange to obtain updated tax information, and requirements for certain issuers related to the collection of a separate payment for the premium portion attributable to coverage for certain abortion services. Many of the provisions in the proposed rule were finalized (2019 Program Integrity rule) in the December 27, 2019 **Federal Register** (84 FR 71674).

3. Market Rules

An interim final rule relating to the HIPAA health insurance reforms was published in the April 8, 1997 **Federal Register** (62 FR 16894). A proposed rule relating to the 2014 health insurance market rules was published in the November 26, 2012 **Federal Register** (77 FR 70584). A final rule implementing the health insurance market rules was published in the February 27, 2013 **Federal Register** (78 FR 13406) (2014 Market Rules).

A proposed rule relating to Exchanges and Insurance Market Standards for 2015 and beyond was published in the

[7] ''Updated 2019 Benefit Year Final HHS Risk Adjustment Model Coefficients.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2019-Updtd-Final-HHS-RA-Model-Coefficients.pdf.*

[8] ''Update on the HHS-operated Risk Adjustment Program for the 2017 Benefit Year.'' July 27, 2018. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/2017-RA-Final-Rule-Resumption-RAOps.pdf.*

[9] The 2019 RADV White Paper is available at *https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.*

March 21, 2014 **Federal Register** (79 FR 15808) (2015 Market Standards Proposed Rule). A final rule implementing the Exchange and Insurance Market Standards for 2015 and Beyond was published in the May 27, 2014 **Federal Register** (79 FR 30240) (2015 Market Standards Rule). The 2018 Payment Notice final rule in the December 22, 2016 **Federal Register** (81 FR 94058) provided additional guidance on guaranteed availability and guaranteed renewability. In the Market Stabilization final rule that was published in the April 18, 2017 **Federal Register** (82 FR 18346), we released further guidance related to guaranteed availability.

4. Exchanges

We published a request for comment relating to Exchanges in the August 3, 2010 **Federal Register** (75 FR 45584). We issued initial guidance to states on Exchanges on November 18, 2010. We proposed a rule in the July 15, 2011 **Federal Register** (76 FR 41865) to implement components of the Exchanges, and a rule in the August 17, 2011 **Federal Register** (76 FR 51201) regarding Exchange functions in the individual market and Small Business Health Options Program (SHOP), eligibility determinations, and Exchange standards for employers. A final rule implementing components of the Exchanges and setting forth standards for eligibility for Exchanges was published in the March 27, 2012 **Federal Register** (77 FR 18309) (Exchange Establishment Rule).

In the 2014 Payment Notice and in the Amendments to the HHS Notice of Benefit and Payment Parameters for 2014 interim final rule, published in the March 11, 2013 **Federal Register** (78 FR 15541), we set forth standards related to Exchange user fees. We established an adjustment to the FFE user fee in the Coverage of Certain Preventive Services under the Affordable Care Act final rule, published in the July 2, 2013 **Federal Register** (78 FR 39869) (Preventive Services Rule).

In an interim final rule, published in the May 11, 2016 **Federal Register** (81 FR 29146), we made amendments to the parameters of certain special enrollment periods (2016 Interim Final Rule). We finalized these in the 2018 Payment Notice final rule, published in the December 22, 2016 **Federal Register** (81 FR 94058). In the April 18, 2017 Market Stabilization final rule **Federal Register** (82 FR 18346), we amended standards relating to special enrollment periods and QHP certification. In the 2019 Payment Notice final rule, published in the April 17, 2018 **Federal Register** (83 FR 16930), we modified parameters around certain special enrollment periods. In the April 25, 2019 **Federal Register** (84 FR 17454), the final 2020 Payment Notice established a new special enrollment period.

5. Essential Health Benefits

On December 16, 2011, HHS released a bulletin [10] that outlined an intended regulatory approach for defining EHB, including a benchmark-based framework. A proposed rule relating to EHBs was published in the November 26, 2012 **Federal Register** (77 FR 70643). We established requirements relating to EHBs in the Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation Final Rule, which was published in the February 25, 2013 **Federal Register** (78 FR 12833) (EHB Rule). In the 2019 Payment Notice, published in the April 17, 2018 **Federal Register** (83 FR 16930), we added § 156.111 to provide states with additional options from which to select an EHB-benchmark plan for plan years 2020 and beyond.

6. Cost-Sharing Requirements

In the 2020 Payment Notice, published in the April 25, 2019 **Federal Register** (84 FR 17454), we added § 156.130(h)(1) to clarify that issuers are not required to count toward the annual limitation on cost sharing any forms of direct support offered by drug manufacturers to reduce out-of-pocket costs for brand drugs when a generic drug is available and medically appropriate.

7. Excepted Benefit Health Reimbursement Arrangements

In the October 29, 2018 **Federal Register** (83 FR 54420), the Departments of Health and Human Services, Labor, and the Treasury (the Departments) published proposed regulations on HRAs and other account-based group health plans, including a new excepted benefit referred to as an excepted benefit HRA. In the June 20, 2019 **Federal Register** (84 FR 28888), the Departments published final regulations on HRAs and other account-based group health plans, including excepted benefit HRAs (the HRA rule).

8. Medical Loss Ratio (MLR)

We published a request for comment on section 2718 of the PHS Act in the April 14, 2010 **Federal Register** (75 FR 19297), and published an interim final rule with a 60-day comment period relating to the MLR program in the December 1, 2010 **Federal Register** (75 FR 74863). A final rule with a 30-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76573). An interim final rule with a 60-day comment period was published in the December 7, 2011 **Federal Register** (76 FR 76595). A final rule was published in the **Federal Register** on May 16, 2012 (77 FR 28790). The MLR program requirements were amended in final rules published in the March 11, 2014 **Federal Register** (79 FR 13743), the May 27, 2014 **Federal Register** (79 FR 30339), the February 27, 2015 **Federal Register** (80 FR 10749), the March 8, 2016 **Federal Register** (81 FR 12203), the December 22, 2016 **Federal Register** (81 FR 94183), and the April 17, 2018 **Federal Register** (83 FR 16930).

9. Early Retiree Reinsurance Program (ERRP)

In the May 5, 2010 **Federal Register** (75 FR 24450), we published an interim final rule with comment period governing the ERRP. In the April 5, 2011 **Federal Register** (76 FR 18766), we published a notice informing the public that as of May 5, 2011, the ERRP would stop accepting applications for new participants in the program due to the availability of funds. In the December 13, 2011 **Federal Register** (76 FR 77537), we published a notice informing the public that, due to the availability of funds, the ERRP would deny reimbursement requests that include claims incurred after December 31, 2011. In the March 21, 2012 **Federal Register** (77 FR 16551), we published a notice establishing a timeframe within which plan sponsors participating in the program were expected to use ERRP reimbursement funds. Specifically, the notice informed participating plan sponsors that reimbursement funds should be used as early as possible, but not later than January 1, 2014.

10. Quality Rating System (QRS) and Enrollee Satisfaction Survey

Sections 1311(c)(3) of the PPACA directs the Secretary of HHS to develop a quality rating for each QHP offered through an Exchange, based on relative quality and price. Further, section 1311(c)(4) of the PPACA requires the Secretary to establish an enrollee satisfaction survey that evaluates the level of enrollee satisfaction of members with QHPs offered through the Exchanges for each QHP with more than 500 enrollees in the prior year. Exchanges are also required to make quality rating and enrollee satisfaction information available to individuals and

[10] ''Essential Health Benefits Bulletin.'' December 16, 2011. Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/essential_health_benefits_bulletin.pdf.*

employers on their respective websites. Consistent with these statutory provisions, in May 2014, HHS issued regulation at §§ 155.1400 and 155.1405 to establish the Quality Rating System (QRS) and the QHP Enrollee Experience Survey display requirements for Exchanges and has worked towards requiring nationwide the prominent display of quality rating information on Exchange websites.[11] As a condition of certification and participation in the Exchanges, HHS requires that QHP issuers submit QRS clinical measure data and QHP Enrollee Survey response data for their respective QHPs offered through an Exchange in accordance with HHS guidance, which has been issued annually for each forthcoming plan year.[12]

B. Stakeholder Consultation and Input

HHS has consulted with stakeholders on policies related to the operation of Exchanges and the risk adjustment and RADV programs. We have held a number of listening sessions with consumers, providers, issuers, employers, health plans, advocacy groups and the actuarial community to gather public input. We have solicited input from state representatives on numerous topics, particularly EHBs, state mandates and risk adjustment. We consulted with stakeholders through regular meetings with the National Association of Insurance Commissioners (NAIC), regular contact with states through the Exchange Establishment grant and Exchange Blueprint approval processes, and meetings with Tribal leaders and representatives, health insurance issuers, trade groups, consumer advocates, employers, and other interested parties. We considered all public input we received as we developed the policies in this final rule.

C. Structure of Final Rule

The regulations outlined in this final rule are codified in 45 CFR parts 146, 149, 153, 155, 156 and 158.

The changes to 45 CFR part 146 establish a notice requirement for non-Federal governmental plan sponsors that offer an excepted benefit HRA.

The changes to 45 CFR part 149 will delete the regulations related to the ERRP, which ended on January 1, 2014.

The provisions related to 45 CFR part 153 relate to recalibration of the risk adjustment models consistent with the approach outlined in the 2020 Payment Notice to transition away from the use of MarketScan® data and incorporate the most recent benefit years of enrollee-level EDGE data that are available for 2021 and beyond, as well as the ICD–10 HHS–HCC reclassification updates. The updates to the risk adjustment program also relate to the risk adjustment user fee for the 2020 benefit year, and modifications to RADV requirements for the states where HHS operates the risk adjustment program.

We are finalizing an amendment to the definitions applicable to 45 CFR part 155. We discuss future changes to part 155 that would allow Exchanges to implement a verification process for enrollment in or eligibility for an eligible employer-sponsored plan based on the Exchange's assessment of risk for inappropriate payments of APTC/CSR. We also clarify that an Exchange will not redetermine eligibility for APTC/CSRs for enrollees found to be dually enrolled in Medicare and QHP coverage who direct the Exchange to end their QHP coverage; clarify that when an Exchange identifies deceased enrollees via PDM, the Exchange will terminate coverage retroactively to the date of death; allow enrollees and their dependents eligible for a special enrollment period due to becoming newly ineligible for CSRs and are enrolled in a silver-level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment through an Exchange; establish that an Exchange must apply plan category limitations to currently enrolled dependents whose non-dependent household member qualifies for a special enrollment period to newly enroll the non-dependent household member in Exchange coverage; provide that in the FFE, special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection; align retroactive effective date and binder payment rules; establish that qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year would qualify for the existing special enrollment period for individuals enrolled in any non-calendar year group health plan or individual health insurance coverage; and allow enrollees blocked from termination due to an Exchange technical error to terminate their coverage retroactive to the date they attempted the termination.

As we do every year in the HHS notice of benefit and payment parameters, we are updating the required contribution percentage, the maximum annual limitation on cost sharing, and the reduced maximum annual limitation on cost sharing based on the premium adjustment percentage. We are maintaining the FFE and SBE–FP user fees at the current 2020 plan year rates, 3.0 and 2.5 percent of total monthly premiums, respectively, to preserve and ensure that the FFE has sufficient funding to cover the cost of all special benefits provided to FFE and SBE–FP QHP issuers during the 2021 plan year. Further, we are finalizing a change to 45 CFR part 156 to require QHP issuers to send to enrollees a termination notice for all termination events. We also are amending the regulation addressing state selection of EHB-benchmark plans to require the reporting of state-required benefits. We also offer QHP issuers the option to design value-based insurance plans that would empower consumers to receive high value services at lower cost. We are revising § 156.130(h) in its entirety to address how any direct support offered by drug manufacturers to enrollees for specific prescription drugs may be treated with regard to accrual towards the annual limitation on cost sharing.

The changes to 45 CFR part 158 require issuers, for MLR purposes, to report expenses for functions outsourced to or services provided by other entities consistently with issuers' non-outsourced expenses, and to deduct from incurred claims prescription drug rebates and other price concessions received and retained by the issuer and other entities providing pharmacy benefit management services to the issuers. The changes to the MLR regulations would also explicitly allow issuers to report certain wellness incentives as QIA in the individual market.

III. Provisions of the Final Regulations and Analysis and Responses to Public Comments

In the February 6, 2020 **Federal Register** (85 FR 7088), we published the ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2021; Notice Requirement for Non-Federal Governmental Plans'' proposed rule (proposed 2021 Payment Notice or proposed rule). We received 1,082

[11] Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30352 (May 27, 2014). Also see the CMS Bulletin on display of Quality Rating System (QRS) quality ratings and Qualified Health Plan (QHP) Enrollee Survey results for QHPs offered through Exchanges (August 15, 2019), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf.*

[12] See, for example, Center for Clinical Standards & Quality, CMS, The Quality Rating System and Qualified Health Plan Enrollee Experience Survey: Technical Guidance for 2020 (October 2019), available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/QRS-and-QHP-Enrollee-Survey-Technical-Guidance-for-2020-508.pdf.*

comments. Comments were received from state entities, such as departments of insurance and state Exchanges; health insurance issuers; providers and provider groups; consumer groups; industry groups; national interest groups; and other stakeholders. The comments ranged from general support of or opposition to the proposed provisions to specific questions or comments regarding proposed changes. We received a number of comments and suggestions that were outside the scope of the proposed rule that are not addressed in this final rule.

In this final rule, we provide a summary of proposed provisions, a summary of the public comments received that directly related to those proposals, our responses to these comments, and a description of the provisions we are finalizing.

We first address comments regarding the publication of the proposed rule and the comment period.

Comment: Multiple commenters criticized the length of the comment period, stating that a longer comment period is necessary to allow stakeholders to review the proposed rule and provide thoughtful comments.

Response: The timeline for publication of this final rule accommodates issuer filing deadlines for the 2021 plan year. A longer comment period would have delayed the publication of this final rule and created significant challenges for states, Exchanges, issuers, and other entities operating under strict deadlines related to approval of products.

Comment: Multiple commenters criticized the timing of the release of the proposed rule, stating that publishing the proposal for this annual rule in February 2020 creates challenges for states, Exchanges, issuers, and other entities in implementing changes for plan year 2021.

Response: We recognize the importance of a timely release of updates to our regulations, and make every effort to do so efficiently. After the comment period closed, we took steps to expedite the publication of this final rule. We will continue to support consumers and stakeholders in implementing the changes in this final rule in a timely fashion.

A. Part 146—Requirements for the Group Health Insurance Market: Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors

We proposed to add a new paragraph (b)(3)(viii)(E) to § 146.145 to establish notice requirements for excepted benefit HRAs offered by non-Federal governmental plan sponsors. We are finalizing the notice requirements as proposed, except that we are modifying the applicability date so the new notice requirement applies to excepted benefit HRAs offered by non-Federal governmental plan sponsors for plan years beginning on or after 180 days following the effective date of the final rule.

Excepted benefit HRAs are a new type of excepted benefit the Departments recently established in the HRA rule.[13] As proposed, the new paragraph would require sponsors of non-Federal governmental plans that offer excepted benefit HRAs to provide a notice to eligible participants that contains specified information about the benefits available under the excepted benefit HRA.

In the preamble to the HRA rule, the Departments noted that longstanding notice requirements under Part 1 of ERISA already apply to private-sector, employment-based plans. The Departments explained that under those notice requirements, excepted benefit HRAs that are subject to ERISA generally should provide information on eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the plan, and a description or summary of the benefits. Accordingly, the HRA rule included a cross-reference to existing ERISA notice provisions for excepted benefit HRAs that are subject to ERISA, to help ensure that sponsors of such excepted benefit HRAs are aware of their obligations under those provisions. However, the HRA rule did not finalize any notice requirements in addition to those ERISA already imposes on ERISA-covered plans. It also did not subject plans that are not subject to ERISA, such as excepted benefit HRAs sponsored by non-Federal governmental employers, to similar notice requirements.

We proposed to add new paragraph (b)(3)(viii)(E) to § 146.145 under which an excepted benefit HRA offered by a non-Federal governmental plan sponsor would be required to provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the excepted benefit HRA, and a description or summary of the benefits available under the excepted benefit HRA. We explained that this is generally consistent with the content requirements of Department of Labor (DOL) summary plan description regulations that apply to excepted benefit HRAs that are subject to ERISA at 29 CFR 2520.102–3(j)(2) and (3), although the proposed excepted benefit HRA notice provided by a non-Federal governmental plan sponsor would be required to be provided annually and would not necessarily have to include every data element specified in those DOL regulations. We also proposed that the notice must be provided in a manner reasonably calculated to ensure actual receipt by participants eligible for the excepted benefit HRA, such as by providing the notice in the same manner in which the plan sponsor provides other notices or plan documents to plan participants.

Under existing DOL regulations at 29 CFR 2520.104b-2(a), ERISA-covered plans, including ERISA-covered excepted benefit HRAs, generally are required to furnish a copy of the notice to each participant no later than 90 days after the employee becomes a participant in the plan. Given that ERISA-covered plans and non-Federal governmental plans often contract with the same service providers to administer their health plans, to increase efficiencies and minimize costs and confusion, we proposed that the notice provided by non-Federal governmental excepted benefit HRAs must be provided no later than 90 days after the first day of the excepted benefit HRA plan year, or in the case of an employee who becomes a participant after the start of the plan year, no later than 90 days after the employee becomes a participant in the excepted benefit HRA.

We further proposed that the notice requirement would be applicable to excepted benefit HRA plan years beginning on or after 30 days following the effective date of the final rule.

We solicited comment on all aspects of the proposal, including whether to apply a different timing standard than the one proposed for the notices for non-Federal governmental excepted benefit HRAs, and any logistical, cost, and other challenges that would ensue from applying a different timing standard for the notice for such excepted benefit HRAs than for those regulated by ERISA. We also solicited comments on the proposed applicability date and on ways to mitigate the potential costs and burdens this notice requirement may impose on non-Federal governmental plan sponsors interested in offering excepted benefit HRAs. We also sought comment on whether sponsors of non-Federal governmental excepted benefit HRAs should be required to provide the notice annually after the initial notice, or whether, after providing the initial notice, they should only be required to provide the notice with respect to plan years for which the terms of the excepted benefit HRA change from the

[13] 84 FR 28888 (June 20, 2019).

previous plan year, and if so, what type or magnitude of change should trigger such a subsequent notice.

We are finalizing the notice requirement as proposed, except for the applicability date, which we are extending based on comments received. This new notice requirement applies to excepted benefit HRAs offered by non-Federal governmental plan sponsors for plan years beginning on or after 180 days following the effective date of the final rule.

Comment: We received a relatively small number of comments regarding this proposal. Several commenters generally supported a notice requirement on excepted benefit HRAs sponsored by non-Federal governmental employers, without objecting to the proposed timing of the initial notice. Several commenters, while supporting the proposal generally, stated that contrary to the proposal, the notice should be provided *before* enrollment in the excepted benefit HRA, so consumers can make an informed decision about their coverage.

Response: We understand that many non-Federal governmental sponsors of excepted benefit HRAs may use the same third-party administrators as used by sponsors of excepted benefit HRAs that are subject to ERISA's timing requirements for excepted benefit HRA notices. In such cases, for administrative efficiency, non-Federal governmental sponsors of excepted benefit HRAs may prefer to send the notices to participants following their enrollment, within 90 days after they enroll in the excepted benefit HRA. Therefore, we are finalizing the notice timing standard as proposed. Furthermore, we agree that receiving the notices before enrollment may be useful for employees. Thus, we clarify that the timing standard in § 146.145(b)(3)(viii)(E) does not prohibit non-Federal governmental sponsors of excepted benefit HRAs from delivering the notice prior to enrollment. For example, a non-Federal governmental sponsor of an excepted benefit HRA may provide the notice on the 30th day before the start of the plan year and satisfy its obligation to provide the notice no later than 90 days after an employee becomes a participant. In this example, for employees who are not eligible for the excepted benefit HRA on the date the notice is otherwise provided, the notice must be provided no later than 90 days after the employee becomes a participant. We are not finalizing a limit on how early a non-Federal governmental plan sponsor may send the notice, but we encourage sponsors that opt to send the notice before the start of the excepted benefit HRA plan year to send the notice in a timeframe that is reasonably calculated to ensure employees receive the notice at a time that would enable them to make an informed decision about their coverage.

Comment: One commenter supported the proposal that non-Federal governmental sponsors of excepted benefit HRAs be required to provide the notice annually. Another commenter recommended that a subsequent notice should be required only when there is a material change to the excepted benefit HRA from the previous plan year because without a material change, the subsequent notice would be unnecessary and unduly burdensome. Another commenter suggested that rather than require an annual notice, the regulations should track current ERISA requirements regarding subsequent notices, notices of material modifications of coverage, and notices of material reductions in covered services.

Response: We believe that an annual notice will benefit employees by ensuring that employees stay informed of their coverage options and helping employees understand how to utilize their excepted benefit HRA. Although we recognize that an annual notice may be somewhat more burdensome than if the notice were only required in certain circumstances in subsequent plan years, we do not believe the annual requirement will pose a significant burden on non-Federal governmental plan sponsors that would outweigh the benefit to employees. Further, to the extent there are no changes in the plan design, the burdens associated with development of the notice would be minimized for subsequent plan years. Therefore, we finalize the requirement that the notice be provided annually, as proposed.

Comment: One commenter stated that the notice requirement should be applicable for excepted benefit HRA plan years beginning on or after 1 year from the effective date of the final rule. The commenter asserted that understanding the scope of the notice requirements, identifying affected participants, developing the notice language, and delivering the notice would take more than 30 days.

Response: We do not agree that these tasks identified by the commenter are so complex as to justify delaying the proposed applicability date for 11 months. However, after considering comments received, in order to provide additional flexibility and time for non-Federal governmental plan sponsors to develop and send the notice, we are finalizing a later applicability date. As finalized, the notice provision is applicable to excepted benefit HRAs offered by non-Federal governmental plan sponsors for plan years beginning on or after 180 days following the effective date of this final rule.

B. Part 149—Requirements for the Early Retiree Reinsurance Program (ERRP)

We proposed to delete part 149 of title 45 of the CFR, which sets forth requirements for participating in the ERRP, established by section 1102 of the PPACA. We will delete part 149 as proposed.

The ERRP provided financial assistance in the form of reinsurance to employment-based health plan sponsors—including for-profit companies, schools and educational institutions, unions, state and local governments, religious organizations, and other nonprofit plan sponsors—that made coverage available to early retirees, their spouses or surviving spouses, and dependents, for specified claims incurred prior to January 1, 2014, or until funding was depleted, whichever were to occur sooner. The goal of the program was to encourage and support comprehensive, quality health care for early retirees at least 55 years of age, and their spouses and dependents, not otherwise eligible for Medicare during the period preceding the effective date of the Exchanges and many of the market-wide rules created by the PPACA.

Under section 1102(a)(1) of the PPACA, the ERRP expired January 1, 2014. All ERRP payments have been made and there are no outstanding claims or disputes. A portion of the original appropriation remains, and will be returned to the Treasury when the appropriation is closed out in due course. Therefore, we proposed to delete the regulations in part 149 and reserve part 149 for future use, which would reduce the volume of Federal regulations.

We received no comments concerning the proposal. Therefore, we are repealing the regulations as proposed.

C. Part 153—Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment

1. Sequestration

In accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2020,[14] both the transitional reinsurance program and the permanent risk adjustment program are subject to the fiscal year

[14] Available at *https://www.whitehouse.gov/wp-content/uploads/2019/03/2020_JC_Sequestration_Report_3-18-19.pdf.*

(FY) 2020 sequestration. The Federal Government's 2020 fiscal year began October 1, 2019. While the 2016 benefit year was the final year of the transitional reinsurance program, there could be reinsurance payments in FY 2020 for close-out activities. Therefore, the risk adjustment and reinsurance programs will be sequestered at a rate of 5.9 percent for payments made from FY 2020 resources (that is, funds collected during FY 2020).

HHS, in coordination with OMB, has determined that under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99–177, enacted December 12, 1985), as amended, and the underlying authority for the reinsurance and risk adjustment program, the funds that are sequestered in FY 2020 from the risk adjustment or reinsurance programs will become available for payment to issuers in FY 2021 without further Congressional action.

Additionally, in accordance with the OMB Report to Congress on the Joint Committee Reductions for Fiscal Year 2021,[15] the permanent risk adjustment program is subject to the FY 2021 sequestration. The Federal Government's 2021 fiscal year will begin October 1, 2020. Therefore, the risk adjustment program will be sequestered at a rate of 5.7 percent for payments made from FY 2021 resources (that is, funds collected during FY 2021).

HHS, in coordination with OMB, has determined that, under section 256(k)(6) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Pub. L. 99–177, enacted December 12, 1985), as amended, and the underlying authority for the risk adjustment program, the funds that are sequestered in FY 2021 from the risk adjustment program will become available for payment to issuers in FY 2022 without further Congressional action. If Congress does not enact deficit reduction provisions that replace the Joint Committee reductions, the program would be sequestered in future fiscal years, and any sequestered funding would become available in the fiscal year following that in which it was sequestered.

2. Provisions and Parameters for the Risk Adjustment Program

In subparts A, B, D, G, and H of part 153, we established standards for the administration of the risk adjustment program. The risk adjustment program is a permanent program created by section 1343 of the PPACA that transfers funds from lower-than-average risk, risk adjustment covered plans to higher-than-average risk, risk adjustment covered plans in the individual and small group markets (including merged markets), inside and outside the Exchanges. In accordance with § 153.310(a), a state that is approved or conditionally approved by the Secretary to operate an Exchange may establish a risk adjustment program, or have HHS do so on its behalf. HHS did not receive any requests from states to operate risk adjustment for the 2021 benefit year. Therefore, HHS will operate risk adjustment in every state and the District of Columbia for the 2021 benefit year.

Among other things, we proposed changes to recalibrate the risk adjustment models consistent with the methodology we finalized for the 2020 benefit year. For the 2021 benefit year, we proposed to incorporate the 3 most recent benefit years of enrollee-level EDGE data that are available, and to rely only on enrollee-level EDGE data for 2021 and beyond for purposes of recalibrating the HHS risk adjustment models. We also proposed the risk adjustment user fee for the 2021 benefit year, and modifications to certain RADV requirements.

a. HHS Risk Adjustment (§ 153.320)

The HHS risk adjustment models predict plan liability for an average enrollee based on age, sex, and diagnoses (grouped into hierarchical condition categories (HCCs)), producing a risk score. The current structure of these models is described in the 2020 Payment Notice.[16] The HHS risk adjustment methodology utilizes separate models for adults, children, and infants to account for cost differences in each age group. In the adult and child models, the relative risk assigned to an individual's age, sex, and diagnoses are added together to produce an individual risk score. Additionally, to calculate enrollee risk scores in the adult models, we added enrollment duration factors beginning with the 2017 benefit year, and prescription drug categories (RXCs) beginning with the 2018 benefit year. Infant risk scores are determined by inclusion in one of 25 mutually exclusive groups, based on the infant's maturity and the severity of diagnoses. If applicable, the risk score for adults, children, or infants is multiplied by a CSR adjustment that accounts for differences in induced demand at various levels of cost sharing.

The enrollment-weighted average risk score of all enrollees in a particular risk adjustment covered plan (also referred to as the plan liability risk score) within a geographic rating area is one of the inputs into the risk adjustment state payment transfer formula, which determines the payment or charge that an issuer will receive or be required to pay for that plan for the applicable state market risk pool. Thus, the HHS risk adjustment models predict average group costs to account for risk across plans, in keeping with the Actuarial Standards Board's Actuarial Standards of Practice for risk classification.

(1) Updates to Data Used for Risk Adjustment Model Recalibration

We proposed to discontinue our reliance on MarketScan® data to recalibrate the risk adjustment models. Previously, we used the 3 most recent years of MarketScan® data available to recalibrate the 2016, 2017, and 2018 benefit year risk adjustment models. For the 2019 benefit year, we recalibrated the models using 2 years of MarketScan® data (2014 and 2015) with 2016 enrollee-level EDGE data. The 2019 benefit year was the first recalibration year that enrollee-level EDGE data was used for this purpose. In keeping with our previously-stated intention to transition away from the MarketScan® commercial database, we further reduced our use of MarketScan® data in 2020 benefit year model recalibration by using only 1 year of MarketScan® data (2015), and the 2 most recent years of available enrollee-level EDGE data (2016 and 2017). During all prior recalibrations, we implemented an approach that used blended, or averaged, coefficients from 3 years of separately solved models to provide stability for the risk adjustment coefficients year-to-year, while reflecting the most recent years' claims experience available.

Consistent with the policy announced in the 2020 Payment Notice,[17] we proposed to no longer incorporate MarketScan® data in the recalibration process beginning with the 2021 benefit year. Rather, we proposed for the 2021 benefit year and beyond to blend the 3 most recent years of available enrollee-level EDGE data. Specifically, we proposed for the 2021 benefit year to blend the enrollee-level EDGE data from benefit years 2016, 2017, and 2018 to recalibrate the risk adjustment models. We also proposed to maintain the approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk

[15] Available at *https://www.whitehouse.gov/wp-content/uploads/2020/02/JC-sequestration_report_FY21_2-10-20.pdf.*

[16] See 84 FR 17454 at 17463.

[17] 84 FR 17454 at 17464.

adjustment models for future benefit years beyond 2021, unless changed through rulemaking. We sought comment on these proposals.

After reviewing the public comments, we are finalizing our proposal to determine coefficients for the 2021 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. This approach will incorporate the most recent years' claims experience that is available while maintaining stability in risk scores, as the recalibration will maintain 2 years of EDGE data that were used in the previous years' models. It also will continue our efforts to recalibrate the risk adjustment models using data from issuers' individual and small group (including merged) market populations and complete the transition away from the MarketScan® commercial database that approximates individual and small group (including merged) market populations. Additionally, we are finalizing our proposal for future benefit years beyond 2021 to blend the 3 most recent years of available enrollee-level EDGE data.

Due to the timing of the proposed rule, we noted in the proposed rule that we were unable to incorporate the 2018 benefit year enrollee-level EDGE data in the calculation of the proposed coefficients in that rule. Therefore, consistent with the proposed 2017 and 2019 payment notices, the draft coefficients in the proposed rule were based on the 2 most recent years of data available at the time the proposed rule was drafted—the 2016 and 2017 benefit year enrollee-level EDGE data. Considering that 2 of the 3 years of enrollee-level EDGE data that we proposed to use to recalibrate the final 2021 risk adjustment models were reflected in the draft coefficients in the proposed rule, we explained that we believe that the draft coefficients listed in the proposed rule would provide a reasonably close approximation of what could be anticipated from blending the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. We noted in the proposed rule that if we finalize the proposed recalibration approach, but are unable to incorporate the 2018 benefit year EDGE data in time to publish the final coefficients in the final rule, we would publish the final coefficients for the 2021 benefit year in guidance after the publication of the final rule, consistent with our approach in previous benefit years.[18] We were unable to incorporate the 2018 benefit year EDGE data in time to publish the final coefficients in this final rule. Therefore, consistent with § 153.320(b)(1)(i), we will release the final coefficients in guidance by June 2020 to allow for the incorporation in final rates for the 2021 benefit year.

We summarize and respond to public comments received on these proposals below.

Comment: Most commenters supported the proposal to determine coefficients for the 2021 benefit year based on a blend of separately solved coefficients from the 2016, 2017, and 2018 benefit years' enrollee-level EDGE data. Most commenters also supported maintaining the approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk adjustment models for future benefit years beyond 2021.

A few commenters expressed concern about when final blended coefficients for the risk adjustment models would be published. One commenter did not support HHS waiting until the release of the final payment notice to publish the final 2021 blended coefficients, and suggested HHS use coefficients developed from the 2 most recent years of available enrollee-level EDGE data, instead of the 3 most recent years, in order to provide two-year blended factors much earlier, perhaps even before the proposed rule. Another commenter also suggested HHS consider using only the 2 most recent years of data or, if using 3 years, weighting the most recent year more heavily given the lag in the data relative to how quickly changes in medical practice and technology impact the cost of care. Other commenters pointed out that issuers need the information on proposed coefficients for modeling and pricing much earlier than the timing of the proposed payment notice, especially given that many states require rate filings as early as May of the prior year. Another commenter requested confirmation that HHS will continue to publish the proposed coefficients in the proposed rule.

Response: We believe blending multiple years of data promotes stability and certainty for issuers in rate setting, helping to reduce year-to-year changes in risk scores and smooth significant differences in coefficients solved from any one year's dataset, particularly for conditions with small sample sizes. We also believe using the latest data available, especially with new drugs and technology coming to market, is the best approach to improve overall model accuracy.

As we explained when finalizing the amendments to § 153.320(b)(1)(i), due to the fact that some data used to finalize coefficients may not be available until after publication of the applicable benefit year's final payment notice, we may not be able to provide finalized coefficients in the payment notice rulemaking.[19] Instead, in these circumstances, we adopted an approach to release draft coefficients based on the 2 most recent years of data available, identify the datasets that would be used to calculate the final coefficients, and incorporate the additional, more recently available year's data in the final coefficients in subsequent guidance. This approach was followed in 2017 and 2019, and will also be followed for the 2021 benefit year.

We anticipate publishing the final coefficients for the 2021 benefit year by June 2020, which is prior to the deadline for final rate submissions,[20] to provide issuers with an opportunity to update their rate submissions, if necessary. In determining which data years to use, we seek to balance stability in risk scores year-over-year with the desire to incorporate the most recent data available on enrollees' risk. As some commenters noted, incorporating the most recent available year's data allows the risk adjustment models to reflect any changes in medical practice and technology (including newer or cheaper treatments). Particularly given recent rapid changes in treatment costs, we continue to believe incorporating the most recent years of data available more accurately reflects enrollees' risk. Using three years of data allows stability in model factors from the two prior benefit years' recalibration. However, in response to comments, we intend to consider whether overweighing the factors solved from the most recent data year available is warranted for future benefit years, as well as assess using factors solved from only 2 years of enrollee-level EDGE data available at the time of the proposed rule for future benefit years.

We also recognize the comments about the impact of delaying publication of blended coefficients and the comments requesting the final coefficients be made available by the time of initial state rate filing submissions. We will continue to look for opportunities to update our processes to provide draft and final

[18] For example, see the HHS Notice of Benefit and Payment Parameters for 2018 Final Rule (the 2018 Payment Notice), 81 FR 94058 (December 22, 2016). Also see 45 CFR 153.320(b)(1)(i).

[19] See 81 FR at 94084–94085.

[20] See, for example, *https://www.cms.gov/files/document/2020-final-rate-review-timeline-bulletin.pdf.*

recalibrated coefficients earlier, but we did not propose and are not making changes to the current schedule or approach for publication of the recalibrated coefficients at this time.

Comment: Commenters agreed that exclusively using enrollee-level EDGE data to recalibrate the HHS risk adjustment models better reflects the risk in the individual and small group (including merged) markets. One commenter encouraged HHS to continuously monitor and analyze potential long-term impacts of using enrollee-level EDGE data. Another commenter asked HHS to provide additional information about its blending methodology, including whether HHS adjusts the coefficients for expected one-time price hikes that would occur in the benefit year and not the data experience year or vice versa (for example, patent protection on brand drugs, or drugs losing a patent).

Response: We agree with commenters that exclusively using enrollee-level EDGE data to recalibrate the risk adjustment models will more closely reflect the relative risk differences of individuals in the individual and small group (including merged) markets compared to MarketScan® data, which generally reflects the large group market and was used in past years before enrollee-level EDGE data was available to approximate the HHS risk adjustment covered population.

As with every recalibration year, we continue to monitor the year-to-year changes in risk scores related to the data used, and will continue to monitor the potential long-term impacts of exclusively using enrollee-level EDGE data. HHS trends expenditures in each year's data to the applicable benefit year. Beginning with the 2017 benefit year, we trended medical services, preventive services, traditional (including brand and generic) prescription drug and specialty prescription drug expenditures separately based on varying growth rates observed in data available, in consultation with actuaries and industry reports.[21] Except for the Hepatitis C drug pricing adjustment, discussed below, we do not currently adjust the model coefficients for one-time price changes that could occur in the benefit year.

To further explain our blending methodology, the coefficients are separately solved from each of the three years of data used in recalibration with applicable trend factors to account for anticipated cost changes between the data year and the applicable risk adjustment benefit year. The final blended coefficients for the applicable benefit year are created by averaging the separately solved coefficients across each of the three data years. The blending methodology is an average of three years' separately solved factors for each of the models, with each of the data years' factors equally weighted in the average as one-third of the final blended coefficients.[22]

(2) Updates to Risk Adjustment Model Recalibration

i. Payment Hierarchical Condition Categories (HCCs)

The HHS–HCC clinical classification is the foundation of the models used in calculating transfers under the state payment transfer formula in the HHS-operated risk adjustment program established under section 1343 of the PPACA. Except for annual diagnosis code updates and the reconfiguration of one HCC,[23] the HHS–HCC clinical classification in terms of diagnosis code mappings has not been modified since it was implemented in the 2014 benefit year.

In preparation for proposing the changes in the proposed rule, we released a paper on June 17, 2019 entitled ''Potential Updates to the HHS–HCCs for the HHS-operated Risk Adjustment Program'' (HHS–HCC Updates Paper).[24] This paper described our methodology for reviewing and restructuring the HHS–HCC classification to incorporate ICD–10 diagnosis codes, and our intention to evaluate potential changes to the HHS–HCC model classification using enrollee-level EDGE data, which is representative of the population for which the models are targeted. Our main goal for reclassifying HHS–HCCs is to use them to update the HHS–HCC models to better incorporate coding changes made in the transition to the ICD–10 diagnosis classification system. We also used this opportunity to review and use the newly available 2016 and 2017 benefit years' enrollee-level EDGE claims data, which reflect the first 2 full years of ICD–10 diagnosis coding on claims. While this analysis did not consider updates to the RXCs,[25] it examined other components of the clinical classification, including payment and non-payment HCCs, certain clinical hierarchies, HCC groups and *a priori* constraints on HCC coefficients, and other HCC interactions affected by potential changes.

In the HHS–HCC Updates Paper, we explained our considerations for examining potential changes to HCCs and in determining which diagnosis codes should be included, how they should be grouped, and how the diagnostic groupings should interact for risk adjustment purposes, which is a critical step in the development of the HHS–HCC risk adjustment models. To guide the reclassification process, we used 10 principles that were discussed in the proposed 2014 Payment Notice that guided the creation of the original HHS–HCC diagnostic classification system,[26] and that were used to develop the HCC classification system for the Medicare risk adjustment model.[27] These principles included:

- *Principle 1*—Diagnostic categories should be clinically meaningful.
- *Principle 2*—Diagnostic categories should predict medical (including drug) expenditures.
- *Principle 3*—Diagnostic categories that will affect payments should have adequate sample sizes to permit accurate and stable estimates of expenditures.
- *Principle 4*—In creating an individual's clinical profile, hierarchies should be used to characterize the person's illness level within each disease process, while the effects of unrelated disease processes accumulate.
- *Principle 5*—The diagnostic classification should encourage specific coding.

[21] For further details on trending, see the 2017 Payment Notice final rule (81 FR 12204 at 12218), and also the March 31, 2016 HHS Risk Adjustment Models White Paper, available at *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf.*

[22] For further details on blending, see the 2016 Payment Notice (80 FR 10760), and also the March 31, 2016 HHS Risk Adjustment Models White Paper, available at *https://www.cms.gov/cciio/resources/forms-reports-and-other-resources/downloads/ra-march-31-white-paper-032416.pdf.*

[23] As detailed in the 2018 Payment Notice, beginning with the 2018 benefit year, HCC 37 Chronic Hepatitis was split into two HCCs to distinguish the treatment costs of chronic hepatitis C: HCC 37_1 Chronic Viral Hepatitis C and HCC 37_2 Chronic Hepatitis, Except Chronic Viral Hepatitis C. See 81 FR 94058 at 94085 (December 22, 2016).

[24] The Potential Updates to HHS–HCCs for the HHS-operated Risk Adjustment Program (June 17, 2019) paper is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downoads/Potential-Updates-to-HHS-HCCs-HHS-operated-Risk-Adjustment-Program.pdf.*

[25] RXCs were not implemented in the HHS-operated risk adjustment models until the 2018 benefit year and they currently only apply to the adult models.

[26] See the HHS Notice of Benefit and Payment Parameters for 2014, Proposed Rule, 77 FR 73118 at 73128 (December 7, 2012).

[27] Report to Congress: Risk Adjustment in Medicare Advantage (December 2018) also discusses these principles in Section 2.3 under ''Principle for Risk Adjustment Models'' from pages 14–16 and is available at *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.*

• *Principle 6*—The diagnostic classification should not reward coding proliferation.

• *Principle 7*—Providers should not be penalized for recording additional diagnoses (monotonicity).

• *Principle 8*—The classification system should be internally consistent (transitive).

• *Principle 9*—The diagnostic classification should assign all diagnosis codes (exhaustive classification).

• *Principle 10*—Discretionary diagnostic categories should be excluded from payment models.

Using these principles, we conducted a multi-step analysis of the current HHS–HCC classification to develop the list of HCC changes that we proposed.

We began by conducting a comprehensive review of the current HHS–HCC full classification and risk adjustment model classification, including an examination of disease groups with extensive ICD–10 code classification changes, HCCs whose counts had changed considerably following ICD–10 implementation, clinical areas of interest (for example, substance use disorders), and model under-prediction or over-prediction as identified by predictive ratios. We then examined HCC reconfigurations, payment HCC designation, HCC Groups, and hierarchies to develop the preliminary regression analyses using 2016 data.[28] We also conducted a series of clinical reviews to inform potential changes. Next, we reviewed the payment model and full classification regressions to compare frequencies and predicted incremental costs of HCCs. Then, we repeated the preliminary regression analyses using 2017 data, reviewed regression results, and developed the new potential HHS–HCC reclassification.[29]

During our analysis, for some disease groups such as substance use disorders and pregnancy, we explored multiple model variations. For substance use disorders, we tested different configurations to add new drug use disorder HCCs and alcohol use disorder HCCs to the HHS–HCC risk adjustment models—a single hierarchy approach; two hierarchies (drug and alcohol HCCs being additive); interaction terms; and for each of these iterations, grouping HCCs or leaving them ungrouped. For pregnancy, we tested different configurations for adding ongoing pregnancy HCCs to the model, which already includes miscarriage HCCs and completed pregnancy HCCs. These configurations included a single hierarchy or separate additive HCCs to distinguish pregnancy care from delivery; interactions between completed and ongoing pregnancy HCCs to account for when in the episode of care complications occur; and removal of or changes to HCC groups to better reflect cost distinctions. In evaluating options for reclassification, we considered their predictive power, model complexity, and coding incentives.

Based on this analysis, we proposed to incorporate the HCC changes identified in the HHS–HCC Updates Paper beginning with the 2021 benefit year risk adjustment models.[30] As discussed in the proposed rule, the main purpose of the proposed HCC changes is to update the HCCs based on availability of more recent diagnosis code information and the availability of more recent claims data. To provide risk adjustment factors that best reflect more recent treatment patterns and costs, we proposed to update the HHS–HCC clinical classification in the V05 HHS–HCC risk adjustment models by using more recent claims data to develop updated risk factors, as part of our continued assessment of modifications to the HHS-operated risk adjustment program for the individual, small group, and merged markets.

We proposed to apply all of the HHS–HCC changes at one time for the 2021 benefit year and beyond to account for all of the ICD–10 coding changes. Additionally, to assist commenters in reviewing the code level changes, we provided a crosswalk of ICD–10 codes to the proposed HCCs under the ''Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year'', which is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html*.[31] While we recognized that the number of HHS–HCC changes we proposed was significantly higher than in previous annual notices of benefit and payment parameters, we noted in the proposed rule that we do not expect to make significant HHS–HCC changes each year. We solicited comment on all of the proposed HHS–HCC updates. Following our review of public comments, we are finalizing our proposal to update the HHS–HCC classifications to incorporate ICD–10 diagnosis codes with slight modifications to specific payment HCCs as outlined further below, referred to as the Version 07 (''V07'') classification.

Specifically, we carefully considered comments received regarding the HHS–HCC reclassifications and are finalizing certain modifications to our proposals in response. First, although we are finalizing our proposal to revise the current HCCs 81 (Drug Psychosis) and 82 (Drug Dependence) and add separate HCCs related to alcohol use (HCC 83 and 84), we are not finalizing our proposal to create a fifth HCC, HCC 85 (Drug Use Disorder, Mild, Uncomplicated, Except Cannabis), in the adult, child, or infant models. We agree with commenters that further review of HCC 85 is necessary, including within the context of RADV, prior to adding to that HCC.

As also recommended by commenters, we are finalizing the grouping of the two drug use disorders (revised HCCs 81 and 82 together) and the two alcohol use disorders (HCC 83 and 84 together) in the adult models, consistent with the approach proposed for the child models.

Because we proposed to update the hierarchy positions for mental health HCCs, we also proposed to switch the numbering for HCC 88 and HCC 89, while also renaming both HCCs. Commenters found the proposed number switches for these two HCCs in the child and adult models confusing; therefore, we are finalizing the proposed change in hierarchy position of these HCCs and the proposed renaming of both HCCs, but we are finalizing a modified numbering of these HCCs in V07 from those proposed in V06b as

[28] Payment HCCs are those included in the HHS–HCC risk adjustment models. The full classification includes both payment and non-payment HCCs. HCC Groups refers to payment HCCs that are grouped together in the HHS–HCC risk adjustment models.

[29] To further clarify, in the HHS–HCC Updates Paper, V05 reflects the current classification model, V06 is the initial assessment of potential revisions to the classification model developed using the 2016 benefit year data, and V06a is the reassessment of potential revisions to the classification model that included 2017 benefit year data. In this rule, V06b is the revised HCC changes in the proposed rule and V07 is the revised classification model being finalized.

[30] As explained in the proposed rule, we proposed one modification to the child models from the potential updates described in the HHS–HCC Updates Paper. We proposed and are finalizing below in this rule that the removal of a constraint for HCC 159 Cystic Fibrosis to allow it to have higher predicted costs than HCC 158 Lung Transplant Status/Complications.

[31] The Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year reflects changes proposed in the 2021 Payment Notice proposed rule as referenced in this rule as ''V06b.'' This draft crosswalk included Table 3, which crosswalks ICD–10 codes to the Condition Categories (CCs) in the risk adjustment models, and Table 4, which provides the hierarchy rules to apply to the CCs to create HCCs. These Tables are similar to the Tables 3 and 4 that HHS includes as part of the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software. We expect to replace the draft crosswalk with an updated crosswalk based on the V07 changes being finalized in this rule in the future, and will make it available on our website as well.

shown in Table 1. Specifically for V07, we are retaining the numbering, but renaming HCC 88 (Major Depressive Disorder, Severe, and Bipolar Disorders), renumbering and renaming proposed HCC 89 (Reactive and Unspecified Psychosis, Delusional Disorders) as HCC 87.2 (Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis) because it would place HCC 87.2 above HCC 88 in the hierarchy. To accommodate this change, we are also renumbering Schizophrenia from HCC 87 to HCC 87.1 to maintain its place in the hierarchy.

TABLE 1—MODIFIED V07 NUMBERING OF THESE HCCS FROM THOSE PROPOSED IN V06b

V05 HCC	V05 HCC label	V06b HCC	V06b HCC label	V07 HCC	V07 HCC label
87	Schizophrenia	87	Schizophrenia	87_1	Schizophrenia.
		88	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis.	87_2	Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis.
88	Major Depressive and Bipolar Disorders.	89	Major Depressive Disorder, Severe, and Bipolar Disorders.	88	Major Depressive Disorder, Severe, and Bipolar Disorders.
89	Reactive and Unspecified Psychosis, Delusional Disorders.				

In addition to the above modifications, and consistent with HHS's commitment to continuously assess the HHS-operated risk adjustment program based on analysis of more recent available data and the objectives in the HHS–HCC Updates Paper, we further analyzed the HCC classifications using 2018 enrollee-level EDGE data once it was available. Based on this review, we determined the costs related to two HCCs in the infant models were better aligned with severity level four, rather than the proposed classification of severity level three.[32] In addition, we identified two clinically-related HCCs in the child models that have small sample sizes. Therefore, consistent with the general policy that the models should avoid creating HCCs with low sample sizes and possibly unstable estimates, we will group them to improve the predictive power and stability of the child models. We also identified one new proposed HCC in the child model that has a sufficient sample size, and therefore, we will be not be grouping it, as proposed. Details on these changes to the infant and child models are described below. We note that these additional modifications relate to certain HCCs in the infant and child models to further improve the risk prediction and stability of the models. These shifts in placement do not change the number or type of HCCs included in the infant and child models beyond what was proposed. We believe that each change described below, while small in effect, will improve risk prediction and ensure stability of the models. Therefore, we are finalizing the following additional HCC classification changes to the infant and child models:

- In the infant models, we are not finalizing the proposed move of HCC 73 (Combined and Other Severe Immunodeficiencies) from severity level four to severity level three; it will remain classified as severity level four. The costs for HCC 73 are better aligned with severity level four upon further review of an additional data year.
- In the infant models, we are also moving HCC 30 (Adrenal, Pituitary, and Other Significant Endocrine Disorders) from severity level three to level four. Upon review of an additional data year, we concluded that the costs for HCC 30 are better aligned with severity level four.
- In the child models, we are grouping HCC 131 (Acute Myocardial Infarction) and HCC 132 (Unstable Angina and Other Acute Ischemic Heart Disease) because our review of an additional data year identified small sample sizes for these HCCs.
- In the child models, we are finalizing, as proposed, the grouping of HCC 210 ((Ongoing) Pregnancy without Delivery with Major Complications) with HCC 211 ((Ongoing) Pregnancy without Delivery with Complications) due to the small sample sizes associated with these HCCs for this population. However, we are not finalizing the proposal to group these two HCCs with the proposed new HCC 212 ((Ongoing) Pregnancy without Delivery with No or Minor Complications). Upon review of the additional data year, we determined the sample size for HCC 212 in the child models is sufficient such that grouping it with HCC 210 and HCC 211 is not necessary.

Lastly, we are also finalizing one additional diagnosis coding update to the adult risk adjustment models in light of the finalized updates to the HCCs in this rulemaking. We are including the proposed HCC 35.1 (Acute Liver Failure/Disease, Including Neonatal Hepatitis) in the RXC–HCC interaction term for RXC 02 (Anti-Hepatitis C (HCV) Agents). RXC 02 (Anti-Hepatitis C (HCV) Agents) was previously paired with HCC 37.1 (Chronic Viral Hepatitis C), HCC 36 (Cirrhosis of Liver), HCC 35.2 (V05 HCC 35, End-Stage Liver Disease), and HCC 34 (Liver Transplant Status/Complications), listed in ascending order of position in the V05 hierarchy. Anti-Hepatitis C (HCV) Agents are primarily prescribed for HCC 37.1 (Chronic Viral Hepatitis C); however, because of clinical hierarchies, other HCCs that are clinically more severe than the HCC primarily associated with the RXC (HCC 37.1) are also included in the RXC–HCC interaction. In the proposed rule, HHS proposed to move HCC 38 (Acute Liver Failure/Disease Including Neonatal Hepatitis) above HCC 35 (End Stage Liver Disease) in the related HCC hierarchy to address cost implications of chronic versus acute liver failure. Due to the change in hierarchy positions, we proposed to renumber these HCCs to HCC 35.1 (Acute Liver Failure/Disease, Including Neonatal Hepatitis), and HCC 35.2 (Chronic Liver Failure/End Stage Liver Disorders), respectively. Because HCC 35.1 (Acute Liver Failure/Disease, Including Neonatal Hepatitis) was proposed and is being finalized in the hierarchy above the HCC most closely related to RXC 02 (Anti-Hepatitis C (HCV) Agents), HCC 37.1 (Chronic Viral Hepatitis C), we are adding HCC 35.1 to the RXC 02 interaction term as part of

[32] The infant models use a categorical approach because infants (ages 0–1) have low frequencies for most HCCs, which leads to unstable parameter estimates in an additive model. Infants are assigned a birth maturity (by length of gestation and birth weight as designated by their newborn payment HCC) or age 1 category, and a disease severity category (based on HCCs other than birth maturity). There are five maturity categories and five disease severity categories (based on clinical severity and associated costs).

the updates finalized in this rulemaking. Therefore, in addition to finalizing the below revisions to the liver HCC hierarchy, we are also finalizing the addition of this HCC for the RXC 02 interaction term in the adult models.

In the proposed rule, we also proposed one modification to the child models from the potential updates described in the HHS–HCC Updates Paper. In the paper, we noted that we may re-examine the hierarchy violation constraints for non-transplant HCCs in the child models that affect the predicted costs of the transplant set. We explained that HCC 159 (Cystic Fibrosis) in the child models, which has high associated drug costs, has higher predicted costs than HCC 158 (Lung Transplant Status/Complications). For this reason, a hierarchy violation was occurring whereby the higher-cost HCC 159 (Cystic Fibrosis) was being constrained to the lower-cost transplant coefficients. To improve cost prediction, we proposed to not impose a hierarchy violation constraint in the child models beginning with the 2021 benefit year coefficients for HCC 159 (Cystic Fibrosis), allowing it to have higher predicted costs than HCC 158 (Lung Transplant Status/Complications). We are finalizing this proposed change, and are also adding a similar change for parallel reasons. We also will not impose a hierarchy violation constraint in the child models beginning with the 2021 benefit year coefficients for HCC 35.1 (Acute Liver Failure Disease, Including Neonatal Hepatitis) and HCC 35.2 (Chronic Liver Failure/End-Stage Liver Disorders), allowing them to have higher predicted costs than the liver transplant HCC 35 (Liver Transplant Status/Complications). Thus, we are finalizing in V07 not to impose hierarchy violation constraints in the child models for two sets of non-transplant HCCs that have higher associated costs than the transplant HCC above them in their hierarchy: (1) Liver failure HCC 35.1 (Acute Liver Failure Disease, Including Neonatal Hepatitis) and HCC 35.2 (Chronic Liver Failure/End-Stage Liver Disorders) and HCC 34 (Liver Transplant Status/Complications); and (2) HCC 159 (Cystic Fibrosis) and HCC 158 (Lung Transplant Status/Complications).

All of the final payment HCC changes for the 2021 benefit year risk adjustment models and beyond, including these additional modifications, are reflected in Table 2 and referred to as ''V07'' below. The HCC classification for the 2020 benefit year is referred to as ''V05'', the classification changes discussed in the HHS–HCC Updates Paper are referred to as ''V06a,'' and the classification changes proposed in the 2021 Payment Notice proposed rule are referred to as ''V06b.''

TABLE 2—SUMMARY OF FINAL PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES
[V07]

Condition	Payment HCC final change	Summary of final payment HCC changes
Payment HCC Changes		
Substance Use Disorders	+2	• Add 2 new HCCs for alcohol use disorders for all models[1] to risk adjust for a larger number of substance use diagnoses. • Reconfigure drug dependence HCC to include drug use disorders with non-psychotic complications and a subset of drug poisoning (overdose) codes to reflect the revised conceptualization of substance use disorders in ICD–10. • Group the drug use HCCs (81 and 82) into one group and the alcohol use HCCs (83 and 84) in another group for adult and child models. • Impose a new combined hierarchy on drug use and alcohol use HCCs due to the high prevalence of both drugs and alcohol use among those with alcohol or drug use disorders.
Pregnancy	+3	• Add 3 (ongoing) pregnancy-without-delivery HCCs to child and adult models. Leave them ungrouped in the adult models to reflect differences in costs by level of complications. Group the two higher HCCs (210 and 211) in the child models to address small sample sizes and unstable estimates. • Revise two existing pregnancy HCC Groups in both adult and child models, separating out the ectopic/molar pregnancy HCC and the uncomplicated pregnancy-with-delivery HCC to better distinguish incremental costs.
Diabetes	+1	• Add a diabetes type 1 additive HCC to the adult models to distinguish additional costs for diabetes type 1. • Remap hyperglycemia and hypoglycemia codes from the ''chronic complications'' HCC to the ''without complication'' HCC based on clinical input.
Asthma	+1	• Split current asthma HCC into two severity-specific HCCs for all models given new clinical distinctions for severity levels in the ICD–10 and to distinguish costs by severity. • Continue to group asthma HCCs with chronic obstructive pulmonary disease HCC in adult models and leave the 3 HCCs ungrouped to distinguish costs in child models.
Fractures	−1, +1	• Delete an HCC (pathological fractures) for all models to address a clinical distinction that may be inconsistently diagnosed/coded. • Reconfigure an existing HCC (hip fractures) to better distinguish fracture codes by site. • Add a new HCC (vertebral fractures) for all models to better predict vertebral fractures, which may be indicative of chronic disease and frailty.
Third Degree Burns and Major Skin Conditions	+2	• Reconfigure and add 2 HCCs (extensive third degree burns; major skin burns or conditions) for all models in an imposed hierarchy because these HCCs are currently being under-predicted, contain chronic conditions or are burns that involve long-term follow up care. • Impose an *a priori* constraint[2] between extensive third degree burns and severe head injury in child models due to small sample size.
Coma and Severe Head Injury	+1	• Add a new severe head injury HCC (represents a condition with ongoing care costs; similar to the inclusion of other injury HCCs) for all models in a hierarchy above the coma/brain compression HCC. • Impose an *a priori* constraint between extensive third degree burns and severe head injury in the child models due to small sample size.

TABLE 2—SUMMARY OF FINAL PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES—Continued
[V07]

Condition	Payment HCC final change	Summary of final payment HCC changes
Traumatic Amputations	+1	• Add a new HCC in a hierarchy with the current amputation status HCC for all models and reconfigure codes between the new HCC and current amputation status HCC to better distinguish early treatment and complication costs from long-term costs. • Leave HCCs ungrouped in the adult models; group them in the child models for coefficient stability purposes due to small sample size.
Narcolepsy and Cataplexy	+1	• Add a new HCC to both child and adult models because these conditions are currently under-predicted and have associated treatment costs.
Exudative Macular Degeneration	+1	• Add a new HCC to adult models because the condition is currently under-predicted; costs are primarily related to drug treatments.
Congenital Heart Anomalies	new to adult	• Add 3 new HCCs to adult models (already in the child and infant models) because the conditions are currently under-predicted. Group them in the adult models only.
Changes in HCC Groups, Hierarchies		
Metabolic and Endocrine Disorders	N/A	• Group HCCs 26 and 27 together in both the child and adult models to distinguish their significantly higher incremental costs from other HCCs (HCCs 28–30) previously in the full group (HCCs 26 and 27 are currently under-predicted in these models due to grouping). • Ungroup HCCs 29 and 30 in the adult models as they have adequate sample sizes and clinical and cost distinctions. • Group HCCs 28 and 29 in the child models due to small sample sizes, clinical similarity, and similar predicted costs. • Leave HCC 30 ungrouped in the child models because it is clinically distinct from HCCs 28 and 29.
Necrotizing Fasciitis	N/A	• Ungroup the necrotizing fasciitis HCC (HCC 54) in the adult models to better predict higher incremental costs compared to HCC 55 (the condition that is currently grouped with this HCC).
Blood Disorders	N/A	• Revise groups in both adult and child models to move HCC 69 from its previous grouping with HCCs 70 and 71 to the group with HCCs 67 and 68 to better reflect clinical severity and associated costs. • Reconfigure HCCs 69 and 71 based on clinical input.
Acute Myocardial Infarction and Unstable Angina	N/A	• Group HCCs 131 and 132 in the child models for coefficient stability purposes due to small sample size.
Mental Health	N/A	• Move delusional disorders/psychosis HCC above major depressive disorders/bipolar disorders HCC in the hierarchy (the HCCs switch position in the hierarchy) because the costs and diagnoses associated with the delusional disorders/psychosis HCC are more aligned with the schizophrenia HCC. Renumber the two highest HCCs in the hierarchy: HCC 87_1 Schizophrenia (had been 87) and HCC 87_2 Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis (had been 89). HCC 88 Major Depressive Disorder, Severe, and Bipolar Disorders retains its same number. • Relabel HCCs to align with ICD–10 categorizations.
Cerebral Palsy and Spina Bifida	N/A	• Refine hierarchies to exclude paralysis HCCs for enrollees with cerebral palsy HCCs, as ICD–10 coding guidelines prohibit these conditions from coding together. • Refine hierarchies to exclude hydrocephalus HCC for enrollees with spina bifida HCC for similar coding restriction purposes.
Pancreatitis	N/A	• Reconfigure the acute pancreatitis HCC to move pancreatic disorders and intestinal malabsorption out of the acute pancreatitis HCC to differentiate higher cost conditions. • Revise the hierarchy for pancreas transplant HCC to remove exclusion of pancreatitis HCCs because pancreas transplants are done primarily for diabetes and insulin conditions rather than pancreatitis.
Liver	N/A	• Reconfigure codes in liver HCCs to reflect clinical distinctions. • Move acute liver failure HCC above chronic liver failure HCC in the hierarchy and renumber HCCs to address cost implications of chronic versus acute liver failure.
Summary of the Adult Model Specific Changes		
Payment HCC change	+16	• Net change of 16 HCCs; 17 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Severe Illness Interactions	−1 (other model variable)	• Remove medium cost severe illness interaction term from model because its parameter estimate is usually very low or negative.
Summary of the Child Model Specific Changes		
Payment HCC change	+11	• Net change of 11 HCCs; 12 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Transplant *A Priori* Constraints	N/A	• Revise *a priori* constraints applied to the transplant HCCs to better distinguish costs while improving estimate stability due to small sample sizes. • Do not impose hierarchy violation constraints for two sets of non-transplant HCCs that have higher associated costs than the transplant HCC above them in their hierarchy: (1) Liver failure HCCs 35.1 and 35.2 and HCC 34 Liver Transplant Status/Complications; and (2) HCC 159 Cystic Fibrosis and HCC 158 Lung Transplant Status/Complications.

TABLE 2—SUMMARY OF FINAL PAYMENT HCC RISK ADJUSTMENT MODEL CHANGES—Continued
[V07]

Condition	Payment HCC final change	Summary of final payment HCC changes
Summary of the Infant Model Specific Changes		
Payment HCC change	+7	• Net change of 7; 8 HCCs added and 1 HCC deleted (for details see the above portion of this table).
Categorical Model	N/A	• Revise severity level assignments of a subset of HCCs to better reflect clinical severity and costs and assign new HCCs to severity levels. • Reconfigure code assignments to newborn HCCs for subset of codes whose weeks gestation classification in ICD–10 differed from ICD–9.

[1] References to ''all models'' in Table 2 refers to the adult, child and infant models.
[2] In *a priori* constraints, the HCC estimates are constrained to be equal to each other. These are applied to stabilize high cost estimates that may vary greatly due to small sample size.

The following is a summary of the public comments we received on the proposed ICD–10 HHS–HCC reclassification updates to the HHS risk adjustment models.

Comment: Some commenters requested that HHS provide additional transparency about the data used in updating the HCCs, such as the alternatives we considered, the criteria used to develop our proposals and the impact of changes. Other comments requested that HHS demonstrate the contribution of each specific updated or modified HCC to the model and how it improves the accuracy of identifying risk selection compared to the existing model. Some commenters request that the HCC change be tested with the most recent year of EDGE data.

Response: We agree with commenters about the importance of transparency in developing and finalizing HCC updates. We refer commenters to the HHS–HCC Updates Paper, released on June 17, 2019, in which we provided a preview of the proposed changes with detailed estimated costs between the current classification and the proposed classification, as well as the impact of the changes on the adult, child and infant risk adjustment models. In the HHS–HCC Updates Paper and the proposed rule, we outlined the principles (or criteria) used to develop the proposed ICD–10 HHS–HCC reclassifications updates.[33] In both documents, we also explained the process we used to develop the proposed updates.

We began this process by conducting a comprehensive review of the current HHS–HCC full classification and risk adjustment model classification, including an examination of disease groups with extensive ICD–10 code classification changes, HCCs whose counts had changed considerably following ICD–10 implementation, clinical areas of interest (for example, substance use disorders), and model under-prediction or over-prediction as identified by predictive ratios. We then examined HCC reconfigurations, payment HCC designation, HCC Groups, and hierarchies to develop the preliminary regression analyses using 2016 enrollee-level EDGE data.[34] We also conducted a series of clinical reviews to inform potential changes. Next, we reviewed the payment model and full classification regressions to compare frequencies and predicted incremental costs of HCCs. To validate our initial reclassifications, we repeated the preliminary regression analyses using 2017 enrollee-level EDGE data, as well as 2016 and 2017 MarketScan® data. Results of the initial and validation analyses informed the proposed HHS–HCC reclassifications in model V06a, which were based on 2016 and 2017 enrollee-level EDGE data. We analyzed proposed V06b HCCs on 2018 enrollee-level EDGE data once it became available.

In the HHS–HCC Updates Paper, we estimated that the impact of moving from V05 to V06a[35] would result in a slight improvement in model prediction and a slight increase in the number of enrollees with one or more payment HCCs in the adult and child models. Although some commenters requested data showing specifically how changes impact state-level transfers, we note that we do not extract state identifiers in the enrollee-level EDGE data, and therefore, we are unable to directly assess state level impacts. Instead, we evaluated impacts at the national level. Between the proposed and final rules, we conducted an additional analysis of our proposed V06b classifications and the resulting impact on average national enrollee risk scores. We estimated an increase in national enrollee risk scores of approximately one percent.[36]

In addition to the HHS–HCC Updates Paper that was posted in June 2019, we released a crosswalk alongside the proposed rule to allow issuers to assess the impact of the proposed changes on the risk scores for their plans or enrollees. Commenters did not indicate that they had used the crosswalk to analyze claims data.

Comment: Some commenters requested that we maintain the original numbering assignments and labels for certain HCCs or supported using decimals for renumbering. In particular, one commenter cited our proposal regarding HCCs 88 and 89, where we proposed to rearrange the hierarchy between V05 HCC 89 (Reactive and Unspecified Psychosis, Delusional Disorders) and HCC 88 (Major Depressive and Bipolar Disorders) to reflect higher cost similarities between the V05 HCC 89, which described psychotic disorders, and HCC 87 which described schizophrenia. In addition to proposing changes to the hierarchy and modifications to the names of the HCCs, we also proposed switching the numbers for HCCs 88 and 89 so that the numbering sequence between 87, 88, and 89 would reflect the change in

[33] These principles are also repeated earlier in this rule.

[34] Payment HCCs are those included in the HHS–HCC risk adjustment models. The full classification includes both payment and non-payment HCCs. HCC Groups refers to payment HCCs that are grouped together in the HHS–HCC risk adjustment model.

[35] To further clarify, in the HHS–HCC Updates Paper, V05 reflects the current classification model, V06 is the initial assessment of potential revisions to the classification model developed using the 2016 benefit year data, and V06a is the reassessment of potential revisions to the classification model that included 2017 benefit year data. V06b is the revised HCC changes in the proposed rule and V07 is the revisions to the classification model being finalized in this rule. The changes in the proposed rule (V06b) were reflected in the ''Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year'', which is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html.* We expect to replace the draft crosswalk with an updated crosswalk based on the V07 changes being finalized in this rule in the future, and will make it available on our website as well.

[36] The estimated difference in risk scores was calculated between the 2020 benefit year factors and the 2021 benefit year factors using the 2017 benefit year enrollee-level EDGE data.

hierarchy and the incremental cost differences between schizophrenia, delusional disorders, and depression, respectively. This commenter recommended that we rename these HCCs using decimals (instead of the proposed renumbering).

Response: As explained above and in Table 1, we proposed to switch the numbering for HCC 88 and HCC 89 in response to other updates to the hierarchy positions for mental health HCCs. However, after consideration of comments received, we are not finalizing the proposed renumbering. We agree with commenters that changing the numbering or associated labeling of existing HCCs can be confusing and potentially lead to unnecessary errors in certain circumstances. In response, we are finalizing the revised hierarchy and name changes for these conditions as proposed, but we are not finalizing the renumbering of these HCCs as proposed. Instead, in V07, we are retaining the previous V05 numbering for HCC 88 (Major Depressive and Bipolar Disorders), but are renaming it as proposed (Major Depressive Disorder, Severe, and Bipolar Disorders), and are renumbering and renaming previous V05 HCC 89 (Reactive and Unspecified Psychosis, Delusional Disorders) as HCC 87.2 (Delusional and Other Specified Psychotic Disorders, Unspecified Psychosis) to retain its proposed position above HCC 88 in the hierarchy. To accommodate these changes, we are also renumbering Schizophrenia from the previous V05 numbering of HCC 87 to HCC 87.1 to maintain its place in the hierarchy.

Comment: Some commenters objected to some of the newly added HCCs, including those for fractures, third degree burns and major skin conditions, coma and severe head injury, traumatic amputations, necrotizing fasciitis, and pancreatitis, on the basis that these conditions reflect ''acute'' diagnoses that issuers are unable to select against and whose associated costs are (or should be) incorporated into all issuers' pricing assumptions. A subset of these commenters suggested that HHS separate acute and chronic spending in the risk adjustment models if HHS finalizes the HCCs for acute conditions as proposed.

Some comments also suggested that adding or revising HCCs to include the costs associated with acute conditions would be contrary to the risk adjustment program's fundamental principles because they represent unpredictable risk that issuers cannot adversely select against. One of these commenters stated that the costs associated with acute conditions are (or should be) already incorporated into all issuers' pricing assumptions. The commenter further stated that adding these acute condition HCCs to risk adjustment would likely increase the scope of conditions that might affect an issuer's transfer burden, especially given the national-level predictions of these conditions. The commenter also raised concern that these proposed changes would reduce issuer pricing accuracy, thereby, incentivizing issuers to increase premiums higher than necessary to ensure risk is mitigated. This commenter stated that the incorporation of the cost of acute conditions in demographic factors was more consistent with the principles of risk adjustment and would reflect the more random distribution of acute conditions. One commenter, who supported the proposed changes, noted that traumatic amputation is commonly miscoded by providers as traumatic when it should have been captured as acquired.

Response: We continue to believe that the conditions identified by these commenters (fractures, third degree burns and major skin conditions, coma and severe head injury, traumatic amputations, necrotizing fasciitis, and pancreatitis) should be included in the risk adjustment models and are finalizing these additions and revisions as proposed. Based on our analysis, these conditions indicate the presence of underlying chronic conditions and frailty, are underpredicted in the models, and have high costs in the year after the diagnosis. Therefore, we do not agree that including the new and revised HCCs for fractures, third degree burns and major skin conditions, coma and severe head injury, traumatic amputations, necrotizing fasciitis, and pancreatitis challenges the foundational principle of the risk adjustment program. There is evidence of ongoing chronic costs associated with these conditions, and issuers can potentially adversely select against enrollees with a higher risk of developing these conditions in a given benefit year. In addition, many of these HCCs are also incorporated in Medicare's prospective CMS–HCC models.

Several HHS–HCCs related to these conditions were reconfigured or newly added to the risk adjustment models to better predict costs for conditions that have near-term ongoing costs. These included HCC 226 (Hip and Pelvic Fractures), HCC 228 (Vertebral Fractures without Spinal Cord Injury), HCC 218 (Extensive Third Degree Burn), HCC 219 (Major Skin Burn or Condition), and HCC 223 (Severe Head Injury). Because there are ongoing costs of care for these conditions that present risk of adverse selection for plans in the following benefit year, we believe that it is important to reconfigure and add these HCCs to the risk adjustment models given the coding changes made between the ICD–9 and ICD–10 and our review of the enrollee-level EDGE data. We also note that the proposed adoption of the new or reconfigured HCCs for the conditions identified by commenters as ''acute conditions'' aligns with the general approach in the current models, which separates out acute and chronic spending, if possible, when necessary to improve risk prediction. In addition, isolating and omitting the near-term ongoing costs for these conditions would reduce the predictive accuracy of the model without any benefit in reduced model complexity, as the costs for the excluded near-term codes would end up in the associated longer term HCCs.

For example, for the traumatic amputation HCC, which we are finalizing for inclusion in the risk adjustment models as proposed, we analyzed and considered different configurations of the amputation-related HCCs during the reclassification process. We proposed and are finalizing two amputation related HCCs: HCC 234 (Traumatic Amputations and Amputations and Amputation Complications), which is newly added in V07, and HCC 254 (Amputation Status, Upper Limb or Lower Limb), which was a payment HCC in V05. These HCCs were reconfigured to better account for the cost distinctions between the initial treatment, early follow-up, and potential early complications, and the much lower long-term ongoing costs of amputated limbs. Conditions with both acute treatment and permanent ongoing care, such as spinal cord injuries and major limb amputations, have sets of HCCs containing both initial encounter injury codes and additional care and status codes. Since the V05 classification included only the amputation status and complications payment HCC, some costs of the omitted initial episode codes were pulled in via subsequent encounter codes in HCC 254. For example, 38 percent of adult enrollees with HCC 234 also had HCC 254, and therefore, the prediction for enrollees with only amputation status codes were overpredicted, and enrollees with the initial encounter codes were underpredicted. To address underprediction of the initial encounter codes for traumatic amputations of upper limb or lower limb and to better delineate costs between the initial

episode and those for complications and care for ongoing status care, we are finalizing the amputation HCCs as proposed. Additionally, the inclusion of HCC 234 is consistent with the Medicare HCC risk adjustment models.

Another example of a payment HCC in the current risk adjustment models that reflects what commenters identified as ''acute conditions'' is Necrotizing Fasciitis, which is a life-threatening condition that may require ongoing care related to the tissue damage. Because of the severity of the condition and intensity of treatment, HCC 54 (Necrotizing Fasciitis) has always been distinguished from the lower severity conditions in HCC 55 (Bone/Joint/Muscle Infections/Necrosis) but due sample size issues, these HCCs were grouped in the V05 classification. As noted in the HHS–HCC Updates Paper, we found that HCC 54 (Necrotizing Fasciitis) is clinically distinct and has been underpredicted in the adult and child models with its incremental expenditures that when ungrouped are approximately twice as high as HCC 55 (Bone/Joint/Muscle Infections/Necrosis), and now HCC 54 (Necrotizing Fasciitis) has a sufficient sample size to remove the HCC Group between HCC 55 (Bone/Joint/Muscle Infections/Necrosis) and HCC 54 (Necrotizing Fasciitis) in the adult models. For these reasons, we proposed and are finalizing ungrouping HCC 54 (Necrotizing Fasciitis) and HCC 55 (Bone/Joint/Muscle Infections/Necrosis) in the adult models to better distinguish costs for both HCCs. However, because HCC 54 (Necrotizing Fasciitis) has a low sample size in the child models, we are retaining the HCC Group for HCC 54 (Necrotizing Fasciitis) and HCC 55 (Bone/Joint/Muscle Infections/Necrosis) in the child models.

For the pancreatitis HCCs, on the other hand, we proposed and are finalizing a reconfiguration to HCC 47 (Acute Pancreatitis) to differentiate higher cost conditions within the HCC and a revision to HCC 18 (Pancreas Transplant Status/Complications) to remove the pancreatitis HCCs from HCC 18's hierarchy exclusions. We are finalizing this exclusion change because pancreas transplants are done primarily for diabetes and insulin conditions rather than pancreatitis, and ICD–9 had a pancreas-specific code for transplant complications, whereas the ICD–10 code set for other transplant complications is not restricted to pancreas transplants. Additionally, we are relabeling HCC 18 (Pancreas Transplant Status/Complications) to HCC 18 (Pancreas Transplant Status) to accurately reflect its ICD–10 code content. As described in the HHS–HCC Updates Paper, these changes resulted in significant changes in the count and estimated costs for the pancreatitis HCCs in all models. Specifically, the removal of the intestinal malabsorption and other pancreatic disorders from the HCC 47 (Acute Pancreatitis) led to large shifts in sample size and costs, but we believe this reconfiguration of the HCC more accurately captures the risk and costs of acute pancreatitis events that may cause adverse selection issues. We are therefore finalizing the changes to the pancreatitis HCCs as proposed.

We also assessed whether HCCs associated with several of the proposed HCC conditions [37] should be added to the models by analyzing enrollees with the given HCC in 2009 MarketScan® data and the costs associated with those enrollees in the subsequent year's data, 2010 Marketscan® data. The purpose of this analysis was to assess whether the enrollee costs for these conditions, including several conditions that commenters identified as ''acute conditions,'' persisted over both benefit years. We found that enrollees with these conditions were characterized by persistently higher costs in the subsequent year, 2010.[38] This analysis further supports our position that certain HCCs, including several conditions that commenters identified as ''acute conditions,'' involve ongoing follow-up care, were identified as being persistently underpredicted in the current models and should be modified to improve model prediction and better capture the longer-term costs associated with the conditions. This evidence of ongoing chronic costs associated with these conditions, reaffirms that issuers can potentially adversely select against the risk of enrollees with these conditions. Thus, because we believe it is important and consistent with the objectives of the risk adjustment program to improve model prediction and mitigate risk of adverse selection when possible, we believe the newly added or reconfigured HCCs discussed above are consistent with our prior framework for payment HCCs, and we are finalizing the updates related to ICD–10 reclassifications of HCCs that are described in this final rule in Table 2.

Comment: One commenter stated that severe head injury HCC 223 (Severe Head Injury) should not be added to the adult and child risk adjustment models because associated chronic costs are captured in existing HCC 122 (Coma/Brain Compression). Another commenter agreed with including the new HCC 223 (Severe Head Injury) but requested that we exclude the acute costs from the chronic costs associated with the underlying diagnoses.

Response: We disagree with the comment that HCC 223 (Severe Head Injury) should not be added in the models because existing HCC 122 (Non-Traumatic Coma and Brain Compression/Anoxic Damage) already captures the applicable chronic costs associated with these conditions. Although there is overlap between HCC 122 and HCC 223, the inclusion of HCC 122 alone is not sufficient in representing the costs of Severe Head Injury.

We also note that due to difficulty in distinguishing between acute and chronic costs for these HCCs, we are not separating the acute costs from chronic costs for these HCCs. We also believe that by including the acute costs for these conditions, we are also accounting for the ongoing costs of care during the first year.

In the HHS–HCC Updates Paper, we noted that HCC 223 represents a condition with ongoing care costs, similar to other injury HCCs currently included in the current risk adjustment models (for example, hip fractures and vertebral fractures). We explained that the new HCC 223 would be included in a hierarchy above HCC 122 (Coma/Brain Compression, Anoxic Damage).[39] In the child models, due to small sample size, HCC 223 (Severe Head Injury) would be constrained with *a priori* logic to HCC 218 (Extensive Third Degree Burns) so that the HCCs are counted individually, but have the same coefficient. We continue to believe that the proposed addition of HCC 223, along with the constraints described, are appropriate updates to the HHS–HCC reclassification and are similar to the payment HCCs under the Medicare risk

[37] This analysis assessed the following HCCs: HCC 18 (Diabetes with Chronic Complications), HCC 19 (Diabetes without Complication), HCC 20 (Type I Diabetes Mellitus), HCC 80 (Coma, Brain Compression/Anoxic Damage), HCC 161 (Chronic Ulcer of Skin, Except Pressure), HCC 162 (Severe Skin Burn or Condition), HCC 163 (Moderate Skin Burn or Condition), HCC 166 (Severe Head Injury), HCC 167 (Major Head Injury), HCC 169 (Vertebral Fractures without Spinal Cord Injury), HCC 170 (Hip Fracture/Dislocation), HCC 173 (Traumatic Amputations and Complications), HCC 189 (Amputation Status, Lower Limb/Amputation Complications), and HCC 190 (Amputation Status, Upper Limb).

[38] We used MarketScan® data for this analysis as we currently are unable to link enrollees year over year in enrollee-level EDGE data. In the future, we expect to be able to link enrollees year over year in the enrollee-level EDGE data, if the individuals are enrolled with the same issuer over the years.

[39] In all models, HCC 122 would be relabeled to ''Coma/Brain Compression, Anoxic Damage'' to account for the ongoing inclusion of coma codes that may be associated with a traumatic injury.

adjustment models. We are therefore finalizing these changes as proposed.

Comment: While one commenter supported the inclusion of two new HCCs for third degree burns with the recommendation to separate acute costs from ongoing costs, other commenters opposed the proposed changes. Commenters noted that these are random acute events and that the chronic costs associated with third degree burns are separately identifiable. One commenter also suggested that the inclusion of burn HCCs as payment HCCs would lead to upcoding due to higher acute costs than ongoing costs.

Response: In the HHS–HCC Updates Paper, we noted that HCC 218 (Severe Skin Burn or Condition) and HCC 219 (Moderate Skin Burn or Condition) were identified as being underpredicted in the current models and contain chronic conditions or burns that involve long-term follow-up care. To further explore the relationship between these HCCs (HCC 218 and HCC 219) and long term costs, we analyzed Marketscan® data, and found that the presence of these HCCs in 2009 was associated with persistently higher costs in the subsequent year, 2010. The addition of these HCCs to the payment models, as proposed, is also consistent with our goals to improve model prediction and keep with the risk adjustment goal of identifying chronic or systematic conditions that represent insurance risk selection or risk segmentation. However, the ability to separate costs associated with the acute event and chronic condition can be complex for certain HCCs, and in the case of the burn-related HCCs, the enrollees may have chronic conditions or burns that require ongoing follow-up care that is difficult to separate out. For this reason, we are not separating out the costs between the initial acute event and chronic condition.

We are also finalizing the labeling of these HCCs as proposed to reflect the reconfiguration of these HCCs consistent with the ICD–10 updates. Specifically, we reconfigured HCC 218 (Extensive Third Degree Burns, formerly Severe Skin Burn or Condition) to only contain extensive third burns and HCC 219 (Major Skin Burn or Condition, formerly Moderate Skin Burns or Conditions) to contain less extensive third degree burns by site, extensive non-third degree burns, and other serious and chronic skin condition. For these reasons, we are finalizing these changes as proposed.

Comment: While one commenter appreciated the proposed updates to the substance use HCCs, other commenters opposed the proposed substance use HCC changes. Some of the commenters observed that some providers are reluctant to use complete and accurate coding for substance use disorders due to the sensitive nature of the diagnoses. Other commenters also stated that separating out the current V05 HCC 81 (Drug Psychosis) and HCC 82 (Drug Dependence) into five separate HCCs with distinct, ungrouped, coefficients in the adult models rewards poor quality of care and may increase incentives for providers to report additional diagnoses. For example, one commenter noted that an issuer with a high number of enrollees with proposed HCC 85 (Mild and Uncomplicated Drug Use Disorder) to an issuer with some enrollees with proposed HCC 82 (Moderate Drug Use Disorder or with Non-Psychotic Complications), could be a case where differences with complications could be the result of members' selection behavior, poor quality care or issuers' ability to influence provider coding or market segmentation. Some commenters supported retaining the two current substance use HCCs (with constrained coefficients), noting concerns that collecting adequate provider documentation at a new more detailed level of specificity will be a challenge given that the current two HCCs have high error rates in RADV. These commenters also expressed the belief that the proposed changes would not add value in measuring an issuer's risk level.

Response: We understand issuers' concerns regarding challenges in coding substance use disorders. We do, however, believe it is important to distinguish among different types of drug and alcohol use. Our analysis of the data (for example, the 2016 and 2017 enrollee-level EDGE data) indicates that there is a large difference in the costs associated with treatment for an individual with a general, nonpsychotic drug use disorder compared with an individual with alcohol use disorder, either with or without psychosis. Therefore, we are finalizing the proposed revisions to update HCC 81 from Drug Psychosis to Drug Use with Psychotic Complications, to update HCC 82 from Drug Dependence to Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications, as well as to add the new HCC 83 (Alcohol Use with Psychotic Complications) and new HCC 84 (Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications), with the exception of modifications described below with respect to grouping these HCCs in the adult models. Nevertheless, we also agree with commenters that there appears to be limited additional benefit at the present time to distinguish mild drug use disorder, proposed HCC 85 (Drug Use Disorder, Mild, Uncomplicated, Except Cannabis), from other substance use disorders in the revised adult, child, and infant models. We also share commenters' concerns about the possibility of creating incentives for increased reporting of additional diagnoses. We also agree with commenters who suggested that further review of HCC 85 is necessary, including within the context of RADV, prior to adding to this HCC. Therefore, after consideration of comments received, we are not finalizing the addition of HCC 85 in any of the models (adult, child, infant).

In further acknowledgement of commenters' concerns, we are not finalizing our proposal to omit grouping of substance use codes in the adult models and are instead finalizing the grouping parallel to what was proposed for these HCCs in the child models. In both the child and adult models that are being finalized in this rule, HCC 81 (Drug Use with Psychotic Complications) and HCC 82 (Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications) will be grouped, and HCC 83 (Alcohol Use with Psychotic Complications) and HCC 84 (Alcohol Use Disorder, Moderate/Severe, or Alcohol Use with Specified Non-Psychotic Complications) will be grouped.[40] We believe that the grouping of drug use and alcohol use HCCs, as finalized in this rule, will help to mitigate any potential incentives that could influence provider coding of these HCCs.

Comment: Some commenters did not agree with mapping P040 (Newborn affected by maternal anesthesia analgesia in pregnancy, labor, and delivery) to the revised HCC 82 (Drug Use Disorder, Moderate/Severe, or Drug Use with Non-Psychotic Complications), stating that, unlike the effects on infants of opioid addiction or fetal alcohol syndrome, complications from anesthesia exposure are the product of poor quality of care, and that adding it to the models eliminates incentives to reduce complications from anesthesia such as reducing unnecessary use. One commenter stated that the inclusion of P040 will dilute the predictive value of the coefficient when applied to newborns that were exposed to opioids or alcohol, potentially creating more selection issues.

[40] Proposed group number G09B included proposed HCCs 83, 84 and 85.

Response: Consistent with the discussion in the HHS–HCC Updates Paper, we proposed to continue to include all substance use disorder payment HCCs in the infant models. Although most infants who are affected by the mother's substance use via placenta or breast milk are coded with a newborn-specific ICD–10 code from the P04 set, which in the finalized reclassified HHS–HCC updates maps to HCC 82, some infants are coded with substance use codes from the ICD–10 F10–F19 code sets, which map to payment HCCs 81–84 or to non-payment HCCs in the finalized V07 reclassified HHS–HCC updates. To be complete and map the entire set of P04 codes consistently, the diagnosis code P040 Newborn affected by maternal anesthesia and analgesia in pregnancy, labor and delivery was proposed to be added to the infant model within a payment HCC. The substance use disorder HCCs include substance use disorder codes and codes related to effects of noxious substances on infants. Therefore, we are finalizing the substance use disorder payment HCCs with the P040 code mapped to HCC 82 in the infant models to account for these costs and associated risks.

Comment: One commenter specifically opposed the addition of drug poisoning diagnoses to HCC 82 because, they stated, it reflects an acute condition with different patterns of claims, costs, and clinical behavior than other diagnoses in HCC 82. According to the commenter, the majority of drug poisoning diagnoses result from addiction to non-prescribed opioids, and the absence of a prior claim in such circumstances makes the diagnosis difficult to predict. The commenter further observed that an episode of drug poisoning offers a unique opportunity for the enrollee to receive coordinated, high quality care that can help prevent another drug poisoning diagnosis. Lastly, the commenter stated that, because a drug poisoning diagnosis is sometimes the byproduct of a drug addiction associated with treatment for a serious condition, such as cancer, the cost profile for such enrollees will differ from other drug poisoning diagnoses.

Response: We recognize that enrollees with substance use disorders require varied and complicated care. As we showed in the HHS–HCC Updates Paper, however, our estimate of the cost parameter for the revised HCC 82, which includes drug poisoning diagnoses, was not markedly different from the estimate for the current HCC 82 from the same analysis. We do not agree, therefore, that drug poisoning diagnoses are necessarily substantively different in terms of costs from other drug use disorders in that HCC. Additionally, the risk adjustment models adjust for the costs of additional complicating diagnoses, such as cancer, by including HHS–HCCs related to those conditions.

We agree with the commenter that a drug poisoning diagnosis is an opportunity for improving care management and coordination for an enrollee. The primary objective of the risk adjustment program is to improve model prediction and mitigate risk of adverse selection when possible and, insofar as the addition of drug poisoning diagnoses to HCC 82 represents avoidable risk, we believe it is important to include these diagnoses in the models.

Comment: Some commenters appreciated our proposed modifications to HCCs related to pregnancy, in which we added several HCCs to recognize ongoing care for pregnancy, distinguishing between severity of complications. One commenter requested more data from HHS to substantiate the addition of several new HCCs for ongoing pregnancy (HCCs 210–212) [41] with and without delivery, stating that it is unclear how this will impact risk selection and future year premiums. Another commenter stated that, along with changes to acute conditions, the proposed modifications to HCCs related to pregnancy may incentivize upcoding. However, this commenter also stated that pregnancy as a condition is often planned, and as such, may allow costs associated with pregnancy to be predicted early enough that a person has an opportunity to enroll or change coverage, providing a rationale for including HCCs associated with pregnancy as payment HCCs.

Response: We appreciate the comments agreeing with the proposed modifications to HCCs related to pregnancy and are finalizing these HCCs as proposed. We reconfigured the pregnancy HCCs in the adult and child models to reflect the changes in ICD–10 classification systems over the prior ICD–9 classification related to episode of care, multiple gestation, and ectopic or molar pregnancy complications, as described in the HHS–HCC Updates Paper. Our analysis found that the current set of pregnancy HCCs in the existing models do not account well for a variety of pregnancy scenarios. For example, if an enrollee was pregnant during a plan year, with a complicated pregnancy as her only HCC, under the current models, she only receives the age-sex coefficient, which results in an underprediction of risk. If an enrollee had a low severity miscarriage HCC or completed pregnancy HCC, she receives one average HCC coefficient (in addition to an age-sex coefficient) in the current models, which results in a slight overprediction of risk. The primary purpose of the changes to the pregnancy HCCs, including the ungrouping of the ectopic/miscarriage-related HCCs and the delivery and post-partum related HCCs and the addition of new HCCs 210–212, is to more precisely account for the costs associated with the pregnancy and with delivery/postpartum, as complications during pregnancy could be unrelated to complications in delivery/postpartum. We are therefore finalizing these changes as proposed for the adult models. For the child models, as explained above, we are finalizing these changes as proposed, except for the removal of HCC 212 from the ongoing pregnancy group because it has sufficient sample size for this population.

Comment: Some commenters generally supported the proposed HCC updates, however other commenters did not support the HCC changes to the risk adjustment models. Some of these commenters requested that HHS delay the implementation of the HCC changes until issuers receive additional data to estimate the impact of specific HCC updates, such as on statewide average risk scores and payment transfers, and if finalized, one commenter suggested that we phase-in the updates. Comments also suggested that HHS develop an ongoing monitoring policy with respect to claim submissions to identify any possible gaming of the revised classifications. Others comments were concerned that the HCC changes may only serve to add more volatility to RADV. One commenter generally opposed all changes to HCCs and requested that we revisit whether the proposed changes violate the principles of risk adjustment.

Some commenters supported specific HCC changes or supported specific HCC changes contingent on additional data analysis. For example, one commenter asked that HHS provide further information on the change to HCC 47, which filters out all but acute pancreatitis. Additionally, some commenters wanted analysis on the blood disorder HCC changes and metabolic and endocrine disorder changes contingent on additional analysis of expensive new treatments

[41] The new pregnancy related HCCs include HCC 210 for (Ongoing) Pregnancy without Delivery with Major Complications, HCC 211 for (Ongoing) Pregnancy without Delivery with Complications and HCC 212 for (Ongoing) Pregnancy without Delivery with No or Minor Complications.

(such as gene therapy). Some commenters supported the addition of the Diabetes Type 1 HCC to the adult models while one commenter did not. Likewise, some commenters supported the asthma HCC change, but one commenter was concerned that splitting the asthma HCC might create opportunities for gaming.

Response: In considering these concerns, we weighed the competing goals of improving predictive power and limiting discretionary coding. We believe it is important to implement these changes as soon as possible to better reflect the HHS–HCCs with the ICD–10 coding changes, which were implemented in 2015. Additionally, some of these changes are already in effect for the Medicare risk adjustment program, and the HHS classification has lagged in the classification changes associated with the ICD–10 coding changes. As such, we are finalizing these changes as proposed, with the exception of modifications described above.

As previously discussed, we provided stakeholders with advance notice of potential HCC changes in the HHS–HCC Updates Paper, released on June 17, 2019. This paper previewed potential HCC changes with detailed estimated costs between the V05 and the V06a classification, as well as the impact of the changes on the adult, child and infant risk adjustment models. With the proposed rule, we also provided stakeholders with a crosswalk of ICD–10 codes to the proposed HCCs under the ''Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year,'' which is available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.html.*[42] Furthermore, in the HHS–HCC Updates Paper, we detailed the impact of the V06a HCC changes in counts of enrollees with and without HCCs. For all of these reasons, we do not believe delaying the implementation of these HCCs for additional data is needed.

We do not extract state identifiers in the enrollee-level EDGE data, and therefore, we are unable to directly assess state level impacts. However, we will consider for future rulemaking proposing to extract state identifiers in the enrollee-level EDGE data to conduct analyses commenters requested and evaluate changes in risk adjustment models.

With respect to monitoring changes in claims submissions associated with revised HHS–HCC classifications to identify possible gaming, we agree on the importance of maintaining the integrity of the risk adjustment program. We note that there are several existing processes and programs that are intended to ensure program integrity. In addition to RADV, whose principal objective is to identify instances in which a diagnosis submitted to an issuer's EDGE server for risk adjustment is not supported by clinical documentation, we conduct ongoing quality and quantity review of EDGE submissions, and we carefully analyze annual enrollee-level EDGE data for shifts in diagnoses and spending. In addition, § 153.620(b)(9)(iii) and (iv) provides HHS authority to impose civil money penalties for misconduct, as well as the intentional or reckless misrepresentation or falsification of information furnished to HHS, which could be leveraged if there is evidence of gaming of the revised classifications. Should we determine that any changes to the HHS–HCC classification or other program requirements are necessary to address gaming concerns, we would pursue those modifications through notice-and-comment rulemaking.

In response to comments, we clarify that the V07 changes finalized in this rule will not be applicable in RADV until the 2021 benefit year (consistent with the adoption of the changes for the 2021 benefit year of risk adjustment). As noted above, we believe it is important to implement these changes as soon as possible to align the HHS-operated risk adjustment models with the ICD–10 coding changes, which were implemented in 2015, and do not believe the changes will add more volatility to RADV.

ii. Other Updates to Risk Adjustment Model Recalibration

As discussed in the proposed rule, for the 2020 benefit year adult models, we made a pricing adjustment for one RXC coefficient for Hepatitis C drugs.[43] In the 2020 Payment Notice, we stated that we intend to reassess this pricing adjustment in future benefit years' model recalibrations with additional years of enrollee-level EDGE data.[44] For the 2021 benefit year model recalibration, we reassessed the Hepatitis C RXC to consider whether the adjustment was still needed, or needed to be modified. We found that the current data for the Hepatitis C RXC still does not take into account the significant pricing changes due to the introduction of new Hepatitis C drugs and, therefore, it does not precisely reflect the average cost of Hepatitis C treatments applicable to the benefit year in question. We also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score and, therefore, make the risk adjustment transfer results more favorable for the issuer. For these reasons, we noted that we continue to believe that a pricing adjustment is needed for this RXC coefficient and proposed to adjust the Hepatitis C RXC for the 2021 benefit year model recalibration. For the proposed RXC coefficients listed in Table 2 of the proposed rule, we constrained the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs. Similar to the adjustment for the 2020 benefit year model recalibration, this has the material effect of reducing the Hepatitis C RXC, and the RXC–HCC interaction coefficients. For the final 2021 benefit year Hepatitis C factors in the adult models, we proposed to make an adjustment to the plan liability associated with Hepatitis C drugs to reflect future market pricing of these drugs before solving for the adult model coefficients. We sought comment on this proposal.

In light of the recent recommendation by the U.S. Preventive Services Task Force (USPSTF) to expand the use of pre-exposure prophylaxis (PrEP) as a preventive service that must be covered without cost sharing by applicable health plans for persons who are at high risk of HIV acquisition,[45] we also proposed to incorporate PrEP as a preventive service in the simulation of plan liability for HHS's adult and child risk adjustment models in the final 2021 benefit year model recalibration.[46] Although preventive services are incorporated in the simulation of plan

[42] The Draft ICD–10 Crosswalk for Potential Updates to the HHS–HCC Risk Adjustment Model for the 2021 Benefit Year includes Table 4, which crosswalks ICD–10 codes to the Condition Categories (CCs) in the risk adjustment models, and Table 5, which provides the hierarchy rules to apply to the CCs to create HCCs. These Tables are similar to the Tables 3 and 5 that HHS includes as part of the HHS-Developed Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software.

[43] 84 FR 17454 at 17463 through 17466.

[44] Ibid.

[45] Final Recommendation Statement on ''Prevention of Human Immunodeficiency Virus (HIV) Infection: Preexposure Prophylaxis. U.S. Preventive Services Task Force. June 2019. *https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.*

[46] The June 11, 2019 ''Preexposure Prophylaxis for the Prevention of HIV Infection: US Preventive Services Task Force Recommendations Statement'' published in JAMA states that adolescents at high risk of HIV acquisition could benefit from PrEP and it is approved for adolescents who weigh at least 35kg (~77 pounds). *https://jamanetwork.com/journals/jama/fullarticle/2735509.*

liability, they do not directly affect specific HCCs. We incorporate preventive services into the models to ensure that 100 percent of the cost of those services is reflected in the simulation of plan liability; preventive services are applied under relevant recommended conditions or groups. We proposed including PrEP as a preventive service along with our general updates to preventive services in the simulation of plan liability for the HHS risk adjustment models in the final 2021 benefit year adult and child models. We sought comment on this proposal.

As part of the proposed 2021 model recalibration, we also considered whether to add an additional age-sex category for enrollees age 65 and over as part of the recalibration of the adult models. MarketScan® data does not include enrollees who are age 65 and over, but the enrollee-level EDGE data does. Currently, the risk adjustment program incorporates the risk and costs of enrollees age 65 and over using the 60–64 age-sex coefficients. We originally excluded enrollees age 65 and over from recalibration to prevent having different methodologies for the MarketScan® and the enrollee-level EDGE datasets that were used to solve for the blended coefficients for the risk adjustment models.

Since we proposed to no longer use the MarketScan® data to recalibrate the risk adjustment models beginning with the 2021 benefit year, we explained in the proposed rule that we considered whether new age-sex coefficients should be created for enrollees age 65 and over beginning with the 2021 benefit year adult models. In reviewing the enrollee-level EDGE data, we found that over 70 percent of the enrollees age 65 and over are within the 65–66 age range, and we believe these enrollees are likely transferring into Medicare coverage once eligible. Our analysis also found that the enrollees ages 65–66 have lower average annual expenditures than those enrollees between ages 60 and 64. In contrast, we found that enrollees age 67 and over have higher average annual expenditures than those between ages 60 and 64. Due to these two different trends in the age 65 and over population, we did not propose to add new age-sex coefficients to the adult models at this time and would continue to exclude enrollees age 65 and over in the adult models' calibration for the 2021 benefit year. We also noted that we would continue to monitor expenditures for enrollees age 65 and over to determine whether the addition of new age-sex coefficients to the adult models in a future year is appropriate.

After reviewing the comments we received, we are finalizing our proposal to apply an adjustment to the plan liability for the final 2021 benefit year Hepatitis C factors in the adult models to ensure that enrollees can continue to receive incremental credit for having both the RXC and HCC for Hepatitis C, and allow for differential plan liability across metal levels. We will release the final RXC coefficients that reflect constraining the Hepatitis C coefficient to the average expected costs of Hepatitis C drugs in guidance, along with the other final 2021 benefit year coefficients, by June 2020 to allow for incorporation in final rates for the 2021 benefit year, consistent with § 153.320(b)(1)(i).

We are also finalizing our proposal to incorporate PrEP as a preventive service in the simulation of plan liability for HHS's adult and child risk adjustment models in the final 2021 benefit year model recalibration. We did not propose to add new age-sex coefficients to the adult models and are not making any changes to age-sex coefficients for enrollees age 65 and over at this time.

The following is a summary of the public comments we received on the proposed pricing adjustment for the Hepatitis C RXC for the adult models, the proposal to incorporate PrEP as a preventive service in the simulation of plan liability for the adult and child models, and the discussion of the age-sex coefficients in the adult models. We also respond to other comments suggesting additional modifications to the HHS risk adjustment models.

Comment: Most commenters supported the pricing adjustment for the Hepatitis C RXC. These commenters reasoned that this pricing adjustment would more accurately reflect the average cost of treatment in the risk adjustment models, ensure enrollees can continue to receive incremental credit for having both the Hepatitis C RXC and HCC, and account for the introduction of new Hepatitis C drugs. One commenter did not support this proposal, and suggested HHS avoid artificially constraining plan payment until prescription denial rates decrease and to account for potential adverse selection associated with treatment for Hepatitis C Virus (HCV). This commenter also expressed concern about HHS manually adjusting the risk adjustment coefficients downwards, potentially penalizing plans that provide better coverage for innovative drugs. Another commenter recommended HHS clarify the data source and approach it is using to constrain the Hepatitis C RXC coefficient, and cautioned against reducing the coefficient more than the expected decrease in cost.

Response: In response to comments, we reassessed the pricing adjustment for the Hepatitis C RXC for the 2021 benefit year model recalibration and found that the most recent year of data (2018 enrollee-level EDGE data) for the Hepatitis C RXC still does not take into account the significant pricing changes expected due to the introduction of newer and cheaper Hepatitis C drugs. Therefore, the data that will be used to recalibrate the models does not precisely reflect the average cost of Hepatitis C treatments applicable to the 2021 benefit year. We also continue to be cognizant that issuers might seek to influence provider prescribing patterns if a drug claim can trigger a large increase in an enrollee's risk score, and therefore, make the risk adjustment transfer results more favorable for the issuer. Due to the high cost of these drugs reflected in the 2016, 2017 and 2018 enrollee-level EDGE datasets, without a pricing adjustment to plan liability, issuers would be overcompensated for the Hepatitis C RXC in the 2021 benefit year, and could be incentivized to encourage overprescribing practices and game risk adjustment such that the issuer's risk adjustment payment is increased or risk adjustment charge is decreased. This pricing adjustment helps avoid perverse incentives, and leads to Hepatitis C RXC coefficients that better reflect anticipated actual 2021 benefit year plan liability associated with Hepatitis C drugs. It is also consistent with the approach adopted for the 2020 benefit year recalibration to address these concerns.

As such, we are finalizing our proposal to make a pricing adjustment to more closely reflect the expected average additional plan liability of the Hepatitis C RXC for the 2021 benefit year adult risk adjustment models. In making this determination, we consulted our clinical and actuarial experts, and analyzed the most recent enrollee-level EDGE data available (2018 benefit year) to further assess whether lower cost Hepatitis C drugs can be substituted to ensure that plans that cover various treatments would continue to be compensated for their incremental plan liability. We intend to continue to reassess this pricing adjustment in future benefit years' model recalibrations using additional years of available enrollee-level EDGE data.

Comment: Some commenters asked HHS to monitor the market of new expensive therapies and treatments, such as gene therapy drugs, and

incorporate them into the risk adjustment model factors due to the anticipated high costs of these drugs and associated services. These commenters expressed concern about adequate issuer compensation for these drugs and the potential for adverse selection. The comments noted that the costs of very new, high cost treatments will not be reflected in prior year EDGE claims data.

Response: We did not propose to update the risk adjustment model factors to reflect the costs of gene therapy drugs in the proposed rule and are not finalizing such updates in this rule. We intend to assess this issue as additional data becomes available and consider whether model updates should be made to address their anticipated costs in the future. We note that if an enrollee in an issuer's risk adjustment covered plans has gene therapy or other expensive treatments, that enrollee would be eligible for the high-cost risk pool payments if claims for that enrollee are over $1 million. Therefore, this issuer would receive compensation for these high-cost treatments under the HHS-operated risk adjustment program in the 2021 benefit year.

Comment: Most commenters supported our proposal to incorporate PrEP as a preventive service in the simulation of plan liability for HHS's adult and child risk adjustment models in the final 2021 benefit year model recalibration. One commenter sought clarity as to whether issuers can offer both the generic and brand drug at $0 cost sharing. Another commenter requested more information about the incorporation of PrEP into the risk adjustment models, such as how HHS will identify PrEP therapies, given the rapid development of new therapies. Several commenters recommended incorporating PrEP as a prescription drug factor (RXC) in the adult models to adequately compensate plans that disproportionately enroll individuals using PrEP and prevent risk selection, and one commenter requested that HHS disclose any operational issues such as the ability to distinguish between antiretroviral therapy that is provided as a result of HIV acquisition and antiretroviral therapy that is provided as PrEP using logic that would make it difficult to implement an RXC for PrEP. Two commenters also encouraged including recommended ancillary services as part of the PrEP intervention in the risk adjustment models.

Response: We proposed to incorporate PrEP as a preventive service in the simulation of plan liability in the risk adjustment adult and child models with zero cost sharing after careful analysis of preventive drugs that are recommended at grade A or B by the USPSTF. We were able to distinguish enrollees that met the ''at risk'' recommendation in the USPSTF recommendation and were receiving antiretroviral therapy for PrEP, rather than as treatment for HIV/AIDS, in our analysis of the enrollee-level EDGE datasets. We chose not to propose incorporating PrEP as an RXC because, as a general principle, RXCs are incorporated into the HHS risk adjustment adult models to impute a missing diagnosis or indicate severity of a diagnosis.[47] Currently, PrEP is not incorporated into RXC 1 (Anti-HIV) because PrEP does not indicate an HIV/AIDS diagnosis.[48] Unlike the other prescription drugs that we have included in RXCs, PrEP does not adequately represent risk due to an active condition. However, we proposed and are finalizing the incorporation of 100 percent of the PrEP costs for enrollees without HIV diagnosis or treatment in the simulation of plan liability for the adult and child models.

The expected upcoming release of a generic version of PrEP will enable issuers to offer both the generic and brand drug at $0 cost sharing. We recognize that using past enrollee-level EDGE data may not properly predict future costs given the rapid development of new drugs. However, we are only able to analyze the enrollee-level EDGE claims data we have available when developing our proposals to incorporate new preventive services into the risk adjustment models, and do not have claims data on the expected new generic PrEP or any other drugs in development for use for the 2021 benefit year models. Therefore, while our modeling may not identify new PrEP therapies at this time, we were able analyze the data to identify enrollees taking PrEP without HCC 1 (HIV/AIDS) to attribute those costs at 100 percent of simulation of plan liability.

We did not propose and are not finalizing the addition of PrEP as an RXC to the adult risk adjustment models. It is difficult to model the impact of adding PrEP as an RXC at this time because we expect an increase in the number of people taking PrEP after the recent recommendation by the USPSTF Task Force to expand the use of PrEP as a preventive service, and we anticipate price changes with the expected upcoming release of a generic version of PrEP. Further, as noted above, as a general principle, RXCs are incorporated into the adult risk adjustment models to impute a missing diagnosis or indicate severity of a diagnosis. Since the use of PrEP is currently recommended as a preventive service for persons who are not infected with HIV and are at high risk of HIV infection, the use of PrEP does not indicate a diagnosis, and it would be inconsistent with this principle to add it as an RXC at this time.

Additionally, we did not propose changes to the risk adjustment methodology related to ancillary services associated with PrEP as requested by two commenters. Therefore, we are not finalizing any changes to the treatment of ancillary services under the risk adjustment models for the 2021 benefit year, but will consider the comments as we consider further refinements to the risk adjustment models for future years.

We are finalizing our proposal to incorporate PrEP as a preventive service in the simulation of plan liability for HHS's adult and child risk adjustment models in the final 2021 benefit year model recalibration and will continue to explore potentially including PrEP as an RXC in future benefit years.

Comment: One commenter requested HHS propose adding new age-sex coefficients to the adult risk adjustment models for enrollees age 65 and over in a future rulemaking, as HHS moves to using exclusively enrollee-level EDGE data to recalibrate the models. Another commenter recommended further analysis of age-sex coefficients for enrollees age 65 and over and noted factors may need to differ by market or by Medicare status.

Response: We appreciate these comments and intend to continue to monitor expenditures for enrollees age 65 and over to determine whether the addition of new age-sex coefficients for this cohort of the population to the adult models in a future year is appropriate. However, we did not propose and are not making any changes to age-sex coefficients for enrollees age 65 and over at this time. We will continue to exclude enrollees age 65 and over in the adult models' calibration for the 2021 benefit year because we believe most of these enrollees are likely transferring into Medicare coverage once eligible.

[47] See 81 FR 94058 at 94075. Also see March 31, 2016, HHS-Operated Risk Adjustment Methodology Meeting Questions & Answers. June 8, 2016. Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/RA-OnsiteQA-060816.pdf.*

[48] See *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf; https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Draft-RxC-Crosswalk-Memo-9-18-17.pdf.*

(3) Improving Risk Adjustment Model Predictions

In the proposed rule, we solicited comment on different options to modify the risk adjustment models to improve model prediction for enrollees without HCCs or enrollees with low actual expenditures for future benefit years as follow-up from our consideration of these issues in the 2018 Payment Notice. More precisely, in the proposed rule, we discussed how, based on the use of the MarketScan® data, the HHS–HCC models under-predict for enrollees without HCCs, slightly over-predict for enrollees with low HCC counts and under-predict for enrollees with the highest HCC counts. In the proposed rule, we explained that we continued to evaluate potential future options to address these issues and the tradeoffs that would need to be made in model predictive power among subgroups of enrollees under these options and that we continued to believe that further evaluation is appropriate before pursuing these options. However, we also recognized that additional stakeholder comment was a critical aspect to this analysis. Therefore, we outlined and solicited comment on various options that we were continuing to consider to improve the models' predictive ability for certain subgroups of enrollees in light of experience and currently available information.

The first option that was detailed in the 2018 Payment Notice [49] and in the proposed rule involved a constrained regression approach, under which we would estimate the adult risk adjustment models using only the age-sex variables, and then, we would re-estimate the models using the full set of HCCs, while constraining the value of the age-sex coefficients to be the same as those from the first estimation. In the 2018 Payment Notice, we stated that we believed that this two-step estimation approach would result in age-sex coefficients of greater magnitude, potentially helping us predict the risk of the healthiest subpopulations more accurately. However, as noted in the proposed rule, we also found upon further analysis that the mean expenditures of individual HCCs under this approach were under-predicted compared to the current adult models and the mean expenditures of extremely expensive enrollees were more under-predicted under this approach than in the current adult models.

The second option discussed in the proposed rule involved directly adjusting plan liability risk scores outside of the models for the impacted sub-populations. This approach would involve directly increasing underestimated plan liability risk scores or reducing overestimated plan liability risk scores in an attempt to better match the relative risks of these sub-populations.[50] Specifically, we evaluated using a post-estimation adjustment to the current models' individual-level risk scores to address the observed patterns of over- and under-prediction for certain sub-populations. In the proposed rule, we stated that while we believed modifications of this type could improve the model's performance along this specific dimension (deciles of predicted expenditures), there was a risk that such modifications could unintentionally worsen model performance along other dimensions on which the model currently performs well. As described in the proposed rule, we recently reassessed this adjustment option given the availability of the more recent enrollee-level EDGE data and the implementation of several updates to the HHS risk adjustment methodology beginning with the 2018 benefit year.[51] We did not find improvements in the predictive ratios when compared to the predictive ratios of the current approach. Our analysis of this adjustment option showed that the estimates for the lowest-cost decile and top two highest-cost deciles of enrollees were more underpredicted under this approach as compared to the current model. Additionally, this approach resulted in worse prediction along other dimensions, such as for subgroups of enrollees with no HCCs and those with 1 or more payment HCCs.

Given the shortcomings with both of these approaches, we ultimately did not propose or adopt either of them. However, in the proposed rule, we explained that we have continued to consider other potential approaches to address the under-prediction of risk for low-cost enrollees and over-prediction for high-cost enrollees. In particular, we have also been examining non-linear and count model specifications to improve the current adult models' predictive power.

Our initial analysis of the non-linear and count model specifications had shown that these alternatives can improve prediction in the adult models. For the non-linear model, we were considering an option that would add a coefficient-weighted sum of payment HCCs raised to a power to the linear specification. Under this approach, the non-linear term would be added as the exponentiated *p* term as shown in the following formula:

$$\text{Plan liability} = \text{Current Model} + (\Sigma\beta_i HCC_i)^p$$

Where:

$\Sigma\beta_i HCC_i$ = the sum of payment HCCs weighted by their parameter estimates;

p = an exponential factor estimated by the model.

This type of non-linear model would measure the total disease burden by a weighted count of HCCs rather than a simple count of the payment HCCs, while only requiring one additional parameter. This approach would also allow the demographic terms for enrollees with no payment HCCs to be better estimated, while using a nonlinearity for the disease burden that could keep the model reasonably simple. As such, we believed that adding a non-linear term to the models could be a reasonable approach to potentially improve the prediction of the models.

For the count model, we considered adding eight indicator variables corresponding to 1 to 8-or-more payment HCCs. Under this option, the incremental predictions would vary with a person's count of HCCs (from 1 to 8-or-more payment HCCs) as the incremental predictions for HCCs in a HCC count model have two components, the HCC coefficient and the change in the number of HCCs (from 1 to 8-or-more payment HCCs). This option would also generally be more consistent with other programs (Medicare Advantage) than the non-linear model, and has yielded similar results in model performance and improvements in the prediction in the adult models as the non-linear model. However, similar to the non-linear model, the count model may not improve the prediction for all subpopulations in the models.

Additionally, in the proposed rule, we discussed potential adjustments to the enrollment duration factors in the adult models, as well as an assessment of whether such factors should be incorporated into the child and infant models. Using the 2016 and 2017 enrollee-level EDGE data, we investigated heterogeneity in the relationship between partial-year enrollment and predicted expenditures. We explored heterogeneity according to the presence of certain diagnoses,

[49] Ibid.

[50] Ibid.

[51] For example, we incorporated the high costs risk pool parameters into the HHS risk adjustment methodology, added RXCs into the adult risk adjustment models, and applied an administrative cost reduction to the statewide average premiums in the state payment transfer formula starting with the 2018 benefit year. See the 2018 Payment Notice, 81 FR 94058 (December 22, 2016).

market (individual or small group),[52] and enrollment circumstances, such as enrollment beginning later in the year or ending before the end of the year. Our preliminary analysis of 2017 enrollee-level EDGE data found that current enrollment duration factors are driven mainly by enrollees with HCCs, that is, partial year enrollees with HCCs have higher per member per month (PMPM) expenditures on average as compared to full year enrollees with HCCs, whereas partial year enrollees without HCCs have similar PMPM expenditures compared to their full year counterparts. In comparison to the effect of the presence of HCCs on enrollment duration factors, enrollment timing (for example, enrollment at the beginning of the year compared to enrollment after open enrollment period, or drop in enrollment before the end of the year) did not appear to affect PMPM expenditures on average. Our analysis also found that separate enrollment duration factors by market in the adult models may be warranted, given the differences in risk profiles of partial year enrollees between the individual and small group markets.[53] However, due to limitations with the extracted enrollee-level EDGE data for the 2016 and 2017 benefit years that do not permit us to connect non-calendar year enrollees in the small group market across plan years within the same calendar year, we are unable to develop and propose separate enrollment duration factors by market at this time. Based on these analyses, because partial-year enrollees with HCCs seem to have the most distinctive additional expenditures, we explained in the proposed rule that we believed that eliminating the enrollment duration factors and replacing them with monthly enrollment duration factors (up to 6-months), for those with HCCs, would most improve model prediction.

Additionally, in the proposed rule, we analyzed incorporating enrollment duration factors in the child and infant models in the same manner as the adult models. We found that partial year enrollees in the child models did not have the same risk differences as partial year enrollees in the adult models, and partial year enrollees in the child models tended to have similar risk to full year enrollees in the child models. In the infant models, we found that partial year infants have higher expenditures on average compared to their full year counterparts. However, we found that the incorporation of enrollment duration factors created interaction issues with the current severity and maturity factors in the infant models and did not have a meaningful impact on the general predictive accuracy of the infant models. As such, we did not propose to add partial year factors to the child or infant models.

We solicited comments on all of the alternative modeling approaches to help inform our evaluation of the important trade-offs in making improvements to risk prediction for these sub-populations and providing consistency year-to-year for issuers, but did not propose to incorporate any of them as part of the 2021 benefit year risk adjustment model recalibration. We also generally solicited comments but did not propose any changes to the enrollment duration factors (including the potential addition of such factors to the child and infant models) for the 2021 benefit year. Instead, as outlined in the proposed rule, we intend to use stakeholder comments on these issues to aid in consideration of future model updates as we also continue to analyze these options using additional years of enrollee-level EDGE data, once available. The following is a summary of the public comments we received in response to the solicitation of comments on potential approaches to improve risk adjustment model prediction.

Comment: Commenters generally appreciated or supported HHS's solicitation of comments on revisions to the risk adjustment models to improve model prediction. Some commenters supported evaluating count and non-linear models to address the under- and over-prediction of costs in the current models or generally supported making changes to risk adjustment to better account for enrollees without HCCs and enrollees with the highest number of HCCs in the future. Other commenters expressed concerns about the count and non-linear methods introducing more complexity to the risk adjustment models and creating uncertainty in pricing.

Most commenters wanted additional analyses and various types of data, such as issuer and beneficiary level data, on the impact of any potential model changes on the current risk adjustment program and the improvements in accuracy and predictive power that these models could provide to inform whether these types of changes should be pursued. Some commenters recommended that HHS release a White Paper on its analyses and data prior to rulemaking. Others wanted continued HHS engagement with stakeholders on model changes aimed at improving the risk adjustment models' predictions. Some commenters recommended more interaction and severity terms, such as a diabetes and asthma interaction term, in the risk adjustment models as a simpler and more stable change to improve model prediction, compared to the count or non-linear model specifications. One commenter supported finding viable alternative methodologies but urged caution in quickly adopting the count or non-linear models before analysis can be fully validated and another commenter expressed concern about the count and non-linear models given that individual and small group market enrollees have less HCCs that could result in smaller sample sizes and bring volatility to the models. One commenter did not think that any of the approaches described in the proposed rule would impact coding incentives in the risk adjustment program beyond those incentives that already inherent to the risk adjustment program. One commenter supported including the model changes in the 2022 risk adjustment models if the prediction for low-risk enrollees is better and stated that it would be helpful if the methodology used was similar to Medicare, while another commenter suggested providing several years lead time before implementing the model change options discussed in the proposed rule.

Response: We agree with commenters who suggested that further evaluation is needed of the model performance before proposing these types of changes to the risk adjustment models. Although we did not receive many comments that were specific to the model options considered, we intend to continue to evaluate alternative modeling approaches to improve model prediction as described in the proposed rule, and would propose any modifications through future rulemaking.

As explained in the proposed rule, our initial analyses suggested that the non-linear and count models may yield considerable gains in predictive accuracy across several groups in the adult models when compared to the current linear model. Based on the initial testing of both the count and non-linear models' impact on the adult silver risk adjustment models, we found that the enrollees with the lowest costs have better predictive ratios under both the count and non-linear models than under the current model, with the non-linear model slightly over-predicting the costs of those enrollees. We also noted that we do not believe that the count or non-

[52] In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

[53] In the enrollee-level EDGE data, merged market enrollees are assigned to the individual or small group market indicator based on their plan.

linear models would impact coding incentivizes to code additional HCCs in comparison to the current risk adjustment models.

However, we intend to balance the associated trade-offs of making improvements to the models and providing consistency year-to-year for issuers in the HHS-operated risk adjustment program. As such, we intend to further test the model specifications, incorporating the non-linear and count options described above and consider whether we should analyze other options that could address model prediction, with an additional year of data before considering these model changes for future years and will take into consideration the additional analyses recommended by commenters. Based on those results, and in response to comments, we will also consider what types of analyses or data we could release to help stakeholders assess these options and models for any potential future incorporation into the risk adjustment models.

Comment: Commenters generally supported making updates to the enrollment duration factors to prevent adverse selection with one commenter supporting removal of the enrollment duration factors, suggesting it would simplify risk adjustment. Some commenters wanted additional analyses and data on the potential changes to the enrollment duration factors before modifications were made to the existing factors. Some comments supported separate enrollment duration factors by market since the adverse selection considerations differ in the individual and small group markets or supported applying adjustments only to enrollees with HCCs believing this adjustment could help to differentiate enrollees selecting coverage during a Special Enrollment Period (SEP) from those enrolling during open enrollment and dropping coverage early in the year without claims. However, one commenter wanted HHS to apply enrollment duration values to the 2021 benefit year for the individual market (but not small group market enrollees) to capture adverse selection and the differences in churn between markets. Some commenters expressed support for incorporation of enrollment duration factors in the infant models since partial-year infants have higher expenditures on average compared to their full-year counterparts.

Response: As discussed in the proposed rule, due to certain data limitations in the 2016 and 2017 enrollee-level EDGE data, we did not propose changes to 2021 benefit year existing enrollment duration factors for the adult models. However, we intend to continue to review the use of enrollment duration factors in the HHS risk adjustment models, both with respect to the current factors in the adult models and the potential incorporation of such factors in the child and infant models. With the availability of more benefit years of enrollee-level EDGE data, we will consider potential changes to the enrollment duration factors for future benefit years, including whether to make changes to the enrollment duration factors to distinguish market type differences or to distinguish partial year enrollees with HCCs. As part of that analysis, we will also continue to assess the infant models' characteristics, and whether we should consider incorporating enrollment duration factors into those models. We intend to consider recommendations and considerations shared by commenters in response to the proposed rule as part of this analysis.

(4) List of Factors To Be Employed in the Risk Adjustment Models (§ 153.320)

We noted in the proposed rule that if we finalize the proposed recalibration approach, we would incorporate the 2018 benefit year enrollee-level EDGE data in the final rule or in guidance after publication of the final rule, consistent with our approach in previous benefit years.[54] As noted above, we were unable to incorporate the 2018 benefit year EDGE data in time to publish the final coefficients in this final rule. Therefore, for the 2021 benefit year, we will release the final list of coefficients, incorporating the 2018 benefit year enrollee-level EDGE data, in guidance by June 2020, to allow the factors to be incorporated into final rates for the 2021 benefit year.

(5) Cost-Sharing Reduction Adjustments

We proposed to continue including an adjustment for the receipt of CSRs in the risk adjustment models to account for increased plan liability due to increased utilization of health care services by enrollees receiving CSRs in all 50 states and the District of Columbia. For the 2021 benefit year, to maintain stability and certainty for issuers, we proposed to maintain the CSR factors finalized in the 2019 and 2020 Payment Notices.[55] Consistent with the approach finalized in the 2017 Payment Notice,[56] we also proposed to continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent.

We are finalizing the CSR factors as proposed and will maintain the same CSR factors finalized for the 2019 and 2020 benefit years for the 2021 benefit year as shown in Table 3.

TABLE 3—COST-SHARING REDUCTION ADJUSTMENT

Household income	Plan AV	Induced utilization factor
Silver Plan Variant Recipients		
100–150% of FPL	Plan Variation 94%	1.12
150–200% of FPL	Plan Variation 87%	1.12
200–250% of FPL	Plan Variation 73%	1.00
>250% of FPL	Standard Plan 70%	1.00
Zero Cost Sharing Recipients		
<300% of FPL	Platinum (90%)	1.00
<300% of FPL	Gold (80%)	1.07
<300% of FPL	Silver (70%)	1.12

[54] See 45 CFR 153.320(b)(1)(i).

[55] See 83 FR 16930 at 16953 and 84 FR 17454 at 17478 through 17479.

[56] See 81 FR 12203 at 12228.

TABLE 3—COST-SHARING REDUCTION ADJUSTMENT—Continued

Household income	Plan AV	Induced utilization factor
<300% of FPL	Bronze (60%)	1.15
Limited Cost Sharing Recipients		
>300% of FPL	Platinum (90%)	1.00
>300% of FPL	Gold (80%)	1.07
>300% of FPL	Silver (70%)	1.12
>300% of FPL	Bronze (60%)	1.15

The following is a summary of the public comments we received on the proposed CSR factors in the risk adjustment models.

Comment: Many commenters supported the CSR adjustment factors for the 2021 benefit year and continuing the CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans. Some commenters wanted HHS to analyze the CSR adjustment factors and induced demand factors for future benefit years to consider whether changes are needed.

Response: We are finalizing the CSR adjustment factors as proposed. Consistent with the approach finalized in the 2017 Payment Notice,[57] we will continue to use a CSR adjustment factor of 1.12 for all Massachusetts wrap-around plans in the risk adjustment plan liability risk score calculation for the 2021 benefit year, as all of Massachusetts' cost-sharing plan variations have AVs above 94 percent. We have previously reviewed the induced utilization factors with the availability of the enrollee-level EDGE data, and we continue to believe the current CSR adjustments are adequate. However, we will continue to reexamine whether changes to the induced demand factors and CSR adjustments are warranted in the future.

(6) Model Performance Statistics

To evaluate risk adjustment model performance, we examined each model's R-squared statistic and predictive ratios. The R-squared statistic, which calculates the percentage of individual variation explained by a model, measures the predictive accuracy of the model overall. The predictive ratio for each of the HHS risk adjustment models is the ratio of the weighted mean predicted plan liability for the model sample population to the weighted mean actual plan liability for the model sample population. The predictive ratio represents how well the model does on average at predicting plan liability for that subpopulation.

A subpopulation that is predicted perfectly would have a predictive ratio of 1.0. For each of the HHS risk adjustment models, the R-squared statistic and the predictive ratios are in the range of published estimates for concurrent risk adjustment models.[58] Because we blended the coefficients from separately solved models based on the 2016 and 2017 benefit years' enrollee-level EDGE data that were available at the time of the proposed rule, we published the R-squared statistic for each model separately to verify their statistical validity. We noted in the proposed rule that if the proposed 2021 benefit year model recalibration data was finalized, we intended to publish updated R-squared statistics to reflect results from the blending of the 2016, 2017, and 2018 benefit years' enrollee-level EDGE datasets used to recalibrate the models for the 2021 benefit year. For the 2021 benefit year, we will release the final R-squared statistics along with the final coefficients, incorporating the 2018 benefit year enrollee-level EDGE data, in guidance by June 2020.

b. Overview of the Risk Adjustment Transfer Methodology (§ 153.320)

We previously defined the calculation of plan average actuarial risk and the calculation of payments and charges in the Premium Stabilization Rule. In the 2014 Payment Notice, we combined those concepts into a risk adjustment state payment transfer formula.[59] This formula generally calculates the difference between the revenues required by a plan, based on the health risk of the plan's enrollees, and the revenues that the plan can generate for those enrollees. These differences are then compared across plans in the state market risk pool and converted to a dollar amount via a cost scaling factor. In the absence of additional funding, we established, through notice and comment rulemaking,[60] the HHS-operated risk adjustment program as a budget-neutral program to provide certainty to issuers regarding risk adjustment payments and charges, which allows issuers to set rates based on those expectations. In light of the budget-neutral framework, HHS uses statewide average premium as the cost-scaling factor in the state payment transfer formula under the HHS-operated risk adjustment methodology, rather than a different parameter, such as each plan's own premium, which would not have automatically achieved equality between risk adjustment payments and charges in each benefit year.[61]

Risk adjustment transfers (total payments and charges, including high-cost risk pool payments and charges) are calculated after issuers have completed their risk adjustment EDGE data submissions for the applicable benefit year. Transfers (payments and charges) under the state payment transfer

[57] See 81 FR 12203 at 12228.

[58] Winkleman, Ross and Syed Mehmud. ''A Comparative Analysis of Claims-Based Tools for Health Risk Assessment.'' Society of Actuaries. April 2007.

[59] The state payment transfer formula refers to the part of the HHS risk adjustment methodology that calculates payments and charges at the state market risk pool level prior to the calculation of the high-cost risk pool payment and charge terms that apply beginning with the 2018 benefit year.

[60] For example, see Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Proposed Rule, 76 FR 41938 (July 15, 2011); Standards Related to Reinsurance, Risk Corridors, and Risk Adjustment, Final Rule, 77 FR 17232 (March 23, 2012); and the 2014 Payment Notice, Final Rule, 78 FR 15441 (March 11, 2013). Also see, the 2018 Payment Notice, Final Rule, 81 FR 94058 (December 22, 2016); and the 2019 Payment Notice, Final Rule, 83 FR 16930 (April 17, 2018). Also see the Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program Under the Patient Protection and Affordable Care Act for the 2017 Benefit Year, Final Rule, 83 FR 36456 (July 30, 2018) and the Patient Protection and Affordable Care Act; and Adoption of the Methodology for the HHS-Operated Permanent Risk Adjustment Program for the 2018 Benefit Year Final Rule, 83 FR 63419 (December 10, 2018).

[61] See the 2020 Payment Notice for further details on other reasons why statewide average premium is the cost-scaling factor in the state payment transfer formula. See 84 FR 17454 at 17480 through 17484.

formula are calculated as the difference between the plan premium estimate reflecting risk selection and the plan premium estimate not reflecting risk selection. The state payment transfer calculation that is part of the HHS risk adjustment transfer methodology follows the formula:

$$T_i = \left[\frac{PLRS_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot PLRS_i \cdot IDF_i \cdot GCF_i)} - \frac{AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i}{\sum_i (s_i \cdot AV_i \cdot ARF_i \cdot IDF_i \cdot GCF_i)}\right] \overline{P_s}$$

Where:

P_S = statewide average premium;
$PLRS_i$ = plan *i*'s plan liability risk score;
AV_i = plan *i*'s metal level AV;
ARF_i = allowable rating factor;
IDF_i = plan *i*'s induced demand factor;
GCF_i = plan *i*'s geographic cost factor;
s_i = plan *i*'s share of state enrollment.

The denominators are summed across all risk adjustment covered plans in the risk pool in the market in the state. The state payment transfer formula also includes a 14 percent administrative cost reduction to the statewide average premium.[62]

The difference between the two premium estimates in the state payment transfer formula determines whether a plan pays a risk adjustment charge or receives a risk adjustment payment. The value of the plan average risk score by itself does not determine whether a plan would be assessed a charge or receive a payment—even if the risk score is greater than 1.0, it is possible that the plan would be assessed a charge if the premium compensation that the plan may receive through its rating (as measured through the allowable rating factor) exceeds the plan's predicted liability associated with risk selection. Risk adjustment transfers under the state payment transfer formula are calculated at the risk pool level, and catastrophic plans are treated as a separate risk pool for purposes of the risk adjustment state payment transfer calculations.[63] This resulting PMPM plan payment or charge is multiplied by the number of billable member months to determine the plan payment or charge based on plan liability risk scores for a plan's geographic rating area for the risk pool market within the state. The payment or charge under the state payment transfer formula is thus calculated to balance the state market risk pool in question.

To account for costs associated with exceptionally high-risk enrollees we previously added a high-cost risk pool adjustment to the HHS risk adjustment transfer methodology. As finalized in the 2020 Payment Notice,[64] we intend to maintain the high-cost risk pool parameters with a threshold of $1 million and a coinsurance rate of 60 percent for benefit years 2020 and beyond, unless amended through notice-and-comment rulemaking. We did not propose any changes to the high-cost risk pool parameters for the 2021 benefit year.

The high-cost risk pool adjustment amount is added to the state payment transfer formula to account for: (1) The payment term, representing the portion of costs above the threshold reimbursed to the issuer for high-cost risk pool payments (HRP_i), if applicable; and (2) the charge term, representing a percentage of premium adjustment, which is the product of the high-cost risk pool adjustment factor ($HRPC_m$) for the respective national high-cost risk pool *m* (one for the individual market, including catastrophic, non-catastrophic and merged market plans, and another for the small group market), and the plan's total premiums (TP_i). For this calculation, we use a percent of premium adjustment factor that is applied to each plan's total premium amount.

The total plan transfers for a given benefit year are calculated as the product of the plan's PMPM transfer amount (T_i) multiplied by the plan's billable member months (M_i), plus the high-cost risk pool adjustments. The total plan transfer (payment or charge) amounts under the HHS risk adjustment payment transfer formula are calculated as follows:

$$Total\ transfer_i = (T_i \cdot M_i) + HRP_i - (HRPC_m \cdot TP_i)$$

Where:

$Total\ Transfer_i$ = Plan *i*'s total HHS risk adjustment program transfer amount;
T_i = Plan *i*'s PMPM transfer amount based on the state transfer calculation;
M_i = Plan *i*'s billable member months;
HRP_i = Plan i's total high-cost risk pool payment;
$HRPC_m$ = High-cost risk pool percent of premium adjustment factor for the respective national high-cost risk pool *m;*
TP_i = Plan *i*'s total premium amounts.

We proposed to continue to use the HHS state payment transfer formula that was finalized in the 2020 Payment Notice with no changes.[65] We noted in the proposed rule that although the proposed HHS state payment transfer formula for the 2021 benefit year is unchanged from what was finalized for the previous benefit year, we believed it is useful to republish the formula in its entirety in the proposed rule. Additionally, we noted that we republished the description of the administrative cost reduction to the statewide average premium and high-cost risk pool factors, although these factors and terms also remain unchanged in the proposed rule.[66]

We are finalizing our proposal to use the risk adjustment state payment transfer formula finalized in the 2020 Payment Notice for 2021 benefit year risk adjustment. This includes maintaining the 14 percent administrative cost reduction to the statewide average premium for the 2021 benefit year. We also did not propose and are therefore maintaining the threshold of $1 million and coinsurance rate of 60 percent as the high-cost risk pool parameters for the 2021 benefit year. Below is a summary of comments we received on maintaining the risk adjustment state payment transfer formula and high-cost risk pool parameters finalized in the 2020 Payment Notice.

Comment: Most commenters supported maintaining the high-cost risk pool parameters to promote stability in the risk adjustment program and to fulfill its goals of preventing adverse selection while maintaining a level playing field and facilitating fair market competition on the basis of efficiency and quality of care provided. One commenter did not support maintaining the high-cost risk pool due to concerns that issuers may try to ''game'' the system by inflating the costs of high-cost services to push payments over the threshold, and stated that the methodology creates another level of uncertainty that issuers will need to factor into their premiums. This commenter stated that if HHS wants to

[62] This adjustment applied beginning with the 2018 benefit year. See 84 FR 17454 at 17486 for a visual illustration of the equation for this adjustment.

[63] As detailed elsewhere in this final rule, catastrophic plans are considered part of the individual market for purposes of the national high-cost risk pool payment and charge calculations.

[64] 84 FR 17454 at 17466 through 17468.

[65] 84 FR 17454 at 17480 and 17485.

[66] Ibid.

continue the reinsurance program, it should be pursued outside of risk adjustment, and suggested HHS should instead create a permanent reinsurance program, using Medicare pricing to reprice all claims over $1 million and account for geographic pricing variations in its calculation of the high-cost risk pool payment and charge terms. Another commenter supported exempting new issuers from risk adjustment, applying a creditability approach to risk adjustment participation or placing an upper bound on risk adjustment transfer charges.

Response: We did not propose to make changes to the high-cost risk pool adjustment or parameters in the proposed rule. In the 2020 Payment Notice, we finalized the high-cost risk pool parameters and the additional terms to account for the high-cost risk pool in the risk adjustment transfer methodology for the 2020 benefit year and for future benefit years unless changed in notice-and-comment rulemaking. These parameters will therefore continue to apply in the HHS risk adjustment methodology until HHS proposes to change them. As explained in prior rulemakings, we added a high-cost risk pool adjustment in the HHS risk adjustment methodology to better account for the risk associated with high-cost enrollees and to allow the risk adjustment factors to be calculated without the high-cost risk, since the average risk associated with HCCs and RXCs is better accounted for without the inclusion of the high-cost enrollees.[67] We did not propose nor are we finalizing the creation of a new, separate reinsurance program.

Furthermore, we continue to believe a $1 million threshold and 60 percent coinsurance rate for the 2021 benefit year and beyond are appropriate to incentivize issuers to control costs while improving risk prediction under the HHS risk adjustment models and prevent any potential gaming of issuers to inflate costs. We also believe the $1 million threshold and 60 percent coinsurance rate will result in total high-cost risk pool payments or charges nationally that are very small as a percentage of premiums for issuers, and will prevent states and issuers with very high-cost enrollees from bearing a disproportionate amount of unpredictable risk. Lastly, we believe that maintaining the same threshold and coinsurance rate from year-to-year will help promote stability and predictability for issuers.

[67] See, for example, 84 FR at 17466–17467 and 81 FR at 94080–94082.

As detailed further below, HHS established a new process, beginning with the 2020 benefit year, for states to request reductions in transfers calculated under the HHS state payment transfer formula.[68] This process was intended in part to aid smaller issuers that owed substantial risk adjustment charges that they did not anticipate.[69] However, HHS previously considered and otherwise declined to adopt a cap on risk adjustment charges.[70] We remain concerned that a general cap on risk adjustment transfers would reduce the necessary risk adjustment payments to issuers with higher-risk enrollees and undermine the risk adjustment program's effectiveness.[71] More specifically, given the budget-neutral nature of the HHS program, a cap on charges would result in lower payments to issuers with plans with higher-than-average actuarial risk. The cap may also incentivize small issuers with plans that attract healthier-than-average enrollees to underprice premiums because they would know their charges would be capped to a percentage of premium. As described in a previous section of this rulemaking, we are continuing to consider future policy options to improve the predictability and accuracy of the risk adjustment models. Modifications that improve predictably and accuracy would ultimately help new and small issuers. We did not propose and are not finalizing exemptions for new issuers or the adoption of a creditability approach to participation in the HHS-operated risk adjustment program.

(1) State Flexibility Requests (§ 153.320(d))

In the 2019 Payment Notice, we provided states the flexibility to request a reduction to the otherwise applicable risk adjustment transfers calculated under the HHS-operated risk adjustment methodology, which is calibrated on a national dataset, for the state's individual, small group, or merged markets by up to 50 percent to more precisely account for differences in actuarial risk in the applicable state's market(s). We finalized that any requests received would be published in the respective benefit year's proposed notice of benefit and payment parameters, and the supporting evidence would be made available for public comment.[72]

[68] 83 FR at 16955.

[69] 83 FR at 16956.

[70] 81 FR at 94101.

[71] Ibid.

[72] 2019 Payment Notice Final Rule, 83 FR 16930 (April 17, 2018) and 45 CFR 153.320(d)(3).

As finalized in the 2020 Payment Notice, if the state requests that HHS not make publicly available certain supporting evidence and analysis because it contains trade secrets or confidential commercial or financial information within the meaning of the Freedom of Information Act (FOIA) regulations at 45 CFR 5.31(d), HHS will make available on the CMS website only the supporting evidence submitted by the state that is not a trade secret or confidential commercial or financial information by posting a redacted version of the state's supporting evidence.[73]

In accordance with § 153.320(d)(2), beginning with the 2020 benefit year, states must submit such requests with the supporting evidence and analysis outlined under § 153.320(d)(1) by August 1st of the calendar year that is 2 calendar years prior to the beginning of the applicable benefit year. If approved by HHS, state reduction requests will be applied to the plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation).

For the 2021 benefit year, HHS received a request to reduce risk adjustment transfers for the Alabama small group market by 50 percent. Alabama's request states that the presence of a dominant carrier in the small group market precludes the HHS-operated risk adjustment program from working as precisely as it would with a more balanced distribution of market share. The state regulators stated that their review of the risk adjustment payment issuers' financial data suggested that any premium increase resulting from a reduction to risk adjustment payments of 50 percent in the small group market for the 2021 benefit year would not exceed 1 percent, the *de minimis* premium increase threshold set forth in § 153.320(d)(1)(iii) and (d)(4)(i)(B). We solicited comment on this request to reduce risk adjustment transfers in the Alabama small group market by 50 percent for the 2021 benefit year. The request and additional documentation submitted by Alabama are posted under the ''State Flexibility Requests'' heading at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs/index.html.*

Based on our review of the comments received and HHS's analysis of the request submitted by Alabama, HHS is granting Alabama's request to reduce transfers in the small group market by 50 percent for the 2021 benefit year. The following is a summary of the public

[73] See 45 CFR 153.320(d)(3).

comments we received on Alabama's 2021 state flexibility request.

Comment: Multiple commenters claimed that waivers diminish the effectiveness of the risk adjustment program, and recommend that states should implement their own risk adjustment programs instead of seeking state flexibility in the HHS-operated risk adjustment program.

Response: In the 2019 Payment Notice, HHS provided the flexibility for these reduction requests when a state elects not to operate the PPACA risk adjustment program. For some states, an adjustment to transfers calculated by HHS under the state payment transfer formula may more precisely account for cost differences attributable to adverse selection in the respective state market risk pools. Further, allowing these adjustments can account for the effect of state-specific rules or unique market dynamics that may not be captured in the HHS methodology, which is calibrated on a national dataset, without the necessity for states to undertake the burden and cost of operating their own PPACA risk adjustment program.

We reviewed Alabama's supporting evidence regarding the state's unique small group market dynamics that it believes warrant an adjustment to the HHS calculated risk adjustment small group market transfers for the 2021 benefit year. Alabama state regulators noted they do not assert that the HHS formula is flawed, only that it results in imprecise results in Alabama's small group market that could further reduce competition and increase costs for consumers. The state regulators provided information demonstrating that the request would have a *de minimis* impact on necessary premium increase for payment issuers, consistent with § 153.320(d)(1)(iii).

We note that HHS reviewed the state's unredacted supporting analysis in evaluating Alabama's request, along with other plan-level data available to HHS. We found the supporting analysis submitted by Alabama to be sufficient for us to evaluate the market-specific circumstances validating Alabama's request.

We agree with Alabama's assessment that any necessary premium increase for issuers likely to receive reduced payments as a result of the requested reduction to risk adjustment transfers in the Alabama small group market for the 2021 benefit year would not exceed 1 percent. HHS has determined that the state has demonstrated the existence of relevant state-specific factors that warrant an adjustment to more precisely account for relative risk differences and that the adjustment would have a *de minimis* effect. Therefore, we are approving Alabama's requested reduction under § 153.320(d)(4)(i)(B) based on the state regulators' identification of unique state-specific factors in the Alabama small group market and the supporting analysis of a *de minimis* effect of the reduction requested. The 50 percent reduction will be applied to the 2021 benefit year plan PMPM payment or charge transfer amount (T_i in the state payment transfer calculation above) for the Alabama small group market.

Comment: Several commenters asked HHS to consider a multi-year approval process as it could provide stability to state market risk pools seeking these flexibility requests.

Response: Our regulations currently provide a process for the annual review of requests by state regulators seeking a reduction to risk adjustment transfers in the state's individual catastrophic risk pool, individual non-catastrophic risk pool, small group market or a merged market.[74] Therefore, we review any requests received on an annual basis, and currently do not have a process by which a multi-year approval process could be evaluated. It is also unclear if a state would have the necessary information to be able to submit the required justification under § 153.320(d)(1)(iii) in support of a multi-year request (as opposed to a request focused only on one upcoming benefit year). However, we appreciate the comment and intend to consider whether multi-year approval processes are appropriate in the future, and would propose any changes to this process in future rulemaking.

Comment: A commenter suggested that when repeat waiver requests occur that data from years where such a waiver has already occurred that data from past years be released to the public for analysis.

Response: As explained in the 2020 Payment Notice, we are concerned that releasing unredacted information from state flexibility requests can reveal market conditions and issuers' private financial data.[75] We believe it is important to protect information that contains trade secrets or confidential commercial or financial information within the meaning of the HHS FOIA regulations at § 5.31(d) and therefore will not post information the state requests HHS not make publicly available because it contains such trade secrets or confidential commercial or financial information. We note that the 2020 benefit year is the first year for which a state flexibility request was requested and approved (Alabama in the small group market) and we will publish more information, such as issuers' transfers amounts, and the state average factors, including premiums, in the permanent risk adjustment transfers summary report for the 2020 benefit year issued by June 30, 2021. As such, this report will reflect the reduced transfers in Alabama, and stakeholders will be able to assess the impact of the transfers reduction on transfers as a percent of state average premiums for Alabama's small group market. We further note that Alabama's request for the 2020 benefit year remains posted on the CMS website,[76] such that stakeholders could review it alongside the state's new request for the 2021 benefit year.

c. Risk Adjustment User Fee for 2021 Benefit Year (§ 153.610(f))

As noted above, if a state is not approved to operate, or chooses to forgo operating, its own risk adjustment program, HHS will operate risk adjustment on its behalf. For the 2021 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee.[77] Section 153.610(f)(2) provides that, where HHS operates a risk adjustment program on behalf of a state, an issuer of a risk adjustment covered plan must remit a user fee to HHS equal to the product of its monthly billable member enrollment in the plan and the PMPM risk adjustment user fee specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year.

Our authority to operate risk adjustment on the state's behalf arises from sections 1321(c)(1) and 1343 of the PPACA. The authority to charge this user fee can be found under sections 1343, 1311(d)(5), and 1321(c)(1) of the PPACA, and under 31 U.S.C. 9701, which permits a Federal agency to establish a charge for a service provided by the agency. OMB Circular No. A–25 established Federal policy regarding user fees, and specifies that a user charge will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond

[74] See 45 CFR 153.320(d)(3), requiring HHS to publish state requests in the applicable benefit year's notice of benefit and payment parameters rulemaking.

[75] See 84 FR at 248–249. Also see 84 FR at 17484–17485

[76] *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Premium-Stabilization-Programs.*

[77] See 78 FR at 15416–15417.

those received by the general public. The risk adjustment program will provide special benefits as defined in section 6(a)(1)(B) of Circular No. A–25 to issuers of risk adjustment covered plans because it mitigates the financial instability associated with potential adverse risk selection. The risk adjustment program also contributes to consumer confidence in the health insurance industry by helping to stabilize premiums across the individual, merged, and small group markets.

In the 2020 Payment Notice, we calculated the Federal administrative expenses of operating the risk adjustment program for the 2020 benefit year to result in a risk adjustment user fee rate of $0.18 per member per month (PMPM) based on our estimated costs for risk adjustment operations and estimated billable member months for individuals enrolled in risk adjustment covered plans. For the 2021 benefit year, we used the same methodology to estimate our administrative expenses to operate the program. These costs cover development of the model and methodology, collections, payments, account management, data collection, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, operational support, and administrative and personnel costs dedicated to risk adjustment program activities. To calculate the user fee, we divided HHS's projected total annual costs for administering the risk adjustment programs on behalf of states by the expected number of billable member months in risk adjustment covered plans in states where the HHS-operated risk adjustment program will apply in the 2021 benefit year.

In the proposed rule, we estimated that the total cost for HHS to operate the risk adjustment program on behalf of states for 2021 will be approximately $50 million, and the risk adjustment user fee would be $0.19 PMPM. We sought comments on the proposed risk adjustment user fee rate.

We received several comments in support of the proposed risk adjustment user fee rate, however, we are not finalizing the 2021 benefit year risk adjustment user fee amount as proposed. At the time of the proposed rule, we estimated the 2021 benefit year risk adjustment user fee using the best information available on costs, allocations, and enrollment projections. However, as explained below, in light of new information, we are finalizing the risk adjustment user fee amount of $0.25 PMPM for the 2021 benefit year, which reflects our updated estimate of $60 million in total costs for HHS to operate the 2021 benefit year risk adjustment program on behalf of states.

Based on our analysis of newly available data and further evaluation of eligible costs, we now expect estimated risk adjustment user fee costs for the 2021 benefit year to increase, resulting in total estimated costs of $60 million for program operations for the 2021 benefit year. We periodically reexamine user fee eligible costs, and we reevaluated our allocation of risk adjustment costs after the publication of the proposed rule. HHS re-assessed contracts after the publication of the proposed rule to evaluate portions of contracts spent on risk adjustment program activities. As a result of this reexamination, we determined that additional costs were attributable to risk adjustment program operations. This includes costs related to information technology technical assistance and support, cloud computing, collections, payments, program support, data validation, program integrity and audit functions, operational and fraud analytics, stakeholder training, and operational support activities. Additionally, our analysis of interim 2019 benefit year risk adjustment data, which was not available prior to publication of the proposed rule, revealed enrollment in 2019 benefit year risk adjustment covered plans that were lower than previously estimated based on the billable member month enrollment observed for the prior benefit years. The combination of the decline in enrollment estimates and the increase in risk adjustment user fee eligible costs altered our estimates and projections of both costs and collections for the 2021 benefit year risk adjustment program, resulting in an increase to the risk adjustment user fee required to cover the estimated costs of operating the program from the amount proposed. We are therefore finalizing a risk adjustment user fee amount of $0.25 PMPM for the 2021 benefit year, reflecting our updated estimate of $60 million in total costs to operate the program on behalf of states for the 2021 benefit year and the estimated decline in enrollment in risk adjustment covered plans. We believe finalizing a risk adjustment user fee amount of $0.25 PMPM for the 2021 benefit year is necessary to ensure the HHS-operated risk adjustment program is fully funded with no risk of a shortfall. We also note risk adjustment user fee collections are spent on risk adjustment user fee eligible costs only, and while we have not had significant funds remaining in prior years, any amount collected in excess of those required to fund eligible activities would be spent on future years' eligible activities and considered in future risk adjustment user fee rate estimates.

3. Risk Adjustment Data Validation Requirements When HHS Operates Risk Adjustment (§ 153.630)

We conduct RADV under §§ 153.630 and 153.350 in any state where HHS is operating risk adjustment on a state's behalf, which for the 2021 benefit year includes all 50 states and the District of Columbia. The purpose of RADV is to ensure issuers are providing accurate and complete risk adjustment data to HHS, which is crucial to the purpose and proper functioning of the HHS-operated risk adjustment program. The RADV program also ensures that risk adjustment transfers reflect verifiable actuarial risk differences among issuers, rather than risk score calculations that are based on poor data quality, thereby helping to ensure that the HHS-operated risk adjustment program assesses charges to issuers with plans with lower-than-average actuarial risk while making payments to issuers with plans with higher-than-average actuarial risk.

RADV consists of an initial validation audit and a second validation audit. Under § 153.630, each issuer of a risk adjustment covered plan must engage an independent initial validation auditor. The issuer provides demographic, enrollment, and medical record documentation for a sample of enrollees selected by HHS to the issuer's initial validation auditor for data validation. Each issuer's initial validation audit is followed by a second validation audit, which is conducted by an entity HHS retains to verify the accuracy of the findings of the initial validation audit. In the proposed rule, we set forth proposed amendments and clarifications to the RADV program that stemmed from issuer feedback and HHS's examination of results from the first 2 pilot years and first transfer adjustment year of the program.

The following is a summary of the general public comments received related to RADV. Additional comments related to the application of RADV results when HCC counts are low and the designation of a second pilot year for the data validation of prescription drugs are discussed later in this rule.

Comment: Many commenters urged HHS to implement certain policy options discussed in the ''HHS Risk Adjustment Data Validation (HHS–

RADV) White Paper,'' [78] published on December 6th, 2019, with some commenters requesting that white paper policy options be incorporated into this final rule or that separate rulemaking be initiated to enable these provisions to be effective for 2019 RADV. Some of the policy options frequently advocated for include policies related to: (1) The ''payment cliff'' effect that occurs in the current methodology, which results in some issuers with similar RADV findings experiencing different risk score and transfer adjustments; (2) negative failure rates; and (3) the interaction between risk adjustment HCC hierarchies and HCC failure rate groups in RADV. One commenter also asked that the initial validation audit sample size be varied based on issuer-specific parameters or prior RADV results. Another commenter wanted to ensure the proposals outlined in the 2019 HHS–RADV White Paper will not impact 2018 benefit year RADV.

We also received several comments encouraging HHS to modify RADV beyond options discussed in the white paper or in the proposed rule. These include subdividing the RADV process so that the individual and small group markets are each assessed separately; changing the materiality threshold criteria to a percentage of statewide premiums; using the current method for determining outliers, but basing adjustments on divergence from a state mean rather than a national mean; and applying additional scrutiny when issuers' supplemental data is dominated by additional diagnoses rather than modified or deleted diagnoses.

Response: We appreciate these comments and recognize the desire for further changes to the RADV program requirements to improve their reliability and integrity, including implementation of policy options explored in the 2019 HHS–RADV White Paper. However, we did not include in the proposed rule any of the options explored in the 2019 HHS–RADV White Paper and are not finalizing any of those options in this final rule. As explained in the 2019 HHS–RADV White Paper, our goal was to outline and seek feedback on certain RADV issues to inform future policy development.

HHS is committed to ensuring the integrity and reliability of RADV. Although the options explored in the 2019 HHS–RADV White Paper and the additional modifications to RADV suggested by commenters are outside of the scope of this rule, we continue to explore potential modifications to this program and will propose any such changes for future benefit years through rulemaking. In response to the comment, we note that we do not intend to pursue the options explored in the 2019 HHS–RADV White Paper for the 2018 benefit year of RADV.

Comment: One commenter urged HHS to adopt the HEDIS (Healthcare Effectiveness Data and Information Set) audit methodology for RADV, which would only require medical record review for supplemental codes that the plan pulls from medical records.

Response: We continue to seek ways to improve RADV for both accuracy and user experience, and will continue to examine approaches taken by other organizations when making updates to the RADV process for future benefit years. However, because the intent of RADV is to ensure the integrity of the risk adjustment program by validating all diagnoses to confirm the issuer's actuarial risk in a given benefit year as measured by the risk adjustment program, we believe that RADV should include a sample of all diagnoses, and not simply be limited to supplemental diagnoses. Additionally, we note that the HEDIS audit methodology is a two-part process that is customized based on an organization's informational systems, and we believe that the distributed data environment (that is, issuers' EDGE servers) precludes the need for such customization. As such, we are maintaining our current overall approach for RADV, with the modifications detailed below that are finalized in this rule.

Comment: One commenter requested that HHS use our authority to mandate the submission of medical records by providers to initial validation auditors for the purposes of RADV.

Response: Under sections 1321 and 1343 of the PPACA, HHS has authority to regulate issuers of risk adjustment covered plans, but not providers. However, as explained in the 2019 Payment Notice, we appreciate that issuers could experience some level of difficulty retrieving medical records. As a result, we updated the RADV error estimation methodology, by adopting confidence intervals to identify outliers, to account for some level of variation and error in validating HCCs.[79] Only outlier issuers have their risk scores adjusted as a result of RADV for this reason. In addition, recognizing these challenges exist, we have taken steps to provide assistance to issuers with this process. For example, we developed a memorandum [80] that issuers can use to assist in their efforts to obtain medical records from providers for the RADV program. The memo explains the background and purpose of the RADV program and can be sent to providers along with the issuer's request for medical records. We will continue to explore other ways we may be able to help issuers encourage provider response to medical records requests and whether there are mechanisms that would enable us to differentiate between issuers who are outliers due to unverified diagnoses or bad data, and those who are outliers due to unresponsive providers during medical record retrieval.

a. Application of Risk Adjustment Data Validation Adjustments in Cases Where HCC Count is Low

In the 2019 Payment Notice, to avoid adjusting all issuers' risk adjustment transfers for expected variation and error, we finalized a new methodology to evaluate material statistical deviation in data validation failure rates beginning with 2017 benefit year RADV.[81] When an issuer's failure rate within a group of HCCs materially deviates from the mean of the failure rate for that HCC group, we apply the difference between the mean group failure rate and the issuer's calculated failure rate. If all failure rates in a state market risk pool do not materially deviate from the national mean failure rates, we do not apply any adjustments to issuers' risk scores for that benefit year in the respective state market risk pool.[82]

Consistent with the methodology finalized in the 2019 Payment Notice, for RADV for 2017 and 2018 benefit years, we calculate the data validation failure rate for each HCC in issuers' initial validation audit samples as:

$$FR^h = 1 - \frac{Freq_IVA^h}{Freq_EDGE^h}$$

Where:

$Freq_EDGE^h$ is the frequency of HCC code h occurring on EDGE, which is the number of sampled enrollees recording HCC code h on EDGE.

$Freq_IVA^h$ is the frequency of HCC code h occurring in initial validation audit results, which is the number of sampled

[78] See *https://www.cms.gov/files/document/2019-hhs-risk-adjustment-data-validation-hhs-radv-white-paper.*

[79] See 83 FR at 16961–16965.

[80] Available at *https://www.regtap.info/uploads/library/2018_BY_HHS-RADV_Provider_Medical_Record_Request_Memo_073119_5CR_073119.pdf.*

[81] See 83 FR at 16961–16965.

[82] When an issuer is determined to be an outlier in an HCC group, the transfers for other issuers in the state market risk pool (including those who are not outliers in any HCC group) will also be adjusted due to the budget neutral nature of the HHS-operated risk adjustment program.

enrollees with HCC code *h* on in initial validation audit results.

FR^h is the failure rate of HCC code *h*.

HHS then creates three HCC groups based on the HCC failure rates derived in the calculation above. These HCC groups are determined by first ranking all HCC failure rates and then dividing the rankings into three groups, weighted by total observations or frequencies, of that HCC across all issuers' initial validation audit samples, to assign each unique HCC in the initial validation audit samples to a high, medium, or low failure rate group with an approximately even number of observations in each group. That is, each HCC group may have an unequal number of unique HCCs, but the total observations in each group are approximately equal based on total observations of HCCs reflected in EDGE data for all issuers' initial validation audit sample enrollees.

HHS then compares each issuer's failure rate for each HCC group based on the number of HCCs validated in the initial validation audit, compared to the number of HCCs recorded on EDGE within that HCC group for the initial validation audit sample enrollees. The issuer's HCC group failure rate is compared to the weighted mean failure rate for that HCC group. We calculate an issuer's HCC group failure rate as:

$$GFR_i^G = 1 - \frac{Freq_IVA_i^G}{Freq_EDGE_i^G}$$

Where:

$Freq_EDGE_i^G$ is the number of HCCs in group *G* in the EDGE sample of issuer *i*.

$Freq_IVA_i^G$ is the number of HCCs in group *G* in the initial validation audit sample of issuer *i*.

GFR_i^G is i's group failure rate for the HCC group *G*.

We also calculate the weighted mean failure rate and the standard deviation of each HCC group as:

$$\mu^*(GFR^G) = 1 - \frac{\sum Freq_IVA_i^G}{\sum Freq_EDGE_i^G}$$

$$Sd(GFR^G) = \sqrt{\frac{\sum_i Freq_EDGE_i^G * \left(GFR_i^G - \mu(GFR^G)\right)^2}{\sum_i Freq_EDGE_i^G}}$$

Where:

$\mu(GFR^G)$ is the weighted mean of GFR_i^G of all issuers for the HCC group *G* weighted by all issuers' sample observations in each group.

$Sd(GFR^G$ is the standard deviation of GFR_i^G of all issuers for the HCC group *G*.

If an issuer's failure rate for an HCC group falls outside the confidence interval for the weighted mean failure rate for the HCC group, the failure rate for the issuer's HCCs in that group is considered an outlier. We use a 1.96 standard deviation cutoff, for a 95 percent confidence interval, to identify outliers. To calculate the thresholds to classify an issuer's group failure rate as outliers or not, the lower and upper limits are computed as:

$LB^G = \mu\ (GFR^G) - sigma_cutoff * Sd(GFR^G)$

$UB^G = \mu\ (GFR^G) + sigma_cutoff * Sd(GFR^G)$

Where:

sigma_cutoff is the parameter used to set the threshold for outlier detection as the number of standard deviations away from the mean.

LB^G, UB^G are the lower and upper thresholds to classify issuers as outliers or not outliers for group *G*.

When an issuer's HCC group failure rate is an outlier, we reduce (or increase) each of the applicable initial validation audit sample enrollees' HCC coefficients by the difference between the outlier issuer's failure rate for the HCC group and the weighted mean failure rate for the HCC group. Specifically, this results in the sample enrollees' applicable HCC risk score components being reduced (or increased) by a partial value, or percentage, calculated as the difference between the outlier failure rate for the HCC group and the weighted mean failure rate for the applicable HCC group. The adjustment amount for outliers is the distance between issuer *i*'s Group Failure Rate GFR_i^G and the weighted mean $\mu(GFR^G)$, calculated as:

If $GFR_i^G > UB^G$ or $GFR_i^G < LB^G$:

Then $Flag_i^G$ = ''*outlier*'' and $Adjustment_i^G = GFR_i^G - \mu(GFR^G)$

If $GFR_i^G \leq UB^G$ and $GFR_i^G \geq LB^G$:

Then $Flag_i^G$ = ''*not outlier*'' and $Adjustment_i^G = 0$

Where:

$Flag_i^G$ is the indicator if issuer *i*'s group failure rate for group *G* locates beyond a calculated threshold that we are using to classify issuers into ''outliers'' or ''not outliers'' for group *G*.

$Adjustment_i^G$ is the calculated adjustment amount to adjust issuer *i*'s EDGE risk scores for all sampled HCCs in group *G*.

We then compute total adjustments and risk adjustment transfer error rates for each issuer based on the sums of the $Adjustment_i^G$.[83]

Although the failure rate and error estimation methodology described above is based on the number of HCCs within a sample, our sampling methodology samples individual enrollees and varies in size for issuers with fewer than 4,000 enrollees,[84] rather than sampling HCCs directly. This difference in unit of analysis between the error estimation methodology—which applies to all non-exempt RADV issuers, regardless of their size—and the sampling methodology may lead to fewer HCCs in an HCC group than are necessary to reliably determine whether an issuer is an outlier at the targeted precision and confidence levels—that is, whether an issuer is statistically different from the national (average) HCC failure rate, as defined by an unadjusted 95 percent confidence interval.

Standard statistical theorems[85] state that, as sample sizes increase, the

[83] See, for example, the 2018 Benefit Year Protocols: PPACA HHS Risk Adjustment Data Validation, Version 7.0 (June 24, 2019) that are available at *https://www.regtap.info/uploads/library/HRADV_2018Protocols_070319_5CR_070519.pdf.*

[84] For issuers with fewer than 4,000 enrollees, the sample size varies according to a finite population correction (FPC) such that $n_{adjusted} = n_{original}$ * FPC, where $n_{adjusted}$ is the adjusted sample size and $n_{original}$ is the original sample size of 200 enrollees. The FPC is determined by the equation $FPC = (N - n_{_original}/N$, where *N* is the population size. By these formulae, if an issuer's adjusted sample size would be smaller than 50 enrollees, that issuer should sample either a minimum of 50 enrollees or their entire population of enrollees, whichever is smaller. See Ibid at 37.

[85] In other words, the Central Limit Theorem (CLT). For background regarding the CLT, see Ivo D. Dinov, Nicolas Christou, and Juana Sanchez.

Continued

sampling distribution of the means of those samples (in this case, the distribution of mean HCC group failure rates) will more closely approximate a normal distribution. Lower sample sizes are more likely to lead to non-normal distributions of sample summary statistics—for example, the means of multiple samples—if the distribution of the underlying population is non-normal. The divergence from a normally distributed distribution of sample means that can occur at lower sample sizes may result in violations of the assumptions of statistical testing, which may lead to the detection of more apparent outliers than would be desirable.

Taking all of these points into consideration, we conducted an analysis in which we simulated the selection of samples from an average issuer using progressively smaller HCC counts. By this process we identified that, if the number of HCCs per sample of enrollees was below 30 HCCs, the implied alpha of our statistical tests for outliers was higher than our 5 percent target, thereby failing to meet the threshold for statistical significance. Moreover, statistical practice often relies on a standard recommendation regarding the determination of sample size, which states that sample sizes below 30 observations are often insufficient to assume that the sampling distribution is normally distributed.[86]

Based on these findings, we proposed to amend the outlier identification process and not consider as an outlier any issuer's failure rate for an HCC group in which that issuer has fewer than 30 HCCs beginning with 2019 benefit year RADV. Furthermore, we proposed that such issuers' data would continue to be included in the calculation of national metrics for that HCC group, including the national mean failure rate, standard deviation, and upper and lower confidence interval bounds. However, the issuer would not have its risk score adjusted for that group, even if the magnitude of its failure rate appeared to otherwise be very large relative to other issuers. In addition, we clarified that this issuer may be considered an outlier in other HCC groups in which it has 30 or more HCCs. Under the proposal, the adjustment amount for outliers would continue to be the distance between issuer *i*'s Group Failure Rate GFR_i^G and the weighted mean $\mu(GFR^G$ calculated as:

If $GFR_i^G > UB^G$ or $GFR_i^G < LB^G$,
And if $Freq_EDGE_i^G \geq 30$:
Then $Flag_i^G$ = ''*outlier*'' and $Adjustment_i^G = GFR_i^G - \mu(GFR^G)$
If $GFR_i^G \leq UB^G$ and $GFR_i^G \geq LB^G$,
Or if $Freq_EDGE_i^G < 30$:
Then $Flag_i^G$ = ''*not outlier*''and $Adjustment_i^G = 0$

We solicited comments on this proposal.

After consideration of comments, we are finalizing the policy as proposed such that beginning with 2019 benefit year RADV[87], we will not consider issuers with fewer than 30 HCCs in an HCC failure rate group to be outliers in that HCC failure rate group, but will continue to include such issuers in the calculation of national metrics. In addition, these issuers may still be considered outliers in other HCC groups in which they have 30 or more HCCs. The following is a summary of the public comments we received on this proposed policy.

Comment: All commenters that submitted comments on this topic supported the proposed modification to the outlier identification process to not consider issuers with fewer than 30 HCCs in an HCC failure rate group as outliers in RADV beginning with the 2019 benefit year.

Response: After consideration of comments, we are finalizing the policy as proposed such that beginning with 2019 benefit year RADV, we will not consider issuers with fewer than 30 HCCs in an HCC failure rate group to be outliers in that HCC failure rate group, but will continue to include such issuers in the calculation of national metrics. In addition, these issuers may still be considered outliers in other HCC groups in which they have 30 or more HCCs. We also generally remind issuers that when an issuer is determined to be outlier in an HCC group, the transfers for other issuers in the state market risk pool (including those who are not outliers) will also be adjusted due to the budget neutral nature of the HHS-operated risk adjustment program.

b. Prescription Drugs for the 2019 Benefit Year Risk Adjustment Data Validation

In the 2020 Payment Notice,[88] we finalized an approach to incorporate RXCs into RADV as a method of discovering materially incorrect EDGE server data submissions in a manner similar to how we address demographic and enrollment errors discovered during RADV. We also finalized an approach to pilot the incorporation of these drugs into the RADV process for 2018 benefit year RADV, and stated that RXC errors that we identified during the 2018 benefit year RADV RXC pilot will not be used to adjust risk scores or transfers. We stated that we finalized this policy to treat the incorporation of RXCs into 2018 benefit year RADV as a pilot year to allow HHS and issuers to gain experience in validating RXCs before RXCs are used to adjust issuers' risk scores.

Following continued analysis of the issue after publication of the 2020 Payment Notice, in the proposed rule, we proposed that the 2019 benefit year RADV would serve as a second pilot year for the purposes of prescription drug data validation, in addition to the 2018 benefit year RADV pilot for prescription drugs. The proposed second pilot year is consistent with the 2 pilot years provided for the 2015 and 2016 benefit years of the RADV program. We also noted in the proposed rule that the proposal was also responsive to issuer concerns that were previously expressed in comments to the 2020 Payment Notice.[89] We solicited comments on this proposal.

In light of the comments received, we are finalizing the proposal to treat the 2019 benefit year[90] as a second pilot year for RXC validation.

We summarize and respond to the public comments received below.

Comment: All stakeholders who commented on this proposal supported a second pilot year for RXC validation. Several commenters encouraged HHS to

''Central limit theorem: New SOCR applet and demonstration activity.'' Journal of Statistics Education 16, no. 2 (2008). DOI: 10.1080/10691898.2008.11889560.

[86] For example, David C. Howell, ''Hypothesis Tests Applied to Means'' In *Statistical Methods for Psychology (8th Ed.),* 177–228. Belmont, CA: Wadsworth, 2010.

[87] As part of the Administration's efforts to combat the Coronavirus Disease 2019 (COVID–19), we recently announced the postponement of the 2019 benefit year RADV process. We intend to provide further guidance by August 2020 on our plans to begin 2019 benefit year RADV in calendar year 2021. See *https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.*

[88] 84 FR 17454 at 17498 through 17503.

[89] See, for example, America's Health Insurance Plans comment on HHS Notice of Benefit and Payment Parameters for 2020 Proposed Rule, February 19, 2019, *https://www.regulations.gov/contentStreamer?documentId=CMS-2019-0006-23013&attachmentNumber=1&contentType=pdf,* and BlueCross BlueShield Association comment on HHS Notice of Benefit and Payment Parameters for 2020 Proposed Rule, February 19, 2019, *https://www.regulations.gov/contentStreamer?documentId=CMS-2019-0006-23345&attachmentNumber=1&contentType=pdf.*

[90] As noted above, we recently announced the postponement of the 2019 benefit year RADV process as part of the Administration's efforts to combat COVID–19. See, *supra* note 87 and *https://www.cms.gov/files/document/2019-HHS-RADV-Postponement-Memo.pdf.*

provide issuers with additional data and reports of the findings from the 2018 benefit year RADV RXC validation pilot.

Response: As explained in the proposed rule, we recognize that there may be more differences between validating HCCs and RXCs that need to be considered when incorporating RXCs into RADV than initially anticipated and that the metrics to validate a RXC are not the same as coding a HCC. A second pilot year for validation of RXCs provides additional time to examine these issues and any potential mitigating strategies (as may be necessary). Therefore, we are finalizing a second pilot year (2019 benefit year) for RXC validation to give HHS and issuers more time and experience with the prescription drug data validation process before those results will be used to adjust risk scores and transfers. Additionally, we intend to provide issuers with additional data and analysis from the 2018 benefit year RADV prescription drug data validation pilot when we release our 2018 benefit year RADV error rate results memo in May 2020.

Comment: One commenter recommended that HHS include the drug name in the National Drug Code (''NDC'') to RXC mapping because they believed that not all the NDCs in the RXC model are listed in the Federal Drug Administration's drug inventory.

Response: We refer the commenter to the most recent HHS-Development Risk Adjustment Model Algorithm ''Do It Yourself (DIY)'' Software,[91] which contains all NDCs that were active at any point during the benefit year to which the DIY software refers and that crosswalk to RXCs. Some of the Federal Drug Administration's drug reference sources use 10-digit NDC codes, but the DIY Software uses 11-digit NDC codes. Drug names can be identified from the 11-digit NDC code via the National Institutes of Health's RxNorm system.[92] Some of the NDCs in the DIY Software may be marked with an obsolete status in the RxNorm system; however, all NDCs are referenced against the EDGE NDC Global Reference List for active status at the time of the claim.

D. Part 155—Exchange Establishment Standards and Other Related Standards Under the Affordable Care Act

1. Verification Process Related To Eligibility for Insurance Affordability Programs

a. Employer-Sponsored Plan Verification

We proposed that HHS would not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), when the Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), for plan years 2020 and 2021. We also proposed that HHS would exercise such discretion in anticipation of receiving the results of the employer verification study described in the proposed rule. We are finalizing this policy as proposed.

Strengthening program integrity with respect to subsidy payments in the individual market continues to be a top priority. Currently, Exchanges must verify whether an applicant is eligible for or enrolled in an eligible employer-sponsored plan for the benefit year for which coverage is requested using available data sources, if applicable, as described in § 155.320(d). For any coverage year that an Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), an alternate procedure is required. Specifically, Exchanges must select a statistically significant random sample of applicants and meet the requirements of § 155.320(d)(4)(i). We discussed in the proposed rule that we are exploring a new alternative approach to replace the current procedures in § 155.320(d)(4)(i), under which an Exchange may design its verification process based on the Exchange's assessment of risk for inappropriate eligibility or payment for APTC or CSRs.

HHS's experience conducting random sampling revealed that employer response rates to HHS's request for information were low. The manual verification process described in § 155.320(d)(4)(i) requires significant resources and government funds, and the value of the results ultimately does not appear to outweigh the costs of conducting the work because only a small percentage of sampled enrollees have been determined by HHS to have received APTC/CSRs inappropriately. We discussed in the proposed rule that we believe an approach to verifying an applicant's attestation regarding access to an employer-sponsored plan should be rigorous, while posing the least amount of burden on states, employers, consumers, and taxpayers.

Based on our experiences with random sampling methodology under § 155.320(d)(4)(i), HHS questioned whether this methodology was the best approach for all Exchanges to assess the associated risk for inappropriate payment of APTC/CSRs. As such, HHS conducted a study to (1) determine the unique characteristics of the population with offers of employer-sponsored coverage that meets minimum value and affordability standards; (2) compare premium and out-of-pocket costs for consumers enrolled in employer-sponsored coverage to Exchange coverage; and (3) identify the incentives, if any, that drive consumers to enroll in Exchange coverage rather than coverage offered through their current employer. The results of this study, which HHS expects to be finalized sometime in 2020, will inform the approach we would propose in future rulemaking to allow Exchanges to design an employer-sponsored coverage verification based upon their assessment of the risk of potential inappropriate payments of APTC/CSRs to those with offers of affordable employer-sponsored coverage for Exchanges using the Federal eligibility and enrollment platform. HHS also encouraged State Exchanges to conduct similar research of their past and current enrolled populations in anticipation of this future rulemaking.

As HHS continues to explore the best options for verification of employer-sponsored coverage, we proposed that HHS would not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), as an alternative to performing this verification against the data sources required under § 155.320(d)(2)(i) through (iii), for plan years 2020 and 2021. We also proposed that HHS would exercise such discretion in anticipation of receiving the results of the employer verification study described in the proposed rule.

Comment: All commenters on this topic agreed with HHS's proposal to refrain from taking enforcement action against Exchanges that do not conduct random sampling to verify whether an applicant has access to or received an offer of affordable coverage that meets the minimum value standard through their employer. The commenters agreed with HHS's prior study findings that the random sampling process requires significant resources with little return on investment. Commenters also agreed with HHS that an employer-sponsored coverage verification approach should provide State Exchanges with flexibility and more opportunities to use

[91] See *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/index.*

[92] See *https://www.nlm.nih.gov/research/umls/rxnorm/index.html.*

verification processes that are evidence-based, while imposing the least amount of burden on consumers, states, employers, and taxpayers. One commenter supported the proposal, but sought clarification on whether the non-enforcement policy would apply to State Exchanges with corrective active plans currently under § 155.320(d)(4). Another commenter suggested that HHS make available a reliable data source for verification of employer-sponsored coverage.

A commenter suggested that, as HHS reviews the results of the study discussed in the preamble to the proposed rule, we should consider that soliciting additional information from employers and plan sponsors regarding employer-sponsored coverage through the random sampling process under § 155.320(d)(4) is not necessary because this information regarding employer-sponsored coverage for employees is already provided annually on Internal Revenue Service (IRS) Form 1095–C, Employer-Provided Health Insurance Offer and Coverage.

Response: We agree that the current random sampling process required under § 155.320(d)(4)(i) is not only burdensome for states, employers, consumers, and taxpayers, but it also does not provide enough flexibility to all Exchanges to develop a process for employer-sponsored coverage verification that more accurately reflects their respective enrolled Exchange populations. As discussed in the preamble above and in the proposed rule, HHS shares the same concerns regarding the feasibility and effectiveness of random sampling, including the effectiveness of employer and employee notices, and the impact that such a verification process has on Exchanges' appeals processes. We also agree that a verification process should be evidence-based and informed by certain risk-factors for inappropriate payment of APTC/CSRs. HHS will also continue to explore the availability of other data sources that may be used to verify offers of employer-sponsored coverage, such as the National Directory of New Hires (NDNH), however, access to that database would require statutory changes. Finally, we agree that as HHS reviews the results of the study discussed earlier in this preamble, we should also continue to explore whether there may be information that applicable large employers can provide regarding coverage available to employees as we generally agree with the premise that HHS should avoid soliciting duplicative information, if possible. We note however that Forms 1095–C would have limited utility in helping an Exchange to verify a current offer of employer-sponsored coverage because they are provided to employees after a coverage year has ended.

In response to comments on the proposed non-enforcement policy, we clarify that the non-enforcement of the requirement to conduct the random sampling process under § 155.320(d)(4)(i) will apply for plan years 2020 and 2021 to all State Exchanges, including those that currently have existing corrective action plans under which the State Exchange proposed to implement the random sampling process required under § 155.320(d)(4)(i) as an alternative to conducting this verification using the data sources under § 155.320(d)(2).

HHS further reminds State Exchanges that they have existing flexibility under § 155.320(a)(2) and § 155.315(h) to propose an alternative approach to using the verification procedures under § 155.320(d)(2), or an alternative to using the random sampling process described under § 155.320(d)(4), in order to verify whether applicants have received an offer of affordable coverage. We encourage states to use this flexibility to explore evidence or risk-based approaches to conducting this verification. Finally, these changes do not impact State Exchanges that currently verify offers of employer-sponsored coverage using approved data sources under § 155.320(d)(2)(i) through (iii) or use the random sampling procedures under § 155.320(d)(4), and have determined these methods are the appropriate approaches for their Exchanges to meet requirements under § 155.320(d).

Comment: One commenter also supported the proposal, but suggested that HHS consider reinstating timely notices from the Exchanges using the Federal platform to employers, required under § 155.310(h) and referenced at § 155.320(d)(4)(i)(E), regarding employees who are receiving APTC/CSRs.

Response: We did not propose policies or requirements related to employer notices under § 155.310(h) or elsewhere, and this comment is outside the scope of this rulemaking. However, we wish to clarify that there are limitations on the extent to which notification to employers regarding employees who are receiving APTC/CSRs under § 155.310(h) would alleviate the difficulties that employers may face with regard to the assessment of employer shared responsibility payments (ESRPs) in section 4980H of the Code. Based on HHS's experience with the Exchanges issuing such notices to employers, the Exchange does not have the capability to distinguish between employers that are or are not subject to the ESRP. In addition, HHS found that these notices caused substantial confusion among employers, as many employers interpreted the notices as an assessment of the ESRP. HHS also believes that while these notices could offer employers the opportunity to dispute an employee's eligibility for APTC/CSRs, the outcome of such a dispute may have no impact on the IRS's assessment of the ESRP. IRS's assessment of the ESRP and whether an employer is liable for the ESRP, is solely within the purview of the IRS. Therefore, HHS believes that the notice and dispute processes authorized for Exchanges would not contribute positively to verifying whether employees have affordable offers of employer sponsored coverage that meet minimum value. Furthermore, per § 155.310(i), the IRS currently sends letters to employers, known as ''226–J letters,'' to certify to an employer that one or more employees has enrolled for one or more months during a year in a QHP with APTC in order to satisfy the requirement under section 4980H of the Code.

After reviewing the public comments, we are finalizing this proposal as proposed.

2. Eligibility Redetermination During a Benefit Year (§ 155.330)

a. Process for Voluntary Termination Upon a Finding of Dual Enrollment via Periodic Data Matching (PDM)

We proposed to amend § 155.330(e)(2)(i)(D) to provide that Exchanges need not redetermine eligibility for APTC or CSRs for enrollees who (1) are found to be dually enrolled in QHP coverage and MEC consisting of Medicare, Medicaid/CHIP, or, if applicable, the Basic Health Program (BHP); (2) have not responded to the Exchange notice to provide updated information within 30-days; and (3) have previously provided written consent for the Exchange to end their QHP coverage via PDM in the event of dual enrollment or eligibility. We are finalizing these amendments as proposed.

In accordance with § 155.330(d)(3), Exchanges must periodically examine available data sources (beginning with the 2021 calendar year, generally at least twice per calendar year) to determine whether enrollees in a QHP through an Exchange who are receiving APTC or CSRs have been determined eligible for or are enrolled in other qualifying coverage through Medicare, Medicaid, CHIP, or the BHP, if a BHP is operating

in the service area of the Exchange. Individuals enrolled in one of these forms of MEC and Exchange coverage are referred to as 'dually-enrolled' consumers and are identified through periodic data matching against government and commercial sources, known as periodic data matching or PDM.

Section 155.430(b)(1)(ii) requires an Exchange to provide an opportunity at the time of plan selection for an enrollee to choose to remain enrolled in QHP coverage or have their QHP coverage terminated if the Exchange finds that he or she has become eligible for or enrolled in other MEC, or to terminate QHP coverage if the enrollee does not choose to remain enrolled in the QHP upon completion of the redetermination process. As such, for plan year 2018 and thereafter, HHS added language to the single streamlined application generally used by the Exchanges using the Federal platform to allow consumers to authorize the Exchange to obtain eligibility and enrollment data and, if so desired by the consumer, to end their QHP coverage if the Exchange finds during PDM that the consumer has become eligible for or enrolled in other MEC. A consumer's authorization for the Exchange to end QHP coverage is voluntary, as consumers may opt-in to or opt-out of permitting the Exchange to process a voluntary termination of QHP coverage if the consumers are found to be also enrolled in other MEC, via PDM. We note that the PDM operational processes described above pertain only to those Exchange enrollees receiving APTC/CSRs in accordance with § 155.330(d)(ii).

We further noted that for plan year 2019 and beyond, the Exchanges using the Federal platform will continue to end QHP coverage or subsidies for Medicare PDM only; terminations of Exchange coverage based on consumer pre-authorization resulting from Medicaid/CHIP PDM will be implemented at a time deemed appropriate by HHS to ensure the accuracy of the Medicaid/CHIP data before it is utilized for Exchange coverage terminations. Additionally, because the Medicaid/CHIP population may become eligible or ineligible for Medicaid/CHIP throughout a plan year as eligibility for the program is directly tied to fluctuations in income, we discussed that HHS will continue to evaluate the best manner by which to implement this process for Medicaid/CHIP PDM to ensure that Exchange enrollees do not experience unnecessary gaps in coverage. Similarly, we suggested that the two State Exchanges that operate their own eligibility and enrollment platform and that currently offer BHP coverage—New York and Minnesota—consider adding the option for consumer pre-authorization of terminations of Exchange coverage resulting from BHP PDM.

Given that enrollees may permit the Exchanges to terminate their QHP enrollment upon finding that they are dually-eligible for or enrolled in other MEC, in accordance with § 155.330(d), discussed above, we proposed to amend § 155.330(e)(2)(i)(D) to provide that Exchanges need not redetermine eligibility for APTC or CSRs for enrollees who (1) are found to be dually enrolled in QHP coverage and MEC consisting of Medicare, Medicaid/CHIP, or, if applicable, the BHP, (2) have not responded to the Exchange notice to provide updated information within 30-days, as required by § 155.330(e)(2)(i), and (3) have provided written consent to the Exchange to act to end their QHP coverage via PDM in the event of dual enrollment or eligibility. We discussed in the proposed rule that we believe that the revision would ensure more efficient Exchange operations and would make clear that a voluntary QHP termination conducted as part of PDM under § 155.430(b)(1)(ii) follows the same process as other enrollee-initiated voluntary terminations of QHP coverage. Furthermore, we noted that we believe the changes would support HHS's program integrity efforts by helping to ensure that APTC or CSRs are not paid inappropriately to those enrollees who are ineligible to receive subsidies. Finally, we stated that we believe the change would also ensure more efficient termination of unnecessary or duplicative coverage for consumers who have opted to have their coverage terminated in such circumstances.

We solicited comment on this proposal.

Comment: We received multiple comments in support of PDM as an effort to improve Exchange program integrity. These commenters agreed that the process has a positive impact on consumers as it helps inform Exchange enrollees of their enrollment in potentially duplicative other MEC, such as certain Medicare and Medicaid coverage, CHIP, or, if applicable, the BHP. Commenters also noted that the proposed changes help support efficient Exchange operations with respect to the PDM process, while minimizing burden on stakeholders such as states, issuers, consumers, and taxpayers. Commenters appreciated that the proposed changes continue to support flexibility for State Exchanges by providing all Exchanges with the option to allow applicants to provide written consent for Exchanges to end their QHP coverage if later found to be enrolled in Medicare, Medicaid/CHIP, or, if applicable, the BHP. A few commenters supported the proposed changes but sought clarification regarding whether eligibility determinations for APTC/CSRs would still be completed for non-impacted members remaining on the application. A few commenters suggested improvements that could be made to current PDM processes or noted concerns for HHS to consider.

We also received some mixed comments that supported the overall PDM process but cautioned us regarding the impact these proposed changes could have for the Medicaid/CHIP population. Commenters urged HHS to exercise caution as to not create coverage gaps for this population while other comments argued that terminations of QHP coverage through the Medicaid/CHIP process is inconsistent with current PDM requirements under § 155.330(d). One commenter suggested that we revise the current application question where applicants can provide written consent for Exchanges to end their QHP coverage through PDM to exclude Medicaid/CHIP as this language could be confusing for consumers as Exchanges currently do not terminate QHP coverage through Medicaid/CHIP PDM.

Response: We agree with commenters that the PDM process is an important tool for Exchange program integrity. We also agree with commenters that the PDM process helps inform consumers of their enrollment in potentially duplicative other MEC such as certain Medicare and Medicaid coverage, CHIP, or BHP, and helps consumers avoid a tax liability for having to repay APTC received during months of overlapping coverage when reconciling at the time of annual federal income tax filing.

Under current Medicare PDM operations in the Exchanges that use the Federal platform, when enrollees on whose behalf APTC or CSRs are being provided are identified as being enrolled in both an Exchange QHP and in Medicare (dual enrollment), notices are sent to the household contact, who may not always be the Medicare dual enrollee. The notice includes a list of persons on the household contact's Exchange application that the Exchange has identified as dually enrolled in Exchange coverage and Medicare. Enrollees have 30 days to respond to the Medicare PDM notice before the Exchange takes action to either end APTC/CSRs or QHP coverage for the Medicare dual enrollee. For non-dual

enrollees remaining on the application, to the extent they are eligible to continue their coverage, the Exchange will redetermine their eligibility for APTC/CSRs, and their coverage will continue with the APTC/CSR adjusted, as applicable. The same is true for Medicare dual enrollees who do not provide written consent for the Exchange to end their QHP coverage. In these cases, the Medicare dual enrollee is no longer eligible for APTC/CSRs, and eligibility is redetermined for the remaining persons on the application. Furthermore, in both scenarios, non-dual enrollees will receive an eligibility determination notice reflecting any changes to their eligibility for APTC/CSRs. In cases where family members of dual enrollees lose their coverage or their financial subsidies as a result of the PDM process described here, a special enrollment period may be available.

We appreciate commenters' concerns regarding QHP terminations for the Medicaid/CHIP population through PDM. We share these concerns and are exploring ways to implement terminations of QHP coverage for the Medicaid/CHIP population and to reduce consumer confusion. For example, in 2019, we revised the current application question by which applicants may provide written consent for the Exchange to terminate their QHP coverage through PDM to ensure that consumers understand the consequences of dual enrollment. HHS is also currently exploring ways to operationalize terminations through Medicaid/CHIP PDM that are the least disruptive for Medicaid/CHIP dual enrollees, as eligibility for Medicaid/CHIP may change throughout a plan year due to fluctuations in household income. We want to ensure that terminations through Medicaid/CHIP PDM are developed in a manner that still provides a pathway back into QHP coverage should a previously identified Medicaid/CHIP dual enrollee no longer be eligible for Medicaid/CHIP and need to be re-enrolled in an Exchange QHP. We are also exploring ways to improve the accuracy of state Medicaid/CHIP data to ensure that Exchange enrollees are not erroneously identified as also enrolled in Medicaid/CHIP and subsequently lose Exchange QHP coverage due to data errors. We continue to monitor data matching results each round of Medicaid/CHIP PDM and are working to provide guidance directly to states in instances where we believe data matching errors may have occurred.

Finally, we disagree with commenters that terminations of Exchange QHP coverage through Medicaid/CHIP PDM is inconsistent with the current regulation at § 155.330(d). As discussed in the preamble, the Exchange has authority under § 155.430(b)(1)(ii) to provide the opportunity for an enrollee to have their QHP coverage terminated if the Exchange finds that they have become eligible for or enrolled in other MEC, such as Medicare, Medicaid/CHIP, or, if applicable, the BHP. We believe that such terminations through PDM benefit consumers because they mitigate the risk that consumers are paying for duplicate coverage and the risk that consumers will be required to pay back all or some of the APTC received during months of overlapping coverage.

After reviewing the public comments, we are finalizing the proposal as proposed.

b. Effective Date for Termination via Death PDM

In accordance with § 155.330(e)(2), Exchanges must periodically check available data sources to identify Exchange enrollees who are deceased and must terminate a deceased person's QHP coverage after following the process outlined at § 155.330(e)(2)(i) and after a redetermination of eligibility in accordance with § 155.330(e)(1). We proposed to amend § 155.330 to allow Exchanges, under appropriate circumstances, to terminate a deceased enrollee's coverage retroactively to the date of death, with no requirement to redetermine the eligibility of the deceased enrollee. We are finalizing this amendment as proposed.

In 2019, Exchanges using the Federal platform conducted one check for enrollees who are enrolled in QHP coverage and may have become deceased during plan year 2019. For plan year 2019 and beyond, under § 155.430(d)(7), Exchanges currently must terminate QHP coverage retroactively to the date of death when the Exchange terminates coverage due to the death of an enrollee during a plan year. We proposed to further amend § 155.330(e)(2)(i)(D) to provide that Exchanges are not required to redetermine eligibility of a deceased enrollee when the Exchange identifies a deceased enrollee via PDM and the enrollee does not respond or contest the updated information within the 30-day period specified in paragraph (e)(2)(i)(B). Under such circumstances, the Exchange would terminate coverage retroactively to the date of death, as specified in § 155.430(d)(7), with no requirement to redetermine the eligibility of the deceased enrollee. We explained in the proposed rule that we believe this policy will strengthen the integrity of the individual market by mitigating the risk of unnecessary funds leaving the Treasury in the form of APTC or CSRs for enrollees identified as deceased during a plan year.

We solicited comment on this proposal.

Comment: All commenters that submitted comments on this topic supported our proposal that Exchanges terminate coverage retroactively to the date of death without redetermining the eligibility of the deceased enrollee as part of PDM. These commenters noted that this proposal will support the expeditious termination of deceased enrollees and will be helpful to the families of the deceased enrollee, resulting in a positive consumer experience.

Response: We agree that the PDM process is an important tool to identify Exchange enrollees who may have become deceased during a plan year to ensure that issuers do not receive financial assistance on behalf of deceased enrollees and that deceased enrollees are more timely removed from QHP coverage. As commenters noted, the death of a family member or friend is a stressful time and those impacted may delay or forget to end QHP coverage for the deceased enrollee. In these instances, we agree that PDM can play an important role for the families of deceased enrollees by taking action to terminate QHP coverage for the deceased enrollee.

Comment: One commenter suggested that as part of PDM operations to identify deceased enrollees during a plan year, HHS should provide issuers with a specific reason code that identifies QHP plan terminations due to death.

Response: No additional reason code is necessary to identify QHP plan terminations due to death. In 2019, Exchanges using the federal eligibility and enrollment platform began conducting periodic checks for deceased enrollees on single member applications and subsequently terminated the deceased enrollee's QHP coverage back to the date of death. In order to notify issuers of these changes, we developed new maintenance reason codes specific to deceased enrollees discovered through PDM that issuers may use to identify Exchange enrollees who were terminated due to death. Exchange issuers receive these PDM specific maintenance reason codes through the 834 transaction process.

We are finalizing this policy as proposed, to amend § 155.330(e)(2)(i)(D) to reflect that Exchanges must terminate coverage retroactively back to the date of death in accordance with

§ 155.430(d)(7), with no requirement to redetermine eligibility for the deceased enrollee.

3. Automatic Re-Enrollment Process

In the proposed rule, we solicited comment on whether we should modify the automatic re-enrollment process such that any enrollee who would be automatically re-enrolled with APTC that would cover the enrollee's entire premium would instead be automatically re-enrolled without APTC or with some lesser amount of APTC. We are not finalizing changes to the automatic re-enrollment process in this rule.

In the proposed rule titled, ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020'' (84 FR 227) (proposed 2020 Payment Notice) we explained that enrollees in plans offered through Exchanges using the Federal platform can take action to re-enroll in their current plan or to select a new plan, or they can take no action and be automatically re-enrolled in their current plan (or if their current plan is no longer available, a plan selected under a hierarchy designed to identify a plan that is similar to their current plan).

Since the Exchange program's inception, Exchanges using the Federal platform have maintained an automatic re-enrollment process which generally continues enrollment for enrollees who do not take action to actively select the same or a different plan. Automatic re-enrollment significantly reduces issuer administrative expenses, makes enrolling in health insurance more convenient for the consumer, and is consistent with general health insurance industry practice. In the open enrollment period for 2019 coverage, 1.8 million people in FFE and SBE–FP states were automatically re-enrolled in coverage, including about 270,000 persons who were enrolled in a plan with zero premium after application of APTC.

The proposed 2020 Payment Notice sought comment on automatic re-enrollment processes and capabilities, as well as additional policies or program measures that might reduce eligibility errors and potential government misspending. As we noted in the final rule, ''Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2020'' (84 FR 17454) (final 2020 Payment Notice), commenters unanimously supported retaining the automatic re-enrollment processes. Supporters cited benefits such as the stabilization of the risk pool due to the retention of lower-risk enrollees who are least likely to actively re-enroll, the increased efficiencies and reduced administrative costs for issuers, the reduction of the numbers of uninsured, and lower premiums. Commenters believed existing processes, such as eligibility redeterminations, electronic and document-based verification of eligibility information, PDM, and APTC reconciliations, are sufficient safeguards against potential eligibility errors and increased federal spending.

We also noted in the final 2020 Payment Notice that we would continue to explore options to improve Exchange program integrity. As such, in the proposed 2021 Payment Notice, we solicited comment on modifying the automatic re-enrollment process such that any enrollee who would be automatically re-enrolled with APTC that would cover the enrollee's entire premium would instead be automatically re-enrolled without APTC or with a lesser amount of APTC. This modification could address concerns that automatic re-enrollment may lead to incorrect expenditures of APTC, some of which cannot be recovered through the reconciliation process due to statutory caps. We considered that there may be particular risk associated with enrollees who are automatically re-enrolled with APTC that cover the entire plan premium, since such enrollees do not need to make payments to continue coverage. The modifications discussed in the proposed rule could help ensure a consumer's active involvement in their re-enrollment because the consumer would need to return to the Exchange and obtain an updated eligibility determination prior to having the full amount of APTC for which the consumer was eligible paid to an issuer on their behalf for the upcoming year.

We further discussed in the proposed rule that if APTC for this population is reduced to a level that would result in an enrollee premium that is greater than zero dollars, the process would ensure a consumer's active involvement in re-enrollment because any enrollment in a plan with a premium greater than zero would require the enrollee to take action by making the premium payment to effectuate or maintain coverage and avoid termination of coverage for non-payment. We stated in the proposed rule that if we were to implement such a change, we would conduct consumer outreach and education alerting consumers to the new process and emphasizing the importance of returning to the Exchange during open enrollment to update their applications to ensure that their income and other information is correct and that they are still in the best plan for their needs. This outreach could include fact sheets, email or mail outreach depending on preference, and education among issuers, agents, brokers, Navigators, and other assisters.

We noted that under current regulations at § 155.335, each Exchange has some flexibility to define its own annual redetermination procedures. We solicited comment on whether the approaches discussed above should be adopted, and whether they should be adopted only for Exchanges using the Federal platform, maintaining automatic re-enrollment flexibility for State Exchanges that operate their own eligibility and enrollment platforms.

On December 20, 2019, section 1311(c) of PPACA was amended to require the Secretary to establish a process to re-enroll persons enrolled in 2020 QHP coverage through an FFE who do not actively re-enroll for plan year 2021 and who do not elect to disenroll for 2021 coverage during the open enrollment period for 2021.[93] We believe the current automatic re-enrollment process under § 155.335(j) (that was in place during the 2020 open enrollment period and prior years) will satisfy this requirement for automatic re-enrollment for the 2021 plan year.

Comment: All but one commenters on this request for comments opposed modifying the current automatic re-enrollment processes for a variety of reasons. Many believed that adopting the proposed changes could disadvantage the lowest income group of Exchange enrollees by taking away financial assistance for which they are eligible without evidence that they are at greater risk of incurring overpayments of APTC. Others questioned HHS's legal authority to apply an amount of APTC other than that determined in accordance with section 36B of the Code and sections 1411 and 1412 of the PPACA. Some commenters were specifically opposed to any requirement that State Exchanges modify their automatic re-enrollment processes because it would require costly IT system reconfigurations, consumer noticing changes, and additional investments to support increased Exchange customer service capacity that would be necessary to address consumer confusion caused by the change.

Most commenters supported the current automatic re-enrollment

[93] Further Consolidated Appropriations Act, 2020, Division N, title I, subtitle F, section 608 (Pub. L. 116–94: December 20, 2019, enacting H.R. 1865).

process, citing benefits such as the stabilization of the risk pool due to the retention of lower risk enrollees who are least likely to actively re-enroll, the increased efficiencies and reduced administrative costs for issuers, the reduction of the numbers of uninsured, lower premiums, and promotion of continuity of coverage. Many commenters believed that existing processes, including annual eligibility redetermination, periodic data matching, and APTC reconciliation, sufficiently safeguard against potential eligibility errors and increased federal spending. Other commenters noted that HHS provided no data indicating that the groups targeted by the proposed modifications are at a higher risk of receiving APTC overpayments.

Response: In light of commenters' overwhelming opposition to changing our automatic re-enrollment process, we will not change the current process at this time. We believe that existing Exchange safeguards have mitigated the risk of inappropriate APTC payments. These safeguards include requiring checks of the most recent IRS data and APTC reconciliation on the annual federal income tax return. HHS put into place new 'Failure to Reconcile' checks in 2018 that discontinued access to APTC for enrollees who did not file an annual federal income tax return or who filed an annual federal income tax return, but did not reconcile APTC. In addition, recent changes made in the 2019 Program Integrity rule require all Exchanges to conduct period data matching at least twice per year. We appreciate the comments on current processes and we will continue to explore options to improve Exchange program integrity going forward.

Comment: One commenter supported the changes for which HHS solicited comment and suggested HHS should end automatic re-enrollment for all consumers who are eligible for APTC. The commenter stated that requiring consumers who are eligible for APTC to return to the Exchange each year will better ensure integrity of government spending on APTC, citing concerns around insufficient verifications processes.

Response: We appreciate this comment. Notwithstanding, given the concerns many commenters expressed and the safeguards we have implemented to ensure eligibility is verified, we believe it would be inappropriate to end automatic re-enrollment for all consumers who are eligible for APTC at this time. We will continue to monitor the effectiveness of current program integrity safeguards and explore options to strengthen them in future rulemaking.

4. Enrollment of Qualified Individuals Into QHPs (§ 155.400)

We proposed revisions to binder payment deadlines under § 155.400(e)(1)(i) through (iv) to ensure consistency with revisions we proposed to § 155.420. Specifically, we proposed that in the Exchanges using the Federal platform, special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection. We also proposed to align the retroactive effective date and binder payment rules so that any consumer who is eligible to receive retroactive coverage, whether due to a special enrollment period, a favorable eligibility appeal decision, or a special enrollment period verification processing delay, has the option to pay the premium due for all months of retroactive coverage through the first prospective month of coverage, or only the premium for 1 month of coverage and receive prospective coverage only. We are finalizing these revisions as proposed. For a full discussion of the proposals related to prospective binder payment rules at § 155.400(e)(1)(i) and (ii), and retroactive binder payment rules at § 155.400(e)(1)(iii) and (iv), please see the preamble to § 155.420 of the proposed rule.

5. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for Cost-Sharing Reductions

We proposed to revise § 155.420 to allow silver level QHP enrollees and their dependents who become newly ineligible for CSRs to change to a QHP that is one metal level higher or lower than their current plan. We are finalizing these revisions as proposed, except that we are delaying the effective date of the revision related to new plans that may be chosen by an enrollee who loses CSR eligibility.

In 2017, the HHS Market Stabilization Rule preamble explained that HHS would move forward with a pre-enrollment verification of eligibility for certain special enrollment periods in all states served by the Federal platform. This practice was part of an effort to stabilize the individual market, and to address concerns that allowing individuals to enroll in coverage through a special enrollment period without electronic or document-based verification of eligibility could negatively affect the individual market risk pool by allowing individuals to newly enroll in coverage based on health needs during the coverage year, as opposed to enrolling during open enrollment and maintaining coverage for a full year.

To address related concerns that Exchange enrollees were utilizing special enrollment periods to change plan metal levels due to health needs during the coverage year, which negatively affects the individual market risk pool, the Market Stabilization Rule also set forth requirements at § 155.420(a)(4) to limit Exchange enrollees' ability to change to a QHP of a different metal level when they qualify for, or when a dependent(s) newly enrolls in, Exchange coverage through most types of special enrollment periods.[94]

We proposed to amend these rules in order to allow enrollees and their dependents who become newly ineligible for CSRs while enrolled in a silver-level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment in an Exchange. Generally, § 155.420(a)(4) provides that enrollees who newly add a dependent through most types of special enrollment periods may add the dependent to their current QHP or enroll the dependent in a separate QHP,[95] and that if an enrollee qualifies for certain special enrollment periods, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b). To ensure that individuals who are newly eligible for CSRs can access this benefit, § 155.420(a)(4)(ii) provides that if an enrollee and his or her dependents become newly eligible for CSRs in accordance with paragraph § 155.420(d)(6)(i) or (ii) and are not enrolled in a silver-level QHP, the Exchange must allow them to change to

[94] These limitations do not apply to enrollees who qualify for certain types of special enrollment periods, including those under §§ 155.420(d)(4), (8), (9), (10), (12), and (14). While special enrollment periods under §§ 155.420(d)(2)(i) and (d)(6)(i) and (ii) are excepted from § 155.420(a)(4)(iii), § 155.420(a)(4)(i) and (ii) apply other plan category limitations to them. See also the proposals about applicability of plan category limitations to certain special enrollment periods in this section of this final rule.

[95] Section 155.420(a)(4)(i) and (a)(4)(iii)(B) also provide that alternatively, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in 45 CFR 156.140(b).

a silver-level QHP so that they may access CSRs for which they are eligible.

However, as discussed in the proposed rule, there was no corresponding provision to permit enrollees and their dependents who become newly ineligible for CSRs in accordance with § 155.420(d)(6)(i) or (ii), and who are enrolled in a silver-level QHP, to change to a QHP of a different metal level in order to account for their change in financial assistance. Instead, if they wish to change plans, § 155.420(a)(4)(iii)(A) currently limits them to changing to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available). As explained in the proposed rule, since the implementation of § 155.420(a)(4) in states served by the Federal platform, HHS has received questions and concerns about this issue from Navigators, agents and brokers, and other enrollment assisters. Based on their experiences, consumers who lose eligibility for CSRs are often unable to afford cost sharing for their current silver-level QHP, and therefore, may need to change to a lower-cost QHP in order to maintain their coverage.

We proposed to redesignate § 155.420(a)(4)(ii) as (a)(4)(ii)(A) and add a new § 155.420(a)(4)(ii)(B) in order to allow enrollees and their dependents who become newly ineligible for CSRs in accordance with paragraph (d)(6)(i) or (ii) of this section, and are enrolled in a silver-level QHP, to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment in an Exchange. We further proposed to modify § 155.420(a)(4)(iii) to include § 155.420(d)(6)(i) and (ii) for becoming newly ineligible for CSRs in the list of trigger events excepted from the limitations at § 155.420(a)(3)(iii). As discussed, the proposal may help affected enrollees' ability to maintain continuous coverage for themselves and for their dependents in spite of a potentially significant change to their out of pocket costs. For example, an enrollee affected by an increase to his or her monthly premium payment could change to a bronze-level plan, while an enrollee who has concerns about higher copayment or co-insurance cost-sharing requirements could change to a gold-level plan. Finally, current regulations at 45 CFR 147.104(b)(2)(iii) establish that plan category limitations do not apply off-Exchange. Therefore, in the case of an individual who loses eligibility for CSRs and wishes to use his or her special enrollment period to purchase coverage off-Exchange, he or she is not limited to any specific metal level(s) of coverage.

We solicited comments on these proposals.

Comment: No commenters opposed this proposed change, and many commenters supported it for the reasons described above, explaining that allowing enrollees the flexibility to change to a plan of a different metal level based on a change in their financial assistance would allow more individuals to maintain coverage. Several commenters suggested that we provide more flexibility for Exchange enrollees to change to a different metal level plan. One commenter suggested allowing enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP to change to a QHP of any metal level. Another commenter suggested that enrollees who lose eligibility for APTC during the plan year should also be able to change to a plan of a different metal level. Several commenters disagreed with the need for plan category limitations in general. Of these commenters, one asked that State Exchanges have the option not to implement plan category limitations requirements at all. Another commenter noted that any loosening of special enrollment period regulations can affect the level of adverse selection in the market.

Response: We are finalizing these changes as proposed, but delaying to January 2022 the effective date for the modification of plan category limitations to allow Exchanges more time to implement the change. We agree with commenters who stated that it will help enrollees and their dependents who lose eligibility for CSRs during the plan year to stay enrolled in coverage by switching to a new QHP that better suits their changed financial situation. We disagree with commenters who suggested that the plan category limitation policy is not necessary to prevent adverse selection and protect the individual market risk pool. However, we acknowledge that enrollees who experience changes in their financial situation, such as an increase in income that makes them ineligible for APTC, may wish to change to a different metal level QHP for reasons that are not health related. Nonetheless, we share concerns that incorporating additional flexibility into plan category limitations rules could increase the risk of adverse selection; therefore, we are not doing so at this time.

Comment: While supporting this proposal in general, several commenters raised concerns that enrollees changing plans mid-coverage year might not realize that their out of pocket costs could increase if their deductible and other accumulators are re-set.

Response: HHS acknowledges these concerns, and works to promote health insurance literacy including an understanding of the implications of changing plans mid-coverage year.

Comment: One commenter asked that HHS permit and encourage or require issuers to preserve progress towards a deductible and other accumulators for enrollees who switch to a different metal level plan with the same issuer.

Response: These comments are outside the scope of the proposal; however, we clarify that HHS does allow issuers the option to preserve or to re-set progress towards accumulators for enrollees who switch plans mid-year.

Comment: Some commenters expressed support for this proposal based on a misunderstanding that it would allow Exchange enrollees who become newly *eligible* for CSRs to change to a silver-level QHP if they elect to change their QHP.

Response: We clarify that this flexibility already exists through § 155.420(a)(4)(ii), newly designated by this final rule as § 155.420(a)(4)(ii)(A).

Comment: Several commenters expressed strong support for providing State Exchanges with flexibility related to special enrollment period policy implementation, explaining that any special enrollment period changes require significant State Exchange effort and potentially unpredictable costs. Additionally, several commenters expressed the belief that this provision does provide Exchanges with flexibility in terms of whether and when to implement it.

Response: While we generally support flexibility for State Exchanges' policy and operations, we will continue to require all Exchanges to implement plan category limitations as established at § 155.420(a)(4), including changes finalized in this rule. These limitations are necessary to prevent adverse selection and to protect the individual market risk pool. To provide Exchanges with additional time to comply with new plan category limitations finalized in this rule, we are delaying the effective date of these changes to January 2022.

b. Special Enrollment Period Limitations for Enrollees Who Are Dependents

We proposed to apply the same plan category limitations to dependents who are currently enrolled in Exchange coverage that applies to current, non-dependent Exchange enrollees. We are finalizing this policy as proposed.

As discussed in the preceding section of this preamble, under § 155.420(a)(4)(i) and (a)(4)(iii)(B), enrollees who newly add a dependent through most types of special enrollment periods may add the dependent to their current QHP or enroll the dependent in a separate QHP.[96] Specifically, § 155.420(a)(4)(i) establishes that if an enrollee has gained a dependent in accordance with § 155.420(d)(2)(i), the Exchange must allow the enrollee to add the dependent to his or her current QHP. But if the current QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b), or, at the option of the enrollee or dependent, enroll the dependent in any separate QHP.[97] Per § 155.420(a)(4)(iii)(B), if a dependent qualifies for a special enrollment period not related to becoming a new dependent, and an enrollee is adding the dependent to his or her QHP, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the QHP's business rules do not allow the dependent to enroll in that plan, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b), or enroll the new qualified individual in a separate QHP. Finally, § 155.420(a)(4)(iii)(A) requires that if an enrollee qualifies for certain special enrollment periods, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b).

Per § 155.420(a)(2), a dependent refers to any individual who is or who may become eligible for coverage under the terms of a QHP because of a relationship to a qualified individual or enrollee. As described in the proposed rule, the rules at § 155.420(a)(4) did not previously address all situations in which a current enrollee is a dependent of a qualified individual who is newly enrolling in Exchange coverage through a special enrollment period. For example, the current rules do not explicitly address what limitations apply when a mother loses her self-only employer-sponsored coverage, thereby gaining eligibility for a special enrollment period for loss of MEC, and seeks to be added as an enrollee to the Exchange coverage in which her two young children are currently enrolled. Applying the limitations at § 155.420(a)(4) to such circumstances is consistent with HHS's goals of establishing equivalent treatment for all special enrollment period eligible qualified individuals, and preventing enrollees from changing plans in the middle of the coverage year based on ongoing or newly emerging health issues. Preamble language from the 2017 Market Stabilization Proposed Rule explained that the requirement at § 155.420(a)(4)(iii) would extend to enrollees who are on an application where a new applicant is enrolling in coverage through a special enrollment period, using general terms to convey that restrictions should apply to enrollees and newly-enrolling individuals regardless of whether the new enrollee is a dependent.[98]

To ensure that Exchange enrollees and qualified individuals are treated consistently under our special enrollment period rules, we proposed to apply the same limitations to dependents who are currently enrolled in Exchange coverage that applies to current, non-dependent Exchange enrollees. Specifically, we proposed to add a new § 155.420(a)(4)(iii)(C) to establish that the Exchange must allow a qualified individual who is not an enrollee, who qualifies for a special enrollment period and has one or more dependents who are enrollees, to add him or herself to a dependent's current QHP; or, per similar existing rules at § 155.420(a)(4)(iii)(B), if the QHP's business rules do not allow the qualified individual to enroll in such coverage, to enroll with his or her dependent(s) in another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b), or enroll him or herself in a separate QHP.

As proposed, § 155.420(a)(4)(iii)(C) would be parallel to § 155.420(a)(4)(iii)(B), which applies plan category limitations to current enrollees whose dependent(s) qualify for a special enrollment period to newly enroll in coverage, and specifies that the Exchange must permit the enrollee to change plans in order to add the dependent when the enrollee's current plan's business rules do not permit adding the dependent, notwithstanding whether the enrollee also qualifies for a special enrollment period. In other words, as proposed, § 155.420(a)(4)(iii)(C) would apply plan category limitations in allowing currently enrolled dependents who are enrolled in a plan that has business rules that do not permit the non-dependent to be added to the enrollment, to change plans in order to enroll together with the non-dependent.

Current regulations at § 147.104(b)(2)(iii) provide that § 155.420(a)(4) does not apply off-Exchange. Therefore, the existing and proposed requirements and restrictions under § 155.420(a)(4) do not apply off-Exchange. However, our regulations do not prohibit issuers off-Exchange from newly enrolling with currently enrolled dependents a non-dependent household member(s) who qualifies for a special enrollment period, or from newly enrolling dependent household members who qualify for a special enrollment period with currently enrolled individuals of whom they are a dependent, to the extent consistent with applicable state law.

Comment: Several commenters supported this proposal based on their position that it is appropriate to apply the same limitations to any individual seeking to newly enroll in Exchange coverage with a currently-enrolled household member(s), and a few supported this proposal because it would simplify special enrollment period rules. One of these commenters asked that HHS continue not to apply the plan category limitations policy to off-Exchange enrollments.

Response: We agree with these comments, and note that at this time we do not plan to apply plan category limitations off-Exchange.

Comment: Multiple commenters supported this proposal, but misunderstood it to be either the creation of a new special enrollment period or of a new process for those who qualify for an existing special enrollment period to allow parents or guardians to add themselves to a dependent's Exchange coverage.

Response: Here, we clarify that the proposal would not create a new special enrollment period or incorporate additional flexibility into existing plan category limitations rules; in fact, it clarifies that these limitations apply to Exchange enrollees who are dependents in the same way that they apply to

[96] Section 155.420(a)(4)(i) and (a)(4)(iii)(B) also provide that alternatively, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in 45 CFR 156.140(b).

[97] Per § 155.420(a)(2), ''dependent'' has the same meaning as it does in 26 CFR 54.9801–2, referring to any individual who is or who may become eligible for coverage under the terms of a QHP because of a relationship to a qualified individual or enrollee.

[98] 82 FR at 10986.

Exchange enrollees who are not dependents.

Comment: Additionally, one commenter misunderstood the proposal to be a change in how the Federally-facilitated Exchanges operationalize special enrollment periods for individuals newly enrolling in coverage with dependents.

Response: We clarify that we are not proposing any changes to how Exchanges using the Federal platform operationalize special enrollment periods for these individuals, including how these Exchanges send this type of enrollment to issuers.

Comment: Several commenters opposed this proposal, citing opposition to plan category limitations more generally. As discussed above, one commenter asked that HHS provide State Exchanges with flexibility in terms of when, and whether, to implement plan category limitations.

Response: While we generally support flexibility for State Exchanges' policy and operations, we will continue to require all Exchanges to implement plan category limitations as established at § 155.420(a)(4), including changes finalized in this rule. These limitations are necessary to prevent adverse selection and to protect the individual market risk pool.

Comment: Some commenters stated that a household should be able to re-assess plan choice, including choice of metal level, in situations where a parent or guardian newly enrolls in Exchange coverage with his or her dependents. These commenters expressed doubt that permitting this flexibility would cause adverse selection.

Response: As discussed in the proposed rule, we agree with comments that expressed support for applying plan category limitations to all Exchange enrollees in the same way. Relatedly, we do not think that Exchange enrollees who are dependents are any less likely than enrollees who are not dependents to change to a different metal level plan through a special enrollment period due to ongoing health needs during the coverage year. Therefore we believe it is appropriate to apply the same plan category limitations to all enrollees, whether or not they are dependents.

Comment: One commenter requested clarification of the proposed regulation text; specifically, how it would impact Exchange enrollees who are dependents and whose parent or guardian is newly enrolling in coverage with them, and who themselves are also eligible for a special enrollment period.

Response: Exchange enrollees who are dependents and whose parent or guardian is newly enrolling in coverage with them through a special enrollment period, and who themselves are also eligible for a special enrollment period, will be limited based on the rules at § 155.420(a)(4) that apply to them. For example, if a parent enrolls in coverage with her dependent child through a special enrollment period due to a move for which they both qualify, then per § 155.420(a)(4)(iii)(A), the currently-enrolled dependent may change to a QHP of the same metal level as his current plan (or one metal level higher or lower, if no such QHP is available). Per § 155.420(a)(iii)(C), the parent may enroll in her child's QHP, or, if the QHP's business rules do not allow her to enroll, the Exchange must allow her and her child to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), or enroll herself in a separate QHP of any metal level.

c. Special Enrollment Period Prospective Coverage Effective Dates

We proposed that in the Exchanges using the Federal platform, special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection. Specifically, we proposed to amend § 155.420(b)(3) for improved clarity and to specify how Exchanges using the Federal platform would implement the proposal. We are finalizing these policies as proposed, but delaying the effective date until January 2022 to allow the sufficient time to implement these changes.

Under regular special enrollment period effective date rules at current § 155.420(b)(1), the Exchange is required to ensure a coverage effective date of the first day of the following month for individuals who select a QHP between the 1st and the 15th day of any month. The Exchange was required to ensure a coverage effective date of the first day of the second following month for individuals who select a QHP between the 16th and the last day of any month. Under those rules, it could take as many as 47 days from plan selection to effectuate coverage under a special enrollment period (that is, from the 16th of a month to the first of the next following month; or for example, from July 16 to September 1). In the Exchanges using the Federal platform and pursuant to § 155.420(b)(1), those rules apply to special enrollment periods provided under § 155.420(d)(3), (d)(6)(i), (ii), (iv), and (v), and (d)(7), (8), (10), and (12). Under other special enrollment periods, such as those under § 155.420(d)(4), (5), and (9), in the Exchanges using the Federal platform, the consumer is generally offered a choice of regular effective dates that would apply under § 155.420(b)(1), or an effective date that is retroactive to the date that would have applied if not for the triggering event. In addition, under § 147.104(b)(5), the coverage effective date rules in § 155.420(b) apply to each of those special enrollment periods to the extent they apply off-Exchange, as specified in § 147.104(b)(2)(i).

These regular special enrollment period effective date rules under § 155.420(b)(1), along with the initial open enrollment period effective date rules under § 155.410(c), were originally designed to provide issuers several weeks to collect binder payments, mail identification cards, and complete other administrative actions prior to the policy's start date. However, QHP issuers that offer coverage through the Federal Exchange, already effectuate coverage and process changes in circumstance using first-of-the-month rules. In 2017, issuers processed 88 percent of special enrollment periods for individuals newly enrolling in coverage through Exchanges using the Federal platform under accelerated or retroactive effective date rules.[99] HHS internal data on enrollments through Exchanges using the Federal platform in 2018 indicates that issuers processed a majority of changes in circumstances (including those resulting in special enrollment periods) under accelerated or faster effective date rules. Because issuers in Exchanges using the Federal platform routinely effectuate coverage on a shorter timeframe, we do not anticipate that this change would be difficult for issuers to implement.

Additionally, we explained that as a program integrity measure, we believe any enrollment changes related to changes in eligibility for Exchange coverage or for insurance affordability programs should be implemented as soon as practicable. This is particularly important for consumers with special enrollment periods based on changes in eligibility for APTC under § 155.420(d)(6)(i) and (ii), which currently follow regular effective date rules in the Exchanges using the Federal platform.

As discussed in the proposed rule, the provision will permit Exchanges, including Exchanges using the Federal platform, and issuers to more rapidly implement changes in QHP enrollment, particularly those related to changes in financial assistance eligibility, and

[99] Centers for Medicare & Medicaid Services, The Exchanges Trends Report (July 2, 2018), available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-3.pdf.*

would standardize prospective special enrollment period effective dates across the Exchanges using the Federal platform, such that consumers eligible for prospective coverage would have a single effective date. It will also help reduce consumer confusion regarding different effective date rules and minimize gaps in coverage.

Finalizing this proposal will also allow State Exchanges the flexibility to retain current special enrollment period regular effective date rules or to adopt the approach that will be taken in the Exchanges using the Federal platform. State Exchanges already had flexibility under § 155.420(b)(3) to effectuate coverage in a shorter timeframe if their issuers agree. Several State Exchanges had already transitioned to faster than regular effective date rules for special enrollment periods. Under these changes, State Exchanges may retain their current effective date rules or implement faster ones without needing to demonstrate issuer concurrence.

By reference, the effective-date-of-coverage rules at § 155.420(b) apply off-Exchange, under § 147.104(b)(5). The proposal would continue to provide the applicable state authority with flexibility regarding the options for effective dates under current rules for off-Exchange coverage.

This change will also help reduce confusion around binder payment deadlines, since these deadlines depend on a policy's coverage effective date. Accordingly, we proposed to make updates to binder payment deadlines in § 155.400(e)(1)(ii) to ensure that special enrollment periods using effective dates under revised § 155.420(b)(3) would also be subject to the same binder payment rules as other special enrollment periods that are effective the first of the month following plan selection. Because the Exchanges using the Federal platform would no longer be following regular coverage effective dates for special enrollment periods under § 155.420(b)(1), we also proposed to remove reference to that provision in § 155.400(e)(1)(i) and to replace ''regular effective dates'' in § 155.400(e)(1)(iii) with a reference to § 155.420(b)(3). This latter change provides that in the Exchanges using the Federal platform, coverage would be effective on the first of the month following plan selection for consumers who are eligible for retroactive coverage but just pay 1 month's premium and receive only prospective coverage. This change will help ensure that prospective effective dates across the Exchanges using the Federal platform are streamlined under one rule.

We solicited comments on these proposals.

Comment: Most commenters supported this proposal, noting that it will reduce consumer confusion and minimize gaps in coverage. Several commenters stressed the importance of continued flexibility for State Exchanges. One commenter cautioned that this provision could create operational challenges that are difficult to overcome if it is implemented without accounting for a reasonable timeframe for binder payment to effectuate coverage. A commenter urged HHS to ensure that controls are in place to reduce gaming. Specifically, the commenter asked that HHS review current special enrollment period verification processes and make any updates needed to verify eligibility for first of the month coverage following special enrollment periods.

Response: We agree with commenters that this provision will help reduce coverage gaps for consumers who enroll with a special enrollment period and, by harmonizing with coverage effective dates that apply to many of the most common special enrollment periods, will also reduce consumer confusion regarding enrollment through special enrollment periods. As we noted in the preamble to the proposed rule, because issuers in Exchanges using the Federal platform routinely effectuate coverage on a shorter timeframe, we do not anticipate that this change will be difficult for issuers to implement. We continue to monitor the special enrollment period verification process. If any changes are needed to verify eligibility for special enrollment periods that are effective on the first of the month following plan selection, we will explore solutions. Further, current special enrollment period verification processes require many enrollments submitted through the Federal platform to be pended until after verification, after which the enrollment will be released to the issuer with the appropriate effective date. Therefore, we do not anticipate this change will result in additional consumer gaming.

Comment: One commenter requested that this provision be implemented off-Exchange as well, while one commenter asked HHS to confirm that proposed changes for on-Exchange enrollments alone do not seek to regulate existing off-Exchange practices.

Response: Because we believe states are generally in the best position to determine the effective dates that apply in State Exchanges and off-Exchange, we are limiting this provision to QHPs on the Exchanges using the Federal platform. States will continue to have the same flexibility off-Exchange and in State Exchanges to adopt earlier effective dates as they currently have.

We are finalizing the rule as proposed, but delaying the effective date until January 2022 to allow sufficient time to implement these changes.

d. Special Enrollment Period Retroactive Coverage Effective Dates

We proposed to eliminate the option for a consumer whose enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, under certain circumstances, to elect a coverage effective date that is no more than 1 month later than the effective date the consumer would otherwise have had but for the delay. This provision will align the retroactive effective date and binder payment rules so that any consumer who is eligible to receive retroactive coverage, whether due to a special enrollment period, a favorable eligibility appeal decision, or a special enrollment period verification processing delay, has the option to pay the premium due for all months of retroactive coverage through the first prospective month of coverage, or only the premium for 1 month of coverage and receive prospective coverage only. Specifically, we proposed to eliminate § 155.420(b)(5).

We are finalizing this policy as proposed.

Section 155.400(e)(1)(iii) states that for coverage to be effectuated under retroactive special enrollment period effective dates, as provided for in § 155.420(b)(2), a consumer's binder payment must include the premium due for all months of retroactive coverage through the first prospective month of coverage. If only the premium for 1 month of coverage is paid, only prospective coverage should be effectuated, in accordance with regular effective dates. As an example, a consumer has a special enrollment period that is not subject to verification with a March 1 effective date, but the enrollment is delayed due to an Exchange error. The issuer does not receive the transaction until April 15. Under this rule, to effectuate retroactive coverage beginning March 1, the issuer must receive premiums for March, April, and May. If the issuer only receives a premium payment for 1 or 2 months of coverage, it must effectuate only prospective coverage beginning May 1. This rule was designed to allow consumers who might have difficulty paying for retroactive coverage through a special enrollment period or a favorable eligibility appeal decision to

enroll with prospective coverage only.[100]

The Market Stabilization Rule added a different set of binder payment rules at § 155.400(e)(1)(iv) for retroactive effective dates after an enrollment has been delayed due to a prolonged special enrollment period verification under § 155.420(b)(5).[101] Under current rules, if a consumer's enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, and the assigned effective date would require the consumer to pay 2 or more months of retroactive premium to effectuate coverage or avoid cancellation, the consumer has the option to choose a coverage effective date that is no more than 1 month later than had previously been assigned. If the consumer does not move her effective date, her binder payment would be the premium due for all months of retroactive coverage through the first prospective month of coverage, consistent with other binder payment rules. For instance, if the consumer's special enrollment period in the above example were subject to verification, and, as above, the March 1 effective date were pended until April 15 due to pre-enrollment verification, the consumer's only effective date options require payment for retroactive months, unlike the previous example. To effectuate coverage under the special enrollment period verification rules in current §§ 155.400(e)(1)(iv) and 155.420(b)(5), she could either pay the premiums for March, April, and May; or move her effective date forward only 1 month to April 1, and must still pay for April and May coverage.

HHS established the special enrollment period verification effective date rules in response to issuer concerns that delays in special enrollment period verification and an un-checked ability of consumers to move their effective date later (as contemplated in the original version of that paragraph in the 2018 Payment Notice) would result in adverse selection, with healthier enrollees requesting a later effective date and sicker enrollees keeping the original retroactive date. However, we have been able to manage our operational processes so that delays in special enrollment period verification processing have not materialized. As described in the proposed rule, in 2017, we averaged a response time of 1 to 3 days to review consumer-submitted special enrollment period verification documents and provide consumers a response.[102] The response time in 2018 was substantially similar. Additionally, in 2018 and 2019, we resolved over 800,000 special enrollment period verifications, and fewer than 300 enrollees subject to special enrollment period verification have requested to move forward their effective date under §§ 155.400(e)(1)(iv) and 155.420(b)(5). This indicates that these rules are largely unnecessary.

We also proposed to remove the corresponding cross-reference at § 155.420(b)(1) and the special enrollment period verification binder payment rule at § 155.400(e)(1)(iv). Finally, we proposed to amend § 155.400(e)(1)(iii) to state more explicitly that any consumer who can effectuate coverage with a retroactive effective date, including those whose enrollment is delayed until after special enrollment period verification, also has the option to effectuate coverage with the applicable prospective coverage date by choosing to only pay for 1 month of coverage by the applicable deadline, notwithstanding the retroactive effective date that the Exchange otherwise would be required to ensure.

Standardizing a single binder payment rule for retroactive effective dates will improve operational efficiency for issuers and Exchanges using the Federal platform. Issuers have indicated that it is difficult to determine the appropriate binder payment rule to apply to an enrollment with a retroactive effective date when they receive fewer than all retroactive months of premium, because issuers need to discern whether the consumer's eligibility stems from an appeal, a non-verified special enrollment period, or a special enrollment period with a delay in verification processing. For example, if on March 5, an issuer receives a plan selection for a mother and child enrolling through an adoption special enrollment period with a January 10 effective date, and neither the mother nor child are current enrollees with the issuer, the issuer has no way of knowing whether this transaction was subject to verification. If the issuer in this case only receives 1 month's premium, it would not know whether to cancel the enrollment or effectuate prospective-only coverage. This change will simplify issuer operations by eliminating that complexity.

Implementing a single set of binder payment rules will help ensure all enrollees (including those subject to special enrollment period verification) can access affordable coverage without being required to pay for months of retroactive coverage that may be prohibitively expensive, and during which most providers would have insisted on direct payment in order to provide health care services.

Finally, by reference, the effective-date-of-coverage rules at § 155.420(b) apply off-Exchange, in accordance with § 147.104(b)(5). Therefore, removing § 155.420(b)(5) will also remove this requirement off-Exchange.

We solicited comments on these proposals, including alternative approaches to streamlining retroactive effective date rules.

Comment: Many commenters supported our proposal. One commenter suggested that to the extent HHS proceeds with the proposal, HHS should afford flexibility to State Exchanges in how they address retroactive coverage.

Response: For the reasons explained elsewhere in this subsection of the preamble, this provision, simply reverts retroactive coverage effective date policy to the policy that was in place prior to the 2018 Payment Notice. State Exchanges were previously required to follow retroactive special enrollment period effective date rules, and this change does not alter that.

Comment: Several commenters asked that we continue to monitor special enrollment period verification speed and return to the earlier process should any delays in verification resume. One commenter urged us to establish a system whereby the consumer is intentionally selecting their effective date on the Exchange and then that date is communicated from Exchanges using the Federal platform. A number of commenters asked for consumers to be able to select partial or full coverage post-appeal, and a group of commenters urged that consumers may have valid reasons for requesting partial retroactive coverage.

Response: HHS will continue to monitor the speed of special enrollment period verification and will reconsider this change if there is evidence of regular and significant delays. We will consider establishing a system whereby a consumer can select their effective date in the application for Exchanges using the Federal platform, but note that such a program would be operationally complex to implement, as would allowing consumers to select partial

[100] If the enrollee pays some, but not all, months of retroactive premium due (two months in the example above), then the issuer would effectuate coverage prospectively. See 2017 Payment Notice, 81 FR at 12272. The issuer could then apply any amount paid in excess of 1 month's premium but less than the full amount needed to effectuate retroactive coverage to the next month's premium, or refund the excess amount to the enrollee, at the enrollee's request.

[101] Market Stabilization Rule, 82 FR at 18346.

[102] Centers for Medicare & Medicaid Services, The Exchanges Trends Report (July 2, 2018), available at *https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/2018-07-02-Trends-Report-3.pdf.*

retroactive coverage post-appeal. Such a system might also present adverse selection concerns.

Comment: Several commenters expressed concern that this proposal would result in challenges for issuers in determining how to proceed with a binder payment in order to effectuate retroactive or prospective coverage. One commenter suggested that HHS should specify that this option should not be allowed for periods during which an individual used covered services.

Response: Under § 155.400(e)(1)(iv), issuers determine a consumer's effective date if the consumer was eligible for retroactive coverage, based on the premium paid. That provision states that for coverage to be effectuated under retroactive special enrollment period effective dates, as provided for in § 155.420(b)(2), a consumer's binder payment must include the premium due for all months of retroactive coverage through the first prospective month of coverage. If only the premium for 1 month of coverage is paid, only prospective coverage should be effectuated, in accordance with regular effective dates. This proposal would simply streamline all retroactive effective date rules, including for consumers who enrollment is pended due to special enrollment verification. These rules apply whether or not an individual was using covered services.

After reviewing the public comments, we are finalizing this provision as proposed.

e. Enrollees Covered by a Non-Calendar Year Plan Year QSEHRA

We proposed to codify the policy that qualifying individuals and dependents who are provided a qualified small employer HRA (QSEHRA) with a non-calendar year plan year would be eligible for the special enrollment period at § 155.420(d)(1)(ii) for qualified individuals and dependents who are enrolled in any non-calendar year group health plan or individual health insurance coverage, to allow the same flexibility for employees and dependents who are provided QSEHRAs as is available to those who are offered individual coverage HRAs.[103]

The HRA rule allows employers to offer HRAs and other account-based group health plans integrated with individual health insurance coverage or Medicare Part A and B or Part C, if certain conditions are satisfied.[104] These are called individual coverage HRAs. Among other conditions, an individual coverage HRA must require that the participant and any covered dependent(s) be enrolled in individual health insurance coverage (either on or off-Exchange) or Medicare Part A and B or Part C, for each month that they are covered by the individual coverage HRA.[105]

The HRA rule provides a special enrollment period to employees and dependents who newly gain access to an individual coverage HRA to enroll in individual health insurance coverage, or to change to other individual health insurance coverage in order to maximize the use of their individual coverage HRA.[106] In addition, because employees and dependents with a QSEHRA [107] generally must be enrolled in MEC,[108] and one category of MEC is individual health insurance coverage, the HRA rule provides that individuals who are newly provided a QSEHRA also qualify for the new special enrollment period.

The HRA rule also solicited and addressed public comments on whether the new special enrollment period should be available on an annual basis at the beginning of each new plan year of the employee's individual coverage HRA or QSEHRA, particularly if the new plan year is not aligned with the calendar year.[109] In the preamble to the HRA rule, HHS stated that it had determined that individual coverage HRA or QSEHRA enrollees should have the option to re-evaluate their individual health insurance coverage for each new HRA plan year, regardless of whether the HRA is provided on a calendar year basis. Therefore, while the HRA rule did not make the new individual coverage HRA and QSEHRA special enrollment period available on an annual basis, it clarified that those who are enrolled in an individual coverage HRA with a non-calendar year plan year—that is, the HRA's plan year begins on a day other than January 1—will be eligible annually for the special enrollment period under existing regulations at § 155.420(d)(1)(ii), because individual coverage HRAs are group health plans. While the HRA rule did not make any changes to § 155.420(d)(1)(ii), the preamble of the rule expressed HHS's intention to treat a QSEHRA with a non-calendar year plan year as a group health plan for the limited purpose of qualifying for this special enrollment period, and to codify this interpretation in future rulemaking.[110]

As HHS explained in the HRA rule, we believe making the non-calendar year plan year special enrollment period available annually to individual market enrollees with a non-calendar year plan year individual coverage HRA or QSEHRA appropriately provides employers with flexibility to offer individual coverage HRAs or provide QSEHRAs on a 12-month cycle that meets their needs. The expansion also allows employees and their dependents the flexibility to re-assess their individual health insurance coverage options at the same time that the terms of their individual coverage HRA or QSEHRA may change. We believe accessing this non-calendar year plan year special enrollment period may be important to some individuals, including those who wish to change their individual health insurance plan due to a change in the terms of their individual coverage HRA or QSEHRA. However, we anticipate that most individuals with an individual coverage HRA or a QSEHRA would not seek to change their individual coverage outside of the individual market open enrollment period when their new HRA plan year starts since doing so would generally cause their accumulators to reset. Therefore, we do not anticipate significant additional administrative burden for issuers or a significant increase in the potential for adverse selection in the individual market associated with this special enrollment period. In addition, HHS believes that the applicability of plan category limitations to the non-calendar year plan year special enrollment period for Exchange enrollees will further mitigate the potential risk of adverse selection.

As discussed in the HRA rule preamble,[111] under section 2791 of the PHS Act, section 733 of ERISA, and section 9831 of the Code, QSEHRAs are not group health plans,[112] and

[103] This preamble refers to a QSEHRA being ''provided'' as opposed to being ''offered'' because, per § 146.123(c)(4), an individual coverage HRA eligible employee has an annual opportunity to opt out of and forfeit future payments from the HRA. However, this is not the case for employees and dependents with a QSEHRA.

[104] 84 FR 28888 (June 20, 2019).

[105] For purposes of individual coverage HRAs, references to individual health insurance coverage do not include individual health insurance coverage that consists solely of excepted benefits. See 45 CFR 146.123(c)(1)(i).

[106] See § 155.420(d)(14).

[107] Section 18001 of the Cures Act amends the Code, ERISA, and the PHS Act to permit an eligible employer to provide a QSEHRA to its eligible employees. See IRS Notice 2017–67, 2017–11 IRB 1010, for related guidance: *https://www.irs.gov/pub/irs-drop/n-17-67.pdf.*

[108] Generally, payments from a QSEHRA to reimburse an eligible employee's medical care expenses are not includible in the employee's gross income if the employee has coverage that provides MEC as defined in Code section 5000A(f), which includes individual health insurance coverage.

[109] 84 FR at 28955 through 28956.

[110] Id. at 28956.

[111] 84 FR at 28956.

[112] One exception to this general rule is that a QSEHRA continues to be treated as a group health

employees and their dependents with a QSEHRA do not qualify for the non-calendar year special enrollment period as our special enrollment period rules are currently written. Therefore, we proposed to amend § 155.420(d)(1)(ii) to codify that individuals and dependents who are provided a QSEHRA with a non-calendar year plan year may qualify for this special enrollment period. We noted that this special enrollment period also is incorporated by reference in the guaranteed availability regulations at § 147.104(b)(2). Therefore, individuals provided a non-calendar year plan year QSEHRA would be entitled to a special enrollment period to enroll in or change their individual health insurance coverage through or outside of an Exchange.

We solicited comment on this proposal.

After consideration of the comments received, we are finalizing this policy and the accompanying update to § 155.420(d)(1)(ii) as proposed.

Comments: Many commenters supported this proposal. Several expressed support because it aligns special enrollment period eligibility for consumers whose employer provides them with a QSEHRA with that of consumers whose employer offers them an individual coverage HRA, and several supported it due to their general support of all provisions to promote the use of HRAs. Some commenters supported the proposal, but misunderstood it to be the creation of a new special enrollment period for consumers who are newly provided with a QSEHRA.

Response: We clarify that employees and dependents newly provided with a QSEHRA are already included in the special enrollment period at § 155.420(d)(14), which we established in the HRA Rule for individuals, enrollees, and dependents who newly gain access to an individual coverage HRA *or to a QSEHRA.* We appreciate the general support for allowing employees and dependents with a non-calendar year plan year QSEHRA to change plans annually based on their QSEHRA plan year start date, and we are finalizing the policy and the accompanying update to § 155.420(d)(1)(ii) as proposed.

6. Termination of Exchange Enrollment or Coverage (§ 155.430)

a. Enrollee-Initiated Terminations Upon a Finding of Dual Enrollment in Medicare via PDM

Consistent with our discussion of voluntary terminations upon a finding of dual enrollment in the preamble to § 155.330, we proposed to revise paragraph (b)(1)(ii) by removing the requirement that the Exchange must initiate termination of a Medicare dual enrollee's QHP coverage upon completion of the redetermination process specified in § 155.330. We also proposed to add to § 155.330(b)(1)(ii) a reference to the process and authority outlined in § 155.330(e)(2) to align with the proposed changes to § 155.330(e)(2)(i)(D), discussed in the preamble on the proposed rule at § 155.330. For more detailed discussions of these proposals, please see the preamble discussion in the proposed rule at § 155.330. We are finalizing these revisions as proposed.

Comment: We received multiple comments in support of Medicare PDM as an effort to improve Exchange program integrity. These commenters agreed that the process has a positive impact on consumers as it helps inform Exchange enrollees of their enrollment in potentially duplicative other MEC such as certain Medicare. Commenters also noted that the proposed changes help support efficient Exchange operations with respect to the Medicare PDM process while minimizing burden on stakeholders such as states, issuers, consumers, and taxpayers. Commenters appreciated that the proposed changes continue to support flexibility for State Exchanges by providing all Exchanges with the option to allow applicants to provide written consent for Exchanges to end their QHP coverage if later found to be enrolled in Medicare.

Response: We agree with commenters that the Medicare PDM process is an important tool for Exchange program integrity. We also agree that the process helps inform consumers of their enrollment in potentially duplicative other MEC such as certain Medicare and helps consumers avoid a tax liability for having to repay APTC received during months of overlapping coverage when reconciling at the time of annual federal income tax filing.

After reviewing the public comments, we are finalizing as proposed.

b. Effective Dates for Retroactive Termination of Coverage or Enrollment Due to Exchange Error

In the proposed rule, we proposed to update the rule that defines the effective date for enrollees seeking retroactive terminations due to a technical error to allow their coverage to end retroactive to the date they attempted the termination, without the 14-day advance notice requirement that was otherwise eliminated in the 2019 Payment Notice. We are finalizing this policy as proposed.

The 2019 Payment Notice amended § 155.430(d)(2) to allow additional flexibility regarding the effective date for enrollee-initiated terminations. This flexibility included permitting Exchanges—at the option of the Exchange—to provide for enrollee-initiated terminations to be effective on the date on which the termination was requested by the enrollee, or on another prospective date selected by the enrollee. Previously, enrollees generally had to provide 14-days advance notice before termination became effective. Corresponding updates to reflect the new flexibilities were not made to § 155.430(d)(9), which defines the effective date for retroactive terminations due to a technical error as described in paragraph (b)(1)(iv)(A). The current provision specifies that termination in these circumstances will be no sooner than 14 days after the date that the enrollee can demonstrate he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, unless the issuer agrees to an earlier effective date as set forth in § 155.430(d)(2)(iii).

To ensure that enrollees who suffered technical errors are put in the position they would have been absent the technical error, we proposed to align § 155.430(d)(9) with the provisions for enrollee-initiated terminations at § 155.430(d)(2).

We solicited comment on this proposal.

Comment: While fewer than 10 commenters commented on this proposal, all were in support. A few commenters requested retroactive terminations not be granted if the enrollee continued to incur claims.

Response: This proposal simply addresses the oversight of not uniformly removing the 14-day waiting period for terminations in previous regulation. It does not revisit eligibility for retroactivity under the rule. We expect the number of claims that will be reversed for enrollees whose termination was delayed due to technical error will be very low, given that most consumers taking independent steps to end their coverage would have little reason to keep using it.

After reviewing the public comments, we are finalizing as proposed.

plan under the PHS Act for purpose of Part C Title XI of the Act. See section 2791(a)(1) of the PHS Act.

7. Eligibility Pending Appeal (§ 155.525)

As discussed in the proposed rule, we are considering whether changes to § 155.525 governing eligibility pending appeals are necessary or prudent to provide greater clarity to Exchanges, issuers, and consumers who appeal Exchange determinations, and asked for public comment in the event that we decide to propose regulatory changes in the future. As such, we are not finalizing any changes to eligibility pending appeal in this rule.

Under § 155.525, when an appellant accepts eligibility pending appeal, an Exchange must continue the appellant's eligibility for enrollment in a QHP, APTC, and CSR, as applicable, in accordance with the level of eligibility that was in effect immediately before the eligibility redetermination that the consumer is appealing. We solicited comment on various aspects of the administration of this provision, including: (1) The retroactive application of benefits relative to an appellant's enrollment and applicability of plan category limitations; (2) the advisability of establishing a timeliness standard, whether Exchanges should have the flexibility to determine their own timeliness standards, and what a reasonable timeliness standard should be; (3) how life events and other reported eligibility changes interact with eligibility pending appeal; (4) how the retroactive implementation of an appeal decision interacts with eligibility pending appeal; and (5) how eligibility pending appeal interacts with the consequences of non-payment of premiums. While we decided against proposing any changes to the regulations at this time, we invited comments on this topic. We received the following comments, and our response follows.

Comment: Several commenters were supportive of preserving state flexibility in how State Exchanges administer this provision. A few commenters noted the current absence of data about appeals generally and recommended the provision of data to inform future rulemaking in this area. For example, it was observed that issuers do not have adequate access to data on enrollees who are appealing an eligibility determination, which makes it difficult to offer comment on these proposals and recommend guardrails. We also received a comment questioning the need for any regulatory changes, stating that the current system of administering this provision has been functioning largely as intended. Another commenter advised against any changes to the regulations that reduce or eliminate consumer flexibility while consumers exercise their constitutionally provided due process rights. Finally, one commenter expressed a belief that the most accurate understanding of eligibility pending appeal is not that the appellant is theoretically eligible for certain benefits, but instead that the appellant is in fact able to access the benefits for which they were eligible immediately before the eligibility determination on appeal. This commenter noted that in its state, the provision of eligibility pending appeal involves additional state-based premium and cost-sharing assistance for qualifying residents below 300 percent of the federal poverty level, which are in addition to the APTC and CSRs provided at the federal level.

With respect to the permissibility of changes to plan enrollment, we received many comments supporting a policy that would allow appellants who are granted eligibility pending appeal to enroll in any Exchange plan without regard to issuer or metal level. One of these commenters also recommended that an appellant who is receiving eligibility pending appeal be permitted to switch plans at the end of the appeal, stating that if the appeal is upheld, the appellant will experience a termination of the APTC and may want to switch to a lower metal level plan. Conversely, another commenter supported the ability of appellants who win their appeals to select a different plan from the same issuer, stating that there is a need to balance flexibility with appropriate controls to ensure that frivolous appeals are not filed for individuals who are looking for any opening to change plans, which in turn could create financial and premium instability for health plans. One commenter was in favor of offering retroactive as well as prospective implementation of eligibility pending appeal, while another commenter expressed opposition to prospective implementation on the grounds that doing so would eliminate the very protection eligibility pending appeal is intended to address. One commenter stated that unrestricted plan and issuer changes would be extremely confusing to consumers, while another commenter recommended robust consumer education materials to help individuals understand the implications of their plan choices while they are receiving eligibility pending appeal. In the context of implementing an appellant's request for eligibility pending appeal retroactively, two commenters advised HHS to consider the impact of retroactive changes to plans, products, metal levels or issuer on adverse selection. These commenters noted that retroactive enrollment changes are problematic due to claims reprocessing, changing benefits, and state prompt pay laws, and may expose appellants to increased out-of-pocket costs for services they already received. Finally, we received a comment urging HHS to provide autonomy to states in this area, as rules allowing unrestricted plan and issuer changes would require substantial technological rule and code changes that would likely come with a significant financial burden.

We received numerous comments in opposition to any timeliness standard that would apply to an appellant requesting eligibility pending appeal. One of these commenters noted that consumers who had initially filed an appeal on their own may later appoint an authorized representative or legal counsel who might inform them of this right; similarly, consumers who did not elect eligibility pending appeal at the outset of the appeal may later encounter a situation necessitating the coverage and financial help eligibility pending appeal may provide. We also received several comments supporting either a 15-day or 30-day timeframe in which to request eligibility pending appeal from the receipt date of the appeal request or from the date of the acknowledgment notice, with most of these commenters also supporting an extension if there were exceptional circumstances precluding a timely request. One commenter recommended that Exchanges be permitted to establish their own timeliness standard and determine whether to establish a good cause exception, while another recommended that HHS leave the process as it currently exists in place.

We received a number of comments recommending that consumers who experience a life event during the pendency of the appeal have their appeals considered resolved in their favor, with one commenter noting that the life event, once reported, may negate the need for an appeal. Several commenters noted the importance of appellants being able to report life events even while receiving eligibility pending appeal in order for appellants and members of the household to access coverage on a timely basis. One commenter advised that Exchanges be given the flexibility to determine how to proceed with processing these eligibility changes. Relatedly, one commenter, drawing on its experience administering an Exchange, observed that the hearing decision of an independent hearing officer must be implemented as issued, in order to preserve the fairness and

independence of the hearing process. This commenter stated that if a hearing officer ordered the Exchange to provide an appellant with the option for retroactive coverage at a given level of eligibility, the Exchange would do so, in situations where the appellant had been receiving eligibility pending appeal at a level less generous than what the hearing officer's decision awarded; however, the hearing decision would not be implemented retroactively in situations where a less generous eligibility level was awarded than the eligibility level provided by eligibility pending appeal.

In response to our request for comments on the applicability of the grace period to individuals enrolled in Exchange coverage and receiving eligibility pending appeal, we received a number of comments recommending a 3-month grace period as well as a general prohibition on termination of coverage during the pendency of the appeal. One commenter was in favor of the ability of appellants receiving eligibility pending appeal to select the effective date of retroactive coverage, effectuate the first month of retroactive coverage, and be given a reasonable amount of time to bring their payment current. Another commenter expressed a belief that the grace period does apply and supported a rule clarifying its applicability to the extent that it was not sufficiently clear under the existing regulations. Finally, we received a comment recommending that the enrollee be required to pay the current billed amount and another comment stating that appellants should not be treated any differently than non-appellants with respect to coverage termination.

Response: We thank the commenters for the feedback on these issues. We did not propose and are not finalizing any changes to rules governing eligibility pending appeal. This feedback, however, will help inform future policy in this area.

8. Eligibility Standards for Exemptions (§ 155.605)

a. Required Contribution Percentage (§ 155.605(d)(2))

In the proposed rule, we used the proposed 2021 premium adjustment percentage to calculate the excess of the rate of premium growth over the rate of income growth for 2013 to 2020 as 1.3542376277 ÷ 1.3094029651, or 1.0342405385. This resulted in a proposed required contribution percentage for 2021 of 8.00 × 1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of one percent. We are finalizing the required contribution percentage as proposed.

HHS calculates the required contribution percentage for each benefit year using the most recent projections and estimates of premium growth and income growth over the period from 2013 to the preceding calendar year. We proposed to calculate the required contribution percentage for the 2021 benefit year, using income and premium growth data for the 2013 and 2020 calendar years.

Under section 5000A of the Code, an individual must have MEC for each month, qualify for an exemption, or make an individual shared responsibility payment. Under § 155.605(d)(2), an individual is exempt from the requirement to have MEC if the amount that he or she would be required to pay for MEC (the required contribution) exceeds a particular percentage (the required contribution percentage) of his or her projected household income for a year. Although the Tax Cuts and Jobs Act reduced the individual shared responsibility payment to $0 for months beginning after December 31, 2018, the required contribution percentage is still used to determine whether individuals above the age of 30 qualify for an affordability exemption that would enable them to enroll in catastrophic coverage under § 155.305(h).

The initial 2014 required contribution percentage under section 5000A of the Code was 8 percent. For plan years after 2014, section 5000A(e)(1)(D) of the Code and Treasury regulations at 26 CFR 1.5000A–3(e)(2)(ii) provide that the required contribution percentage is the percentage determined by the Secretary of HHS that reflects the excess of the rate of premium growth between the preceding calendar year and 2013, over the rate of income growth for that period. The excess of the rate of premium growth over the rate of income growth is also used for determining the applicable percentage in section 36B(b)(3)(A) of the Code and the required contribution percentage in section 36B(c)(2)(C) of the Code.

As discussed elsewhere in this preamble, we proposed as the measure for premium growth the 2021 premium adjustment percentage of 1.3542376277 (or an increase of about 35.4 percent over the period from 2013 to 2020). This reflects an increase of about 5.0 percent over the 2020 premium adjustment percentage (1.3542376277/1.2895211380).

As the measure of income growth for a calendar year, we established in the 2017 Payment Notice that we would use per capita personal income (PI). Under the approach finalized in the 2017 Payment Notice using the National Health Expenditure Accounts (NHEA) data, the rate of income growth for 2021 is the percentage (if any) by which the most recent projection of per capita PI for the preceding calendar year ($58,821 for 2020) exceeds per capita PI for 2013 ($44,922), carried out to ten significant digits. The ratio of per capita PI for 2020 over the per capita PI for 2013 is estimated to be 1.3094029651 (that is, per capita income growth of about 30.9 percent).[113] This rate of income growth between 2013 and 2020 reflects an increase of approximately 4.6 percent over the rate of income growth for 2013 to 2019 (1.3094029651/1.2524152976) that was used in the 2020 Payment Notice. Per capita PI includes government transfers, which refers to benefits individuals receive from Federal, state, and local governments (for example, Social Security, Medicare, unemployment insurance, workers' compensation, etc.).[114]

Using the 2021 premium adjustment percentage finalized in this rule, the excess of the rate of premium growth over the rate of income growth for 2013 to 2020 is 1.3542376277 ÷ 1.3094029651, or 1.0342405385. This results in the required contribution percentage for 2021 of 8.00 × 1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of one percent, an increase of 0.04 percentage points from 2020 (8.27392–8.23702).

We solicited comment on the required contribution percentage. After reviewing public comments, we are finalizing the required contribution percentage for 2021 at 8.00 × 1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of one percent. The following is a summary of the public comments we received on the required contribution percentage. We address comments regarding the measures used

[113] The 2013 and 2020 per capita personal income figures used for this calculation reflect the latest NHEA data as of the publication of the proposed rule. These data were published on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Tables 1 and 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed description of the NHE projection methodology is also available on the CMS website.

[114] U.S Department of Commerce Bureau of Economic Analysis (BEA) Table 3.12 Government Social Benefits. Available at *https://apps.bea.gov/iTable/iTable.cfm?reqid=19&step=3&isuri=1&categories=survey&nipa_table_list=110.*

to calculate the excess of the rate of premium growth over the rate of income growth in the section of the preamble related to the premium adjustment percentage, later in this rule.

Comment: One commenter asked that we not increase the required contribution percentage from the value finalized for 2020, as increases to this value reflect increases in the percentage of income enrollees may have to contribute toward health care, thereby reducing affordability for these consumers. A few other commenters expressed concern with the increase in this value as part of their comments on the proposed premium adjustment percentage.

Response: HHS is required to update the required contribution percentage annually by section 5000A(e)(1)(D) of the Code. The updated contribution percentage is used, among other things, for purposes of determining whether individuals above the age of 30 qualify for an affordability exemption, so that they can be eligible to enroll in catastrophic coverage under § 155.305(h). As such, after reviewing the public comments, we are finalizing the required contribution percentage for 2021 at 8.00 × 1.0342405385 or 8.27 percent, when rounded to the nearest one-hundredth of one percent.

9. Quality Rating Information Display Standards for Exchanges (§§ 155.1400 and 155.1405)

We proposed to amend §§ 155.1400 and 155.1405 to codify the flexibility for State Exchanges that operate their own eligibility and enrollment platforms, to customize the display of quality rating information on their websites to display the quality rating information as calculated by HHS or to display quality rating information based upon certain state-specific customizations of the quality rating information provided by HHS. We are finalizing as proposed.

To implement sections 1311(c)(3) and 1311(c)(4) of the PPACA, we developed the QRS and the QHP Enrollee Experience Survey (collectively referred to as the quality rating information). In the Exchange and Insurance Market Standards for 2015 and Beyond Final Rule [115], HHS issued regulations at §§ 155.1400 and 155.1405 to establish quality rating information display standards for Exchanges.[116] Consistent with these regulations, Exchanges must prominently display on their websites, in accordance with § 155.205(b)(1)(iv) and (v), quality rating information assigned for each QHP [117], as provided by HHS and in a form and manner specified by HHS.

To balance HHS's strategic goals of empowering consumers through data, minimizing cost and burden on QHP issuers, and supporting state flexibility, HHS developed a phased-in approach to display of quality rating information across the Exchanges. In particular, during plan years 2017, 2018, and 2019, HHS displayed quality rating information on *HealthCare.gov* in a handful of select FFE states as part of a limited pilot program. During this time, State Exchanges that operated their own eligibility and enrollment platforms were given the option to display the quality rating information for their respective QHPs and several of these State Exchanges voluntarily elected to display this information on their State Exchange websites. The QRS pilot involved focused consumer testing of the display of quality rating information to maximize the clarity of the information provided and to assess how the information was displayed and used on Exchange websites.

In August 2019, HHS issued a Quality Rating Information Bulletin to announce the transition away from the QRS pilot to the public display of quality rating information for plan year 2020 by all Exchanges, including FFEs, SBE–FPs, and State Exchanges that operate their own eligibility and enrollment platform.[118] This included flexibility for State Exchanges that operate their own eligibility and enrollment platforms to display QHP quality rating information on their websites in the form and manner specified by HHS or with some limited state customizations. Based upon experience during the QRS pilot, we recognize there are benefits to permitting some flexibility for State Exchanges that operate their own eligibility and enrollment platforms to customize the quality rating information for their QHPs. As stated in the proposed rule, we understand that during the QRS pilot, some State Exchanges that operate their own eligibility and enrollment platforms displayed the quality rating information as provided by HHS, while others displayed the quality rating information with certain state-specific customizations in order to best reflect local priorities or information. Therefore, we proposed to amend §§ 155.1400 and 155.1405 to codify this flexibility and provide State Exchanges that operate their own eligibility and enrollment platforms some flexibility to customize the display of quality rating information for their respective QHPs.

For example, we would allow State Exchanges that operate their own eligibility and enrollment platform to make state-specific customizations, such as to incorporate additional state or local quality information or to modify the display names of the QRS quality ratings. However, we clarified under this approach State Exchanges that operate their own eligibility and enrollment platform could not develop their own programs to replace the quality ratings calculated by HHS. Consistent with the statute, the Secretary remains responsible for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings under these programs across all Exchanges.[119] We further noted that we believe the proposed flexibility supports the feedback we received from a Request for Information, entitled ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act and Improving Healthcare Choices to Empower Patients'', published in the June 12, 2017 **Federal Register** (82 FR 26885), in identifying ways to reduce burden and promote State Exchange flexibility. We solicited comment on this proposal.

After consideration of the comments received, we are finalizing these changes as proposed.

Comment: All commenters who provided feedback regarding this proposal expressed support for codifying the flexibility for State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information for their respective QHPs. One commenter urged HHS to clarify that states are not permitted to develop their own programs and replace the quality ratings developed by HHS in their entirety.

Response: We are finalizing as proposed and maintain in the final rule that State Exchanges that operate their own eligibility and enrollment platforms have the flexibility to engage

[115] See the Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond; Final Rule; (May 27, 2014), 79 FR 30240 at 30310, available at *https://www.gpo.gov/fdsys/pkg/FR-2014-05-27/pdf/2014-11657.pdf.*

[116] Patient Protection and Affordable Care Act; Exchange and Insurance Market Standards for 2015 and Beyond, Final Rule, 79 FR 30240 at 30352 (May 27, 2014).

[117] Exchanges can satisfy the requirement to display the QHP Enrollee Survey results by displaying the Quality Rating System (QRS) quality ratings (which incorporate member experience data from the QHP Enrollee Survey). See 79 FR at 30310.

[118] Quality Rating Information Bulletin for Plan Year 2020. Available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/QualityRatingInformationBulletinforPlanYear2020.pdf.*

[119] See sections 1311(c)(3) and (c)(4) of the PPACA.

in some customization of the display of quality rating information for their respective QHPs, such as by incorporating additional state or local quality information or by modifying the display names of the QRS quality ratings. However, consistent with sections 1311(c)(3) and 1311(c)(4) of the PPACA, the Secretary of HHS is responsible for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings for QHPs across all Exchanges. Although State Exchanges may continue to provide additional state or local healthcare quality information or display additional state-level quality ratings as part of their plan shopping experience, State Exchanges cannot develop their own programs to replace the quality ratings calculated by HHS because the Secretary remains responsible for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings under these programs across all Exchanges.

Comment: A few commenters requested greater flexibility for State Exchanges that operate their own eligibility and enrollment platforms, including the option for these State Exchanges to perform their own calculations in determining QRS information. One commenter supported the need for common national and performance benchmarks, but noted that State Exchanges should retain the flexibility to modify the QRS rating methodology since periodic and future refinements are expected of the federal quality rating methodology. Further, one commenter suggested that State Exchanges on the Federal platform should be allowed the same flexibility to customize the display of quality rating information.

Response: We support flexibility for State Exchanges that are consistent with the statute and available technical systems. Sections 1311(c)(3) and 1311(c)(4) of the PPACA require each Exchange to provide information to individuals and employers from the rating and enrollee satisfaction systems on the Exchange's website. Therefore, the information from the QRS and the QHP Enrollee Survey must be displayed on each Exchange website. In addition, sections 1311(c)(3) and 1311(c)(4) direct the Secretary of HHS to develop a rating system and a system to assess enrollee satisfaction. Therefore, to be consistent with the statute, the greater flexibility for State Exchanges that operate their own eligibility and enrollment platforms is related to the display of quality rating information and not the development of separate quality ratings. This rule finalizes flexibility for State Exchanges that operate their own eligibility and enrollment platforms to be able to customize the display of quality rating information. State Exchanges that use the Federal platform, however, would follow the display requirements of the HealthCare.gov system, which is currently unable to accommodate state-specific customizations of this nature.

We clarify that, as outlined in the statute and in the 2015 Market Standards Rule, HHS will continue to calculate federal quality ratings based on data submitted by eligible QHP issuers across Exchanges and using a standardized methodology. HHS will also continue providing federal quality rating information to State Exchanges that operate their own eligibility and enrollment platforms for display on each Exchange website. In this final rule, HHS is allowing certain state-specific modifications to the display of federal quality rating information including incorporating additional state or local quality information or modifying the display names of the quality ratings, for State Exchanges that operate their own eligibility and enrollment platforms. This flexibility does not include the ability to recalculate or modify the quality ratings provided by HHS. As detailed above, sections 1311(c)(3) and 1311(c)(4) of the PPACA assign responsibility for the development of the QRS and QHP Enrollee Survey and the calculation of quality ratings for QHPs across all Exchanges to the Secretary. Therefore, we did not propose and are not finalizing changes to permit states greater flexibility to calculate quality ratings for QHPs offered through Exchanges.

We agree that, as with all HHS quality reporting programs and initiatives, periodic evaluation of and refinements to the QRS rating methodology are appropriate and we expect to continue to improve the program with such refinements for future benefit years. HHS will continue to transparently communicate program and methodology refinements and request stakeholder feedback.

Comment: Two commenters requested additional clarification from HHS regarding how and what QRS information would be displayed, including certain state-specific customizations, and on how local and state quality ratings could be incorporated into the greater QRS.

Response: We intend to continue to require display of the QHP quality rating information for all Exchanges and will provide guidance in a subsequent QRS Bulletin, as in previous years, on the form and manner of display of quality rating information by Exchanges and direct enrollment entities.[120] The upcoming QRS Bulletin will clarify the quality rating information to be displayed beginning in the individual market open enrollment period for the 2021 plan year, which starts on November 1, 2020.[121]

The changes made in this final rule provide flexibility to State Exchanges that operate their own eligibility and enrollment platforms to make certain state-specific customizations to the quality rating information provided by HHS, including the incorporation of additional local and state QHP quality information or the modification of the display names of the quality ratings. State Exchanges that operate their own eligibility and enrollment platforms can determine whether and how to take advantage of this flexibility, including if and how to incorporate local and state quality rating information.

Comment: Two commenters provided general recommendations regarding the display of quality rating information. One commenter encouraged HHS to continue working with issuers and consumers relating to display of QRS information in a meaningful manner and to be transparent in disclosing information on the use of QRS information during plan selection and enrollment. Another commenter requested that if there are changes for a specific display format, sufficient time and funding be provided to State Exchanges that operate their own eligibility and enrollment platforms to implement system changes and that State Exchanges be included early in the development process for any potential changes.

Response: We agree that transparency of information will help issuers, states and consumers make informed decisions related to QHP quality. We will continue working with issuers, consumers, states, quality measurement technical experts, and others to help ensure that the display of quality rating information for QHPs offered on Exchanges is useful, meaningful and understandable to individuals and families shopping for a QHP. We intend to conduct focus groups and cognitive testing directly with consumers

[120] As part of the Administration's efforts to combat COVID–19, we recently announced the suspension of activities related to the collection of clinical quality measures for the QRS and survey measures for the QHP Enrollee Survey for the 2021 plan year (2020 ratings year). See the COVID–19 Marketplace Quality Initiatives memo, available at: *https://www.cms.gov/files/document/covid-qrs-and-marketplace-quality-initiatives-memo-final.pdf.*

[121] See 45 CFR 155.410(e)(3).

regarding the enrollee experience survey measures, some of which are part of the QRS. We also anticipate providing consumers with technical assistance if needed and additional materials to clarify the details and uses of QHP quality rating information. We also agree that State Exchanges and other stakeholders should be provided opportunities to give input on potential future changes to the display of quality rating information. We believe it is important to obtain diverse feedback from stakeholders to continue to improve the utility and comprehension of displayed QHP quality rating information and to help inform plan selection. Since this final rule is providing an additional option to State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information for their QHPs, we believe that states that elect to take advantage of this flexibility will have adequate time to make any changes. Should we pursue changes to the formatting or other display requirements in the future, we will keep in mind the comments about providing time for State Exchanges to make the necessary updates to their respective systems to implement any such changes.

E. Part 156—Health Insurance Issuer Standards Under the Affordable Care Act, Including Standards Related to Exchanges

1. Definitions (§ 156.20)

We proposed to remove the definition of the term ''generic'' at § 156.20 because we proposed a revision at § 156.130(h) which would no longer use the term ''generic.'' For a discussion of that policy, please see the preamble related to § 156.130(h).

We received no comments on the proposed removal of the term ''generic''. Therefore, we are finalizing this change as proposed.

2. FFE and SBE–FP User Fee Rates for the 2021 Benefit Year (§ 156.50)

We proposed maintaining the FFE user fee for all participating FFE issuers at 3.0 percent of total monthly premiums. Likewise, we proposed maintaining a user fee rate of 2.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. These proposed rates were based on internal projections of Federal costs for providing special benefits to FFE and SBE–FP issuers during the 2021 benefit year, as well as estimates of premium increases and enrollment decreases. We stated that we were considering, and we solicited comment on, lowering the user fee rates below the proposed rates. We are finalizing maintaining the FFE and SBE–FP user fee rates at 3.0 percent and 2.5 percent, respectively, as proposed for the 2021 benefit year.

Section 1311(d)(5)(A) of the PPACA permits an Exchange to charge assessments or user fees on participating health insurance issuers as a means of generating funding to support its operations. If a state does not elect to operate an Exchange or does not have an approved Exchange, section 1321(c)(1) of the PPACA directs HHS to operate an Exchange within the state. Accordingly, in § 156.50(c), we specify that a participating issuer offering a plan through an FFE or SBE–FP must remit a user fee to HHS each month that is equal to the product of the annual user fee rate specified in the annual HHS notice of benefit and payment parameters for FFEs and SBE–FPs for the applicable benefit year and the monthly premium charged by the issuer for each policy where enrollment is through an FFE or SBE–FP. In addition, OMB Circular No. A–25 establishes Federal policy regarding the assessment of user fee charges under other statutes, and applies to the extent permitted by law. Furthermore, OMB Circular No. A–25 specifically provides that a user fee charge will be assessed against each identifiable recipient of special benefits derived from Federal activities beyond those received by the general public. Activities performed by the Federal Government that do not provide issuers participating in an FFE with a special benefit, or that are performed by the Federal government for all QHPs, including those offered through State Exchanges, are not covered by this user fee. As in benefit years 2014 through 2020, issuers seeking to participate in an FFE in the 2021 benefit year will receive two special benefits not available to the general public: (1) The certification of their plans as QHPs; and (2) the ability to sell health insurance coverage through an FFE to individuals determined eligible for enrollment in a QHP.

a. FFE User Fee Rate

For the 2021 benefit year, issuers participating in an FFE will receive special benefits from the following Federal activities:

- Provision of consumer assistance tools;
- Consumer outreach and education;
- Management of a Navigator program;
- Regulation of agents and brokers;
- Eligibility determinations;
- Enrollment processes; and
- Certification processes for QHPs (including ongoing compliance verification, recertification, and decertification).

Activities through which FFE issuers receive a special benefit also include the Health Insurance and Oversight System (HIOS) and Multidimensional Insurance Data Analytics System (MIDAS) platforms, which are partially funded by Exchange user fees. Based on estimated costs, enrollment (including changes in FFE enrollment resulting from anticipated establishment of State Exchanges or SBE–FPs in certain states in which FFEs currently are operating), and premiums for the 2021 plan year, we solicited comment on two alternative proposals. First, we proposed maintaining the FFE user fee for all participating FFE issuers at 3.0 percent of total monthly premiums in order to preserve and ensure that the FFE has sufficient funding to cover the cost of all special benefits provided to FFE issuers during the 2021 benefit year.

We also solicited comment on an alternate proposal that would reduce the FFE user fee rate below the 2020 benefit year level. As discussed in the proposed rule, the alternative proposal reflected our estimates of premium increases and enrollment decreases for the 2021 benefit year, as well as potential savings resulting from cost-saving measures implemented over the last several years that we expect would enable HHS to collect user fees at a lower rate, thereby reducing the user fee burden on consumers and creating downward pressure on premiums, while still fully funding FFE operations. As discussed in the proposed rule, if these savings did not materialize, we would have increased user fee rates for the subsequent benefit year, to ensure that sufficient funds would be available to cover the costs of special benefits provided to FFE issuers. We solicited comment on this proposal. We also solicited comment on trends in usage of Exchange functions and services, potential efficiencies in Exchange operations, and premium and enrollment projections, all of which might inform a change in the user fee rate in the final rule. We did not receive any comments on the trends in usage of Exchange functions and services, potential efficiencies in Exchange operations, and premium and enrollment projections.

b. SBE–FP User Fee Rate

As previously discussed, OMB Circular No. A–25 establishes Federal policy regarding user fees, and specifies that a user charge will be assessed

against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public. SBE–FPs enter into a Federal platform agreement with HHS to leverage the systems established for the FFEs to perform certain Exchange functions, and to enhance efficiency and coordination between state and Federal programs. Accordingly, in § 156.50(c)(2), we specify that an issuer offering a plan through an SBE–FP must remit a user fee to HHS, in the timeframe and manner established by HHS, equal to the product of the monthly user fee rate specified in the annual HHS notice of benefit and payment parameters for the applicable benefit year, unless the SBE–FP and HHS agree on an alternative mechanism to collect the funds from the SBE–FP or state. The benefits provided to issuers in SBE–FPs by the Federal Government include use of the Federal Exchange information technology and call center infrastructure used in connection with eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, as defined at section 1413(e) of the PPACA, and QHP enrollment functions under § 155.400. The user fee rate for SBE–FPs is calculated based on the proportion of FFE costs that are associated with the FFE information technology infrastructure, the consumer call center infrastructure, and eligibility and enrollment services, and allocating a share of those costs to issuers in the relevant SBE–FPs.

We proposed a user fee rate of 2.5 percent of the monthly premium charged by the issuer for each policy under plans offered through an SBE–FP. Similar to our proposal to maintain the FFE user rate applicable to benefit year 2020, maintaining the SBE–FP user rate at 2.5 percent of premium would result in stability in the amount of user fees collected.

We also considered and solicited comment on an alternate proposal that would lower the SBE–FP user fee rate below the 2020 benefit year level to a level that would reduce the user fee burden on consumers, while still covering the costs of the special benefits HHS provides to SBE–FP issuers. We discussed that we will continue to examine contract cost estimates for the special benefits provided to issuers offering QHPs on the Exchanges using the Federal platform for the 2021 benefit year as we finalize the FFE and SBE–FP user fee rates. We solicited comment on the alternative proposal.

In addition, we solicited comment on trends in usage of Federal platform functions and services, potential efficiencies in Federal platform operations, and premium and enrollment projections, all of which might inform a change in the user fee level in the final rule.

After reviewing the public comments, we are finalizing the proposed rates of 3.0 percent for the FFE user fee rate and 2.5 percent for the SBE–FP user fee rate for the 2021 benefit year.

The following is a summary of the public comments we received.

Comment: A group of commenters supported lowering user fee rates only if the reduction would not adversely affect FFE operations. Another group of commenters supported maintaining current user fee rates in favor of HHS re-investing excess user fees into consumer outreach and education activities, the improvement of *HealthCare.gov*, or otherwise increasing funding of these activities to 2017 levels. One commenter recommended HHS spend additional funding on providing additional in-language resources for those with limited English proficiency.

Response: We are finalizing user fee rates at 3.0 percent for FFE issuers and 2.5 percent for SBE–FP issuers, which is the same as the user fee rates for the 2020 benefit year. These user fees will provide ample funding for the full functioning of the Federal platform. Based on projected changes in costs, enrollment and premiums, we project that we can readily fund Federal platform costs associated with providing special benefits to these issuers. HHS remains committed to providing a seamless enrollment experience for consumers who enroll in coverage through an Exchange that uses the Federal platform. We will continue to apply resources to cost-effective, high-impact outreach and marketing activities that offer the highest return on investment. Thus, we are not committing to increasing funding for outreach and education activities in excess of current levels or to levels similar to those that existed in prior years, but we will continue to evaluate consumer outreach and education needs within the normal annual budget process. Consistent with OMB Circular No. A–25, any collections in excess of user fee-eligible costs for a given year will be rolled over for spending on the subsequent year's user fee-eligible expenses.

Comment: Some commenters expressed support for lower user fee rates for issuers participating in Enhanced Direct Enrollment (EDE), or who take on additional administrative functions.

Response: While we expect long-term economies of scale and cost reductions associated with EDE, HHS incurs costs associated with building, maintaining and improving the infrastructure associated with EDE. However, we will continue to review the costs associated with EDE and potential interactions between EDE implementation and user-fee eligible costs.

Comment: One commenter suggested that HHS lower the SBE–FP user fee rate to 1.5 percent for SBE–FPs for several reasons. The commenter stated that SBE–FP states can take on federal tasks, such as eligibility and enrollment processes, Navigator and agents programs, and consumer selection tools. The commenter also stated that call centers can be reduced since most enrollments are automatic re-enrollments, and the Federal Platform and call center tasks can be taken on by issuers. Further, the commenter stated that the Exchanges are not to the benefit of the issuers, since there is no competitive advantage to being on the Exchanges, the existence of the Exchanges are mandated by law, and the benefits associated with user fees are all to the consumers, and not the issuers who pay them.

Response: We calculated the SBE–FP user fee rate based on the proportion of all FFE functions that are also conducted for SBE–FPs. The final SBE–FP user fee rate for the 2021 benefit year of 2.5 percent of premiums is based on HHS's calculation of the percent of costs of the total FFE functions utilized by SBE–FPs—the costs associated with the information technology, call center infrastructure, and eligibility determinations for enrollment in QHPs and other applicable state health subsidy programs, which we estimate to be approximately 85 percent. As described in this rule, user fee eligible cost estimates are reviewed on an annual basis and developed in advance of the benefit year. Setting the SBE–FP user fee rate below the proportion of costs associated with benefits provided to SBE–FP issuers would result in FFE QHPs subsidizing the functions used by QHPs in SBE–FPs.

Comment: Several commenters asked HHS to provide more data and transparency into how user fee rates are calculated.

Response: The FFE and SBE–FP user fee rates for the 2021 benefit year are based on expected total costs to offer the special benefits to issuers offering plans on FFEs or SBE–FPs, and evaluation of expected enrollment and premiums for the 2021 benefit year. Annually, HHS and CMS also publish detailed information on Federal Exchange Activities and budget request estimates,

including expected Exchange user fee eligible costs.[122]

User fee eligible costs are estimated in advance of the benefit year and are based upon cost targets for specific contracting activities that are not yet finalized, and therefore proprietary. We will continue to outline user fee eligible functional areas in the annual Payment Notices, and will evaluate contract activities related to operation of the federal Exchange user fee eligible functions. The categories that are considered user fee eligible include activities that provide special benefits to issuers offering QHPs through the Federal platform, and do not include activities that are provided to all QHP issuers. For example, functions related to risk adjustment program operations and operations associated with APTC calculation and payment, which are provided to all issuers in states where HHS operates the risk adjustment program (all 50 states and the District of Columbia for the 2021 benefit year), are not included in the FFE or SBE–FP user fee eligible costs. However, costs related to Exchange-related information technology, health plan review, management and oversight, eligibility and enrollment determination functions including the call center, and consumer information and outreach are considered FFE user fee eligible costs. SBE–FPs conduct their own health plan reviews and consumer information and outreach, and therefore, the SBE–FP user fee rate is determined based on the portion of FFE costs that are also applicable to issuers offering QHPs through SBE–FPs.

3. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or after January 1, 2020 (§ 156.111)

a. Annual Reporting of State-Required Benefits

We proposed to amend § 156.111 to require states each year, beginning in plan year 2021, to identify required benefits mandated by state law and which of those benefits are in addition to EHB in a format and by a date specified by HHS. If the state does not comply with this annual reporting submission deadline, we proposed that HHS will determine which benefits are in addition to EHB for the state. We are finalizing the annual reporting of state-required benefits policy as proposed, with minor revisions. We are also finalizing as proposed that the first annual submission deadline for states to notify HHS of their state-required benefits will be July 1, 2021.

Section 1311(d)(3)(B) of the PPACA permits a state to require QHPs offered in the state to cover benefits in addition to the EHB, but requires the state to make payments, either to the individual enrollee or to the issuer on behalf of the enrollee, to defray the cost of these additional state-required benefits. In the EHB final rule,[123] we finalized a standard at § 155.170(a)(2) that specifies benefits mandated by state action taking place on or before December 31, 2011, even if not effective until a later date, may be considered EHB, such that the state is not required to defray costs for these state-required benefits. Under this policy, benefits mandated by state action taking place after December 31, 2011 are considered in addition to EHB, even if the mandated benefits also are embedded in the state's selected EHB-benchmark plan. In such cases, states must defray the associated costs of QHP coverage of such benefits, and those costs should not be included in the percentage of premium attributable to coverage of EHB for purpose of calculating APTC.

We also finalized in the EHB final rule that, because the Exchange is responsible for certifying QHPs, the Exchange would be the entity responsible for identifying which additional state-required benefits, if any, are in addition to the EHB. We also finalized that it is the QHP issuer's responsibility to quantify the cost attributable to each additional required benefit based on an analysis performed in accordance with generally accepted actuarial principles and methodologies conducted by a member of the American Academy of Actuaries and to then report this to the state. Although § 155.170 contemplates issuers conducting the cost analysis independently from the state, we now clarify that it would also be permissible for issuers to choose to rely on another entity, such as the state, to produce the cost analysis, provided the issuer remains responsible for ensuring that the quantification has been completed in a manner that complies with § 155.170(c)(2)(i) through (iii).

We also finalized that this calculation should be done prospectively to allow for the offset of an enrollee's share of premium and for purposes of calculating the PTC and reduced cost sharing. We reminded states and issuers that section 36B(b)(3)(D) of the Code specifies that the portion of the premium allocable to state-required benefits in addition to EHB shall not be taken into account in determining a PTC. We also finalized that because states may wish to take different approaches with regard to basing defrayal payments on either a statewide average or each issuer's actual cost that we were not establishing a standard and would permit both options for calculating state payments, at the election of the state. As discussed in the proposed rule, we clarified that we interpret actual cost to refer to the actuarial estimate of what part of the premium is attributable to the state-required benefit that is in addition to EHB, which is an analysis that should be performed prospectively to the extent possible.

In the 2017 Payment Notice,[124] we clarified that section 1311(d)(3)(B) of the PPACA governing defrayal of state-required benefits is not specific to state statutes and we thus interpreted that section to apply not only in cases of legislative action but also in cases of state regulation, guidance, or other state action. We also finalized a change to § 155.170(a)(3), designating the state, rather than the Exchange, as the entity required to identify which benefits mandated by state action are in addition to EHB and require defrayal. We also clarified in the 2017 Payment Notice [125] that there is no requirement to defray the cost of benefits added through supplementation of the state's base-benchmark plan, as long as the state is supplementing the base-benchmark to comply with the PPACA or another Federal requirement. We also explained in the 2017 Payment Notice that this means benefits mandated by state action after December 31, 2011 for purposes of compliance with new Federal requirements would not require defrayal. Examples of such Federal requirements include: requirements to provide benefits and services in each of the ten categories of EHB; requirements to cover preventive services; requirements to comply with the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA); and the removal of discriminatory age limits from existing benefits.

In the 2017 Payment Notice, we also affirmed a transitional policy originating from the 2016 Payment Notice,

[122] FY2021 CMS Budget Request is available at *https://www.cms.gov/About-CMS/Agency-Information/PerformanceBudget/FY2021-CJ-Final.pdf.* and FY2021 HHS Budget Request is available at *https://www.hhs.gov/sites/default/files/fy-2021-budget-in-brief.pdf.*

[123] Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation, 78 FR 12834, 12837 through 12838 (February 20, 2013), available at *https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.*

[124] 81 FR at 12242.

[125] This was originally clarified in the 2016 Payment Notice, and reiterated in the 2017 Payment Notice.

specifying that § 156.110(f) allows states to determine services included in the habilitative services and devices category without triggering defrayal if the state's base-benchmark plan does not include coverage for that category. We interpreted this to mean that, when a state has an opportunity to reselect its EHB-benchmark plan, a state may use this as an opportunity to also update its habilitative services category within the applicable Federal parameters for doing so as part of EHB-benchmark plan reselection. As such, once a state has defined its habilitative services category under § 156.110(f), state-required benefits related to habilitative services may trigger defrayal in accordance with § 155.170 if they are in addition to EHB and/or outside of an EHB-benchmark plan selection process.

In the 2019 Payment Notice,[126] we finalized that, as part of the new EHB-benchmark plan selection options for states at § 156.111, we would not make any changes to the policies governing defrayal of state-required benefits at § 155.170. That is, whether a benefit mandated by state action could be considered EHB would continue to depend on when the state enacted the mandate (unless the benefit mandated was for the purposes of compliance with Federal requirements). We reminded states of their obligations in light of the new EHB-benchmark plan selection options for states at § 156.111 in an October 2018 FAQ.[127] In this FAQ, we also reminded states that, although it is the state's responsibility to identify which state-required benefits require defrayal, states must make such determinations using the framework finalized at § 155.170. For example, a law requiring coverage of a benefit passed by a state after December 31, 2011, is still a state-required benefit requiring defrayal even if the text of the law says otherwise. We affirmed that in the proposed rule. We also noted that we are monitoring state compliance with the defrayal requirements regarding state-required benefits in addition to EHB at § 155.170, and that we encouraged states to reach out to us concerning any state defrayal questions in advance of passing and implementing benefit mandates.

As explained in the proposed rule, HHS is concerned that there may be states that are not defraying the costs of the state-required benefits in accordance with federal requirements. State noncompliance with section 1311(d)(3)(B) of the PPACA, as implemented at § 155.170, may result in an increase in the percent of premium that QHP issuers report as attributable to EHB, more commonly referred to as the ''EHB percent of premium,'' which is used to calculate PTCs. Due to state noncompliance with defrayal of state-required benefits, issuers may be covering benefits as EHB that were required by state action after December 31, 2011 that actually require defrayal under federal requirements, but for which the state is not actively defraying costs. As such, to strengthen program integrity and potentially reduce improper federal expenditures, we proposed to amend § 156.111(d) and to add a new § 156.111(f) to explicitly require states to annually notify HHS in a form and manner specified by HHS, and by a date determined by HHS, of any state-required benefits applicable to QHPs in the individual and/or small group market that are considered to be ''in addition to EHB'' in accordance with § 155.170(a)(3). Given the proposed changes, we further proposed to rename § 156.111 ''State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020, and annual reporting of state-required benefits'' to better reflect its contents.

After reviewing and carefully considering the comments, we are finalizing these policies at § 156.111(d) and (f), but with changes explained below. We are also finalizing the revision of the heading of § 156.111 so that it accurately describes the new requirements in this final rule.

Comment: Most commenters objected to the proposed annual reporting policy as unnecessary and without adequate justification, asking that we withdraw the proposed changes entirely. A minority of commenters supported the proposed changes, supporting the observation that states have not been defraying state benefit requirements consistently. Supporting commenters agreed that requiring states to report their state benefit requirements to HHS would improve transparency and accountability of states that may not be appropriately defraying the costs of state benefit requirements in addition to EHB and that this reporting policy will help to ensure that Exchange subsidies are calculated and used appropriately.

Commenters objecting to the proposed policy stated that HHS did not provide sufficient evidence that states are not complying with federal defrayal requirements, and that HHS should first develop a strong evidentiary basis that states are not properly compensating issuers or enrollees for state-required benefits in addition to EHB before imposing onerous new requirements on states. Several commenters explained that, contrary to HHS's concerns expressed in the proposed rule, states are already regularly making careful assessments about whether their state benefit requirements are in addition to EHB and are doing so in accordance with federal requirements. One commenter noted that its state has coordinated a robust inter-agency process since 2013 to comply with section 1311 of the PPACA and defrayed the cost of state benefit requirements in addition to EHB since 2014. This commenter urged HHS to withdraw the proposal, expressing that finalization would be disruptive and unnecessary to states such as its own which have already set up a fully functional process. Other commenters noted that this reporting requirement is unnecessary given that we already publish information about state benefit requirements on the CMS website.

Commenters opposing the reporting policy as unnecessary also stated that existing regulations already establish robust requirements for states and issuers to follow when a state benefit requirement is in addition to EHB and requires defrayal, including performing actuarially sound analyses of costs associated with state benefit requirements in addition to EHB when calculating APTCs. Commenters also noted that HHS already has existing authority to investigate states that are not complying with defrayal requirements and that, as such, imposing a reporting requirement on states is not necessary for federal oversight purposes.

Many commenters also opposed the annual reporting policy because it would be an additional administrative burden on states, the type this administration instructed agencies to reduce to the maximum extent permitted by law. They also noted the burden states already bear as the entities responsible for identifying which mandates require defrayal. One commenter recommended that HHS leverage existing reporting related to EHB rather than creating a new, duplicative report, though the commenter did not provide clarity on what reporting this is. One commenter stated that HHS making determinations in the state's place about which state-required benefits are in addition to EHB conflicts with Executive Order 13865, ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients,'' which directs HHS ''to the maximum extent permitted

[126] 83 FR 16930, at 16977.

[127] Frequently Asked Questions on Defrayal of State Additional Required Benefits (October 2018), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQ-Defrayal-State-Benefits.pdf.*

by law, provide relief from any provision or requirement of the PPACA that would impose a fiscal burden on any State. . . .'' [128] Commenters also expressed concern that the annual reporting requirement will be so burdensome that it will discourage states from adopting changes to provide additional health benefits to consumers or even deter states from updating their EHB-benchmark plan.

Response: We continue to have concerns that states are not defraying the costs of their state-required benefits in addition to EHB in accordance with federal requirements. As a result of this noncompliance, QHP issuers may be covering benefits as EHB that actually require state defrayal under federal requirements, but for which the state is not actively defraying costs, resulting in improper expenditures of APTC paid by the federal government. This contravenes section 36B(b)(3)(D) of the Code, which specifies that the portion of the premium allocable to state-required benefits in addition to EHB shall not be taken into account in determining a PTC.

HHS must ensure that APTC is paid in accordance with federal law. We continue to believe that requiring states to annually report their state benefit requirements to HHS will strengthen program integrity in this regard.

We note that, contrary to some commenters' assertions, we do not currently collect detailed information from states with regard to their state benefit requirements. We therefore do not have an existing means of assessing whether states are complying with federal defrayal requirements or whether federal APTC payments are properly allocated solely to EHB. The ''State-Required Benefits'' links listed under each state on the ''Information on Essential Health Benefits (EHB) Benchmark Plans'' page on the CMS website[129] are not actively updated by the states or by HHS. Those records of state benefit requirements were collected in conjunction with state updates to EHB-benchmark plans in 2015 for plan years beginning in 2017. Furthermore, we do not collect detailed information about state-required benefits when states update their EHB-benchmark plans pursuant to the new flexibility we finalized at § 156.111(a).[130] Therefore, our records are outdated by several years and do not reflect the most current information about state benefit requirements in addition to EHB, nor do they contain the level of detail we will collect as part of the annual reporting requirement we are finalizing here.

State submissions of annual reports on state-required benefits will enable HHS to determine whether HHS is paying APTC correctly. The information states submit will provide the necessary information to HHS for increased oversight over whether states are appropriately identifying which state benefit requirements are in addition to EHB and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs.

We acknowledge that some states may already be appropriately identifying which state-required benefits are in addition to EHB and require defrayal, and that these states may have developed processes for defraying these state-required benefits. However, other states may not be doing so. This annual reporting policy will assist in achieving greater compliance with § 155.170 in all states, which will help to resolve HHS's current program integrity concerns.

Furthermore, we disagree that requiring already compliant states to annually report would be disruptive and unnecessary. Every state should already be defraying the costs of state-required benefits in addition to EHB. Thus states should already have ready access to the information required to be reported to HHS. This reporting requirement should be complementary to the process the state already has in place for tracking and analyzing state-required benefits. We also note that this regulation provides that if the state does not notify HHS of its required benefits considered to be in addition to EHB by the annual reporting submission deadline, or does not do so in the form and manner specified by HHS, HHS will identify the state-mandated benefits it believes are in addition to EHB for the applicable plan year. HHS prefers for states to provide the required information on their state-required benefits to support HHS's efforts to determine whether it is paying APTC correctly. However, if states choose not to provide this information in accordance with § 156.111(d) and (f), HHS must rely on its own ability to assess the scope of EHB in that state to ensure that only proper federal expenditures of APTC are made by the federal government.

Finalizing an annual reporting requirement for states to provide information regarding their state benefit requirements to HHS properly aligns with federal requirements for defraying the cost of state-required benefits; will generally improve transparency with regard to the types of benefit requirements states are enacting; and will provide the necessary information to HHS for increased oversight over whether states are appropriately identifying which state-required benefits require defrayal and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs.

Therefore, we are finalizing § 156.111(d) and (f) as proposed, to require states to annually notify HHS of any state-required benefits applicable to QHPs in the individual and/or small group market that are considered to be ''in addition to EHB'' in accordance with § 155.170(a)(3). We are also finalizing as proposed that the first annual submissions deadline for states to notify HHS of their state-required benefits in accordance with § 156.111(d) and (f) will be July 1, 2021.

Comment: One commenter stated that HHS should make the determination about which benefits require defrayal in every instance, because relying on the state's determination does not provide adequate program integrity. All other commenters on this topic stated we should retain § 155.170(a)(3) as is, designating the state as the entity responsible for identifying which mandates are in addition to EHB because they believe states are best positioned to make these determinations. Some commenters opposed any change making the Exchange or HHS the entity responsible for making such determinations, even in instances where the state does not submit an annual report to HHS by the annual reporting deadline or does not do so in the form and manner specified by HHS. Commenters stated that states should be able to continue their own processes for reviewing and defraying state-mandated benefits, and that to require otherwise would be disruptive and unnecessary, especially in states that have set up an already complete process for making these determinations and defraying costs when necessary.

[128] Executive Order 13865, ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients,'' 82 FR 26885, 26886 (June 12, 2017) available at *https://www.govinfo.gov/content/pkg/FR-2017-06-12/pdf/2017-12130.pdf.*

[129] Information on Essential Health Benefits (EHB) Benchmark Plans available at *https://www.cms.gov/cciio/resources/data-resources/ehb.*

[130] If a state chooses to utilize the flexibility finalized at § 156.111(a) to select a new EHB-benchmark plan starting with the 2020 plan year, we currently only ask the selecting state if the EHB-benchmark plan includes benefits mandated by state action taking place after 2011, other than for purposes of compliance with Federal requirements, for which payment is required under § 155.170. For more information, please refer to the State Confirmation Template in the information collection currently approved under OMB control number: 0938–1174 (Essential Health Benefits Benchmark Plans (CMS–10448)).

Commenters stated that shifting authority away from the state as the entity responsible for making these determinations would be inconsistent with the administration's goals of promoting state flexibility. For example, one commenter stated that HHS's identification of state-required benefits that are in addition to EHB conflicts with Executive Order 13865, ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients.'' That Executive Order directs HHS, ''to the maximum extent permitted by law, to afford the States more flexibility and control to create a more free and open health care market. . . .'' [131] One commenter noted that state insurance regulation and oversight dates back to the 1800s, has been recognized by Congress in the McCarran Ferguson Act,[132] and that the Supreme Court has also recognized states being the primary regulators of insurance.

Commenters also stated that shifting authority away from the state would be inconsistent with HHS deference to states in other areas of EHB policy. Commenters explained that the EHB-benchmark plan selection process appropriately relies on state choices to set the EHBs under federal guidelines and that, as the primary regulators of individual and small group markets, states should continue to maintain the authority to mandate certain benefits in those markets and are the best positioned entities to determine which, if any, mandated benefits are in addition to EHB. One commenter also noted that defrayal determinations necessarily rely to some extent on state interpretation and judgment. Commenters stated it would be counterproductive for HHS to offer the tremendous increase in state flexibility offered through the new EHB-benchmark plan selection options finalized at § 156.111, only to take unprecedented federal control over another aspect of EHB in the near future. Commenters emphasized that allowing states to continue their own processes supports the administration's general approach of deference to states and their expertise in local market issues. Commenters also stated that HHS does not have expertise in evaluating state-mandated benefit laws and enforcing state requirements.

One commenter also stated that HHS's identification of state-required benefits that are in addition to EHB when a State chooses not to do so is internally inconsistent because § 155.170(a)(3) establishes the state's right to identify which state-mandated benefits are in addition to the EHB. This commenter therefore questioned how HHS acting in the state's place would be consistent with § 155.170(a)(3).

Response: We agree that states are uniquely positioned to track and analyze state-required benefits and identify which state benefit requirements are in addition to EHB and require defrayal. State expertise about the unique legislative and regulatory framework involving proposing, enacting, and implementing state benefit requirements is the reason we also believe states are best situated to populate and submit the proposed annual report, which will serve as documentation for states, issuers, the federal government, and the general public of the state benefit requirements that are in addition to EHB.

We note that the annual reporting policy we are finalizing at § 156.111(d) and (f) does not restrict the state's ability to mandate any particular benefit—it merely requires states to report these state actions to HHS in order to assist in ensuring that HHS is not paying APTC for portions of premiums attributable to non-EHB.

We disagree that § 156.111(d)(2) conflicts with the flexibility offered to states as part of the new EHB-benchmark plan selection process finalized at § 156.111. We believe the annual reporting policy we are finalizing is consistent with this goal of state flexibility and acknowledges state expertise. In the 2019 Payment Notice, we finalized that, as part of the new EHB-benchmark plan selection options for states finalized at § 156.111, we would not make any changes to the policies governing defrayal of state-required benefits at § 155.170. Therefore, whether a benefit mandated by state action can be considered EHB continues to depend on when the state enacted the mandate (unless the benefit mandated was for the purposes of compliance with federal requirements).[133] Under any of the three methods for a state to select a new EHB-benchmark plan at § 156.111, the act of selecting a new EHB-benchmark plan does not alone create new state mandates, but it also does not relieve the state of its obligation to continue defraying the cost of QHPs covering any state-mandated benefits that are in addition to EHB. The annual reporting policy we are finalizing at § 156.111(d) and (f) does not change that standard. In other words, although states will be required to provide HHS with additional information with regard to state-required benefits, the annual reporting policy itself does not affect whether a state benefit requirement is or is not in addition to EHB.

States are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of those benefits, and states should already be complying with this requirement regardless of the annual reporting policy and regardless of the EHB-benchmark plan selection options at § 156.111.

Although there may be states that do not currently have in place an effective process for tracking, analyzing, and identifying state-required benefits for purposes of identifying whether they are in addition to EHB and require defrayal, all states should be able to readily track, analyze, and identify the requirements they themselves have established. For such states, the annual reporting policy may restrict perceived flexibility in the state to the extent that this annual reporting policy improves the state's compliance with defrayal requirements. However, we believe any such restriction in state flexibility in these otherwise noncompliant states is illusory because states should have already been identifying which benefits require defrayal. Further, we believe that this regulatory change is necessary to ensure that such noncompliant states are diligent about their framework for identifying which mandates are in addition to EHB in accordance with § 155.170 and to ultimately strengthen program integrity and reduce improper federal expenditures.

Finally, the policy does not shift responsibility for identifying whether a mandate is in addition to EHB from the state to HHS, unless the state chooses not to submit an annual report to HHS in accordance with § 156.111(d) and (f). Thus, this policy adds flexibility for states since HHS will identify required benefits that are in addition to EHB only where the state opts not to do so.

Therefore, we are finalizing the proposal with only a minor revision. We originally proposed at § 156.111(d)(2) that for states that do not report to HHS by the annual submission deadline in accordance with § 156.111(d) and (f), HHS would determine which benefits are in addition to EHB consistent with § 155.170(a)(3). We agree with the commenter, however, that referring back to § 155.170(a)(3) is inappropriate because that subsection requires the state, not HHS, to identify which state-required benefits are in addition to the

[131] Executive Order 13865, ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients,'' 82 FR 26885, 26886 (June 12, 2017) *available at https://www.govinfo.gov/content/pkg/FR-2017-06-12/pdf/2017-12130.pdf.*

[132] 15 U.S.C. 1011–1015.

EHB. We are thus finalizing a revision such that § 156.111(d)(2) refers instead to § 155.170(a)(2). Section 155.170(a)(2) specifies that benefits required by state action taking place on or before December 31, 2011, are considered EHB and benefits required by state action taking place on or after January 1, 2012, other than for purposes of compliance with Federal requirements, are considered in addition to EHB.

Comment: Many commenters expressed concern that HHS is proposing to increase its oversight of state compliance with defrayal requirements when HHS's policy governing which state benefit requirements are in addition to EHB is still unclear. Commenters also stated that HHS has not codified or formally clarified comprehensive standards that states must use, or that HHS would use under § 156.111(d)(2) to determine whether a state mandate is in addition to EHB and subject to defrayal. Commenters stated that, in the past, HHS has provided subregulatory guidance and verbal technical assistance about defrayal upon which states have relied, and upon which HHS should confirm states can still rely. Commenters also expressed concern that, because much of this guidance provided by HHS was unpublished or vague, HHS interpretation of defrayal policy could have since changed without warning to states, and therefore, states could be subject to unexpected defrayal costs as part of the finalized annual reporting policy. Commenters added that, although HHS provides technical assistance to states regarding what would be considered a state-required benefit in addition to EHB, states have understood these discussions to be examples rather than exhaustive or binding guidance. Commenters urged HHS that further clarifying its defrayal policies is integral for states and legislatures to make fully informed decisions about the consequences of state-required benefits on the state budget. Due to this perceived lack of clarity, commenters urged HHS to not finalize the proposal, but to clarify its defrayal policies and engage in a structured discussion with states to address defrayal questions. These commenters stated that only then should HHS consider issuing more detailed guidance that can be provided uniformly to states moving forward. One commenter recommended that, if this provision is finalized, HHS delay the implementation of an annual reporting requirement and instead take additional time to determine how many states are not complying with defrayal requirements so that HHS can better understand the scope of the problem the reporting policy is intended to address.

Several commenters offered specific policy recommendations about how HHS should modify its current policy on whether a state benefit requirement is in addition to EHB.

Response: We acknowledge commenters' concerns that they do not fully understand when a state-required benefit is in addition to EHB and requires defrayal. However, finalizing an annual reporting policy is important to help resolve HHS's program integrity concerns regarding improper federal expenditures of APTC for benefits that are in addition to EHB. The information states provide to HHS in the annual reports will assist HHS in identifying whether states are appropriately identifying which state-required benefits require defrayal, and therefore, whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs.

In addition to the existing guidance we have provided on defrayal through our past regulations and guidance documents, we intend to continue to engage with states and provide additional technical assistance that helps ensure state understanding of when a state-benefit requirement is in addition to EHB and requires defrayal. We anticipate that this assistance will provide examples and explains how a state could operationalize the defrayal process pursuant to federal requirements at § 155.170. We believe such technical assistance will bolster state compliance with defrayal requirements, as well as result in a smoother annual reporting process for states and review process for HHS.

While we appreciate commenters' recommendations on how HHS should modify its current policy on whether a state benefit requirement is in addition to EHB, such recommendations are outside the scope of this rulemaking, which is limited to reporting of state benefit requirements.

Comment: Several commenters raised concerns that this rule does not specify how HHS will use the information states provide in the annual reports and does not outline what oversight activities HHS will conduct. Commenters urged HHS to provide additional transparency into how it will use state reported information on benefit requirements to enhance its oversight and enforcement of § 155.170. For example, one commenter suggested HHS clarify how it will review state information from state actions taken prior to the first annual reporting submission deadline and clarify whether HHS will take retroactive action to determine if previous state benefit requirements are in addition to EHB and require defrayal. Several commenters stated that the annual reports should only be used to hold states accountable prospectively for defrayal of state benefit requirements in addition to EHB, and that it would be of great concern to states if HHS's intention is to review annual reports for retrospective compliance with defrayal, which would have significant practical consequences.

Other commenters stated that HHS should enhance the already existing oversight that would occur if the policy is finalized as proposed, by developing and providing details on how it intends to ensure that states' annual reports are accurate and complete, for example through annual audits of state reports, and requested specific information regarding whether HHS will review the reports for prior state activity. One commenter suggested that HHS require ''one source of truth'' as to which benefit requirements in a given state are in addition to EHB and require defrayal so that QHP issuers can be sure they have the correct benefits listed as EHBs.

Many commenters requested that, before the reporting requirement is finalized, states understand the potential liabilities the reported information could generate (for example, types of remedial action). Commenters argued that, although section 1311(d)(3)(B) of the PPACA requires states defray the cost of benefits in addition to EHB to either the enrollee or the issuer on behalf of the enrollee, it does not provide a process for how an HHS determination about a state's benefit requirement can substitute the state's own policy conclusion with regard to whether that benefit requirement is in addition to EHB. Commenters argued that section 1311(d)(3)(B) of the PPACA does not give HHS authority to interpret state insurance law. Commenters also requested that HHS clarify the process for when HHS reviews a state's annual report, or makes the determination for a non-reporting state, and the state disagrees with HHS or otherwise refuses to comply with HHS's determination and does not defray the cost of the state benefit requirement that HHS believes is in addition to EHB. One commenter stated that it is not clear what options exist in the event of conflict except for HHS to overrule the will of state legislative and executive branches, state insurance commissioners' authority, and Exchanges' state-based authority.

Commenters argued that HHS must establish a neutral and fair process for

evaluating state-mandated benefits and resolving disputes between HHS and the state. For example, one commenter stated that there needs to be a formal appeals process because HHS has a conflict of interest in determining whether a mandate requires defrayal since such a determination could potentially lower the amount of APTC the government needs to pay out, and therefore, this proposal is arbitrary and capricious without a formal hearing or appeals process. Other commenters expressed concern that there was no proposed dispute resolution or appeals process, especially since the remedial action HHS would take is unclear.

Commenters recommended that federal oversight and compliance actions over state benefit requirements reported in the annual reports remain limited and that retaining the primary authority with the states will help avoid circumstances of conflict between the state and HHS about whether a benefit requirement is in addition to EHB. One commenter stated that there would be far reaching operational problems if HHS incorrectly issues a decision about a state benefit requirement because that interpretation would interfere with state form review, rate review, plan certification, market conduct exams, enforcement, and even consumer assistance. Another commenter understood the proposal to mean that HHS could also determine the amount to be defrayed by the state for a benefit that is in addition to EHB. This commenter stated they are unaware of any authority that would allow the federal government to access and spend money from a state's treasury.

Many commenters questioned whether HHS has any available enforcement authority to actually require states to defray the cost of a state benefit requirements in such situations of disagreement between the state and HHS. Commenters stated that there is no legal mechanism in place for resolving any disputes HHS may have with a state's determination which calls into question the very need for the amendments to § 156.111, if HHS has no viable enforcement authority.

One commenter was critical that the proposed rule did not specify what the procedure would be for direct enforcement states that do not report to HHS. The same commenter argued that HHS making the determinations about which state benefit requirements are in addition to EHB and require defrayal would be unconstitutional commandeering of states, and would violate the Tenth Amendment because it coerces states to act. Commenters noted that, different from the authority HHS has to implement federal law in states that refuse or are unable to, in this case HHS is giving itself authority to interpret state insurance law, which is authority that neither the PPACA nor other laws related to health insurance provide to HHS. This commenter stated that the PPACA requirement to defray is unconstitutional in the first place and that HHS should not seek through this rulemaking to further attempt to implement this unconstitutional requirement. This commenter further stated they are uncertain whether the federal government can compel a direct enforcement state to pay a part of anyone's insurance premium or even any portion of federal subsidies.

Response: We acknowledge the discomfort expressed by some commenters with regard to how HHS intends to use the information included in the annual reports for oversight purposes, especially given commenters' stated concerns regarding lack of clarity about the defrayal policy itself, and how to identify whether a state benefit requirement is in addition to EHB. However, we believe that conducting additional technical assistance to states in the interim will assist in easing state concerns and uncertainty about identifying which state benefit requirements are in addition to EHB and require defrayal.

We further acknowledge that some states already comply with § 155.170, making reasoned assessments about state benefit requirements, and defraying benefits in addition to EHB. Nonetheless, we still believe collecting annual reports for such states is necessary. We also believe collecting annual reports from otherwise compliant states will improve transparency generally with regard to the types of benefit requirements states are enacting.

HHS will review the information states submit in their reports to help determine whether HHS is paying APTC correctly. Without such reports, HHS lacks the information necessary to make these assessments. Although all information submitted in the reports will be helpful to HHS, we anticipate most closely reviewing the information the state provides pursuant to § 156.111(f)(2) and (3), regarding whether a state-required benefit is or is not in addition to EHB and the basis the state provides for why a state-required benefit is not in addition to EHB. To the extent that HHS has concerns about the content of a state's annual report, or has concerns about a non-reporting state's compliance with HHS's identification of which state benefit requirements are in addition to EHB and require defrayal, HHS intends to first reach out to the state directly to resolve any such concerns.

To the extent possible, it is our intent to continue the collaborative process we have cultivated with states up to this point regarding questions states have about defrayal. We continue to believe states are best suited to analyze their own state mandates, which is why we are finalizing the annual reporting policy in a manner that relies first on states to submit information to HHS identifying which state-required benefits are in addition to EHB. We also are finalizing that HHS will identify, rather than determine, which benefits are in addition to EHB in states that opt not to report. We note that, as finalized, the annual reporting requirement is the same for all states regardless of whether they are an enforcing or direct enforcement state. We intend to provide non-reporting states with an opportunity to review our identifications prior to releasing the annual reports on the CMS website for public viewing in an effort to mitigate the potential for disagreement between the state and HHS. We also believe our interim outreach with states to clarify defrayal policy more generally will assist in states' understanding on what basis HHS will assess whether state-required benefits are in addition to EHB in non-reporting states.

Further, we disagree with commenters' assertions that HHS does not have enforcement authority to penalize states that refuse to defray the cost of state benefit requirements in addition to EHB in accordance with § 155.170. Pursuant to section 1313(a)(4) of the PPACA, if the Secretary determines that a state or Exchange has engaged in serious misconduct with respect to compliance with requirements under Title I of the PPACA, which includes the requirement that states defray the cost state benefit requirements in addition to EHB, HHS is authorized to rescind up to 1 percent of payments otherwise due to a state per year until corrective actions are taken by the state that are determined to be adequate by the Secretary. HHS would like to avoid the use of such authority, especially as it would not result in a transfer of any portion of such amounts to the issuer or consumer who is entitled to state defrayal payments under the PPACA. We disagree, however, that using this authority would be overstepping HHS authority.

HHS also disagrees that identifying benefits that are in addition to EHB in a state and requiring defrayal violates the Tenth Amendment. We

acknowledge that HHS's identification of state-required benefits that are in addition to EHB might conflict with the opinion of a non-reporting state. However, as previously noted, HHS must ensure that APTC is paid in accordance with federal law. If a state is not defraying the cost of a state-required benefit that is in addition to EHB, resulting in improper federal expenditures, we believe section 1313(a)(4) of the PPACA provides HHS with the authority to enforce the defrayal requirements outlined in statute.

Program integrity remains a top priority for HHS, and we believe exercising our existing authority to address noncompliance with defrayal requirements under section 1311(d)(3)(B) of the PPACA and § 155.170, if necessary, is warranted to mitigate the risk of federal dollars incorrectly leaving the federal Treasury in the form of APTC during the year. However, we appreciate commenters' desire for further insight into how the notices will play into our policy for enforcing the defrayal requirements. We are not adopting any policy with regard to whether enforcement of the defrayal requirement will be retrospective or prospective in relation to the submission of § 156.111 reports. The requirement to submit reports under this final rule is independent of a state's pre-existing duty under section 1313(a)(4) of the PPACA to defray costs for state-mandated benefits that are in addition to EHB. Whether we discover noncompliance with defrayal requirements through submission of the reports required under this final rule or through a complaint lodged by a consumer or an issuer, HHS will take appropriate action in line with its statutory authority. However, as noted earlier, we intend to continue the collaborative process we have cultivated with states up to this point. We intend to provide non-reporting states with an opportunity to review our identifications of state-mandated benefits that are in addition to EHB prior to releasing the annual reports on the CMS website for public viewing in an effort to mitigate the potential for disagreement between the state and HHS.

Comment: Commenters noted mixed opinions with regard to a public comment period. Some commenters stated that they do not think it is necessary to allow for a public comment period before publicizing state reporting, but suggested HHS develop a procedure to use in the event there ever is a mistake in a state's mandated benefit reporting. Other commenters stated there should be a public comment period on the annual reports. Commenters stated that it is important to allow issuers and other stakeholders to provide formal input, and create a public record, on which benefit requirements require defrayal given that states have a conflict of interest in identifying these mandates themselves, and that HHS should review the record of comments when reviewing state-reported benefit mandates as part of its oversight review.

Response: We agree with commenters that it is unnecessary to require a public comment period on the annual reports submitted to HHS or for the annual reports that HHS completes for non-reporting states. State benefit requirements most often originate from the state legislature and, upon passage, the question of whether or not the benefit requirement is in addition to EHB has a fixed answer. As such, the feedback provided to states or HHS from the public or from stakeholders during a public comment period could not impact the ultimate decision on the part of states, or on the part of HHS for non-reporting states, about whether a benefit requirement is in addition to EHB. Therefore, we do not believe a public comment period would be a beneficial use of time or resources.

Comment: Several commenters had specific recommendations or concerns regarding the type of information states would be required to submit to HHS by the annual submission deadline in a form and manner specified by HHS. One commenter requested that, to support the administration's goals of state flexibility, HHS instead allow states to submit state mandate information in a form and manner determined by the state.

Other commenters expressed concern that HHS did not provide sufficient specificity about the types of data elements states would be required to include in the annual report. For example, one commenter stated that there is not enough detail in the proposed rule about how this reporting process would work and HHS should make the proposed templates available for commenters to review. One commenter urged HHS to include information on the final annual reporting templates to be used by states that would identify whether the state benefit requirement doesn't require defrayal because it falls into an exception to the defrayal policy. Another commenter requested that, after the initial report in the first year of annual reporting, states should only identify changes to benefit requirements to make it easier for HHS and issuers to identify which benefits are new or modified.

One commenter argued that states should also be required to report these additional benefits to the insurance department or other agencies. Another commenter suggested that HHS require states to submit their methodologies for conducting their defrayal analysis to require additional transparency. A different commenter argued that states should not be required to provide a justification or basis for the state's defrayal determination as there is no statutory or regulatory authority for HHS to impose this burden, but that if it finalizes this requirement the commenter agrees such justification should be concise (for example citing to the state constitution amendment that gives the state department of insurance the authority to oversee insurance). One commenter stated that the report should detail the benefits that are included as EHBs in the benchmark plan, state mandated benefits that are part of the benchmark plan, state mandated benefits that are subject to state defrayal, and a list of common benefits that must be considered non-EHB by QHPs.

Response: We appreciate the feedback provided in comments regarding ways to improve the annual reporting process and the data elements that would be most helpful for HHS to collect. We are finalizing as proposed § 156.111(f), which specifies the type of information states are required to submit to HHS by the annual submission deadline in a form and manner specified by HHS. For a reporting package to be complete, it will need to comply with each requirement listed at § 156.111(f)(1) through (6). We believe the descriptions of the required data elements at § 156.111(f)(1) through (6) provide sufficient detail to states regarding the types of information states will be required to include in the annual reports such that states and other stakeholders reviewing those requirements can understand the scope of the information states are required to include in their annual reports without reviewing the actual reporting templates. With respect to § 156.111(f)(4), which provides for states to submit other information about state-required benefits that is necessary for HHS oversight, we reiterate the illustrative examples we previously published. Additional information that is necessary for HHS oversight may include data such as the date of state action imposing the requirement to cover the state-required benefit; the effective date of the applicable state action; the market it applies to (that is, individual, small group, or both); the

precise benefit or set of benefits that QHPs in the individual and/or small group market are required to cover; any exclusions; and the citation to the relevant state action.

In the first reporting year, this annual report must include a comprehensive list of all state benefit requirements applicable to QHPs in the individual and/or small group market under state mandates that were imposed on or before December 31, 2011 and that were not withdrawn or otherwise no longer effective before December 31, 2011, and any state benefit requirements under state mandates that were imposed any time after December 31, 2011, regardless of whether the state believes they require defrayal in accordance with § 155.170.

The first reporting cycle is intended to set the baseline list of state-required benefits applicable to QHPs in the individual and/or small group market. Each annual reporting cycle thereafter, the state will only be required to update the content in its report to add any new benefit requirements, and to indicate whether benefit requirements previously reported to HHS have been amended or repealed. State reports for subsequent years must be accurate as of 60 days prior to the annual reporting submission deadline set by HHS for that year. If a state has not imposed, amended, or repealed any state benefit requirements in the time period between annual reporting deadlines, the state is still required to report to HHS that there have been no changes to state-required benefits since the previous reporting cycle. In such a scenario, we are finalizing that the state should submit the same reporting package as the previous reporting cycle and affirmatively indicate to HHS that there have been no changes.

As stated in the proposed rule, HHS will provide template(s) reflecting the form and manner of the report that states will be required to use for reporting the required information proposed in § 156.111(f)(1) through (6). We believe standardizing the form and manner of the report and the data elements required is important for consistency year after year and for ensuring HHS has the information necessary to adequately oversee that states are defraying the cost of state-required benefits in addition to EHB consistent with § 155.170 and to ensure that HHS is not improperly paying APTC for portions of premium attributable to non-EHB.

We still intend to post state submissions of these documents on the CMS website prior to the end of the plan year during which the annual reporting takes place such that this information is accessible to states, QHP issuers, enrollees, stakeholders, and the general public. HHS will complete a similar document for non-reporting states and post it to the CMS website. As noted above, we intend to provide the non-reporting state with an opportunity to review the HHS's identifications prior to posting the HHS-created report on the CMS website. We do not believe it is necessary to explicitly require the state to provide a copy of the report to the insurance department, as the report will be publicly available on the CMS website.

We emphasize that this reporting requirement would be independent of the state's requirement to defray the cost of QHP coverage of state-required benefits in addition to EHB in accordance with § 155.170. The obligation for a state to defray the cost of QHP coverage of state-required benefits in addition to EHB is an independent statutory requirement under section 1311(d)(3)(B) of the PPACA, as implemented at § 155.170, and would remain fully applicable to states regardless of whether they annually report state-required benefits to HHS or defer to HHS to identify which state-required benefits are in addition to EHB and require defrayal. We also note that issuers would still be responsible for quantifying the cost of these benefits and reporting the cost to the state. States remain responsible for making payments to defray the cost of additional required benefits, either to the enrollee or to the QHP issuer on behalf of the enrollee.

Comment: Many commenters expressed concern with the proposed timing of the annual reporting requirement. Commenters stated that legislative sessions end at different times in different states and that, as such, the annual submission deadline being at the same time during the plan year for every state is not feasible. For example, for states whose legislative sessions end in September, the commenter explained that the proposed reporting deadline in July is too early and would mean the annual reports would include mandates imposed retrospectively rather than prospectively. Another commenter expressed that HHS determinations need to give ample opportunity to states to amend their statutes, be made in advance of rate filings, and only be made on a prospective basis, but that this is impossible given the proposed submission deadline in July. The commenter further explained that their state's legislature adjourns between May 2021 and January 2023, leaving no ability for the state legislature to legislatively respond to determinations made by HHS under this reporting policy. Many other commenters echoed the request that the annual reporting and defrayal requirements be made only on a prospective basis.

Commenters who supported the entire proposal agreed the reporting should occur annually. One commenter noted their appreciation for the proposal but argued the reporting requirement should be every two years at most to reduce administrative burden and unnecessary costs, given that the process for enacting state mandates is often a long one.

We received no comments on the proposed 60-day cut-off date that proposed to require the annual report be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS.

Response: As stated in the proposed rule, we acknowledge that the start and end dates of state legislative sessions vary greatly by state, and that many state legislative sessions may not have concluded by the annual reporting submission deadline. However, we believe that setting the same annual submission deadline for all states is necessary to standardize the annual reporting process and publish the annual reports on the CMS website at or around the same time each year. We agree with commenters that we should require reporting annually and that this frequency will best serve HHS's goals of increased oversight over state compliance with defrayal requirements than would a less frequent collection of annual reports.

We also still believe it is important to set a cut-off date after which states are not expected to report on their state-required benefits until the following annual reporting deadline, which is why we are finalizing at § 156.111(f)(1) that state annual reports must be accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS. We believe that setting this cut-off date at least 60 days prior to the submission deadline allows a state sufficient time to analyze its state benefit requirements imposed, amended, or repealed through state action taken by that date and prepare the required documents we are proposing that states submit to HHS.

A state where a legislative session ends after the 60-day cut-off date (such as a legislative session that ends in September of that plan year) that happens to enact, amend, or repeal a state-required benefit after the cut-off date but before the annual reporting submission deadline will not be expected to report that state-required

benefit in that plan year's annual reporting submission. Instead, the state is expected to include that state-required benefit in the annual reporting package for the following year. States will be permitted to submit their reports any time between the 60-day cut-off date and the applicable deadline.

We acknowledge commenters' concerns that, depending when the annual reporting submission deadline falls in relation to the state's legislative calendar, the state's annual report may be more reflective of state mandates passed in previous plan years than reflective of the plan year in which the annual reporting submission deadline falls. Although we acknowledge this is not ideal, we do not foresee this being a problem, as the state will be able to include any state-required benefits enacted after the annual submission deadline in the annual reporting package for the following year. Further, we again emphasize that the annual reporting requirement and the reporting cut-off date do not alter a state's obligation to defray the cost of benefits in addition to EHB that result from state action taken after the cut-off date. In other words, states must defray benefits in addition to EHB in accordance with § 155.170 regardless of whether the state benefit requirement was imposed, amended, or repealed through state action taken before or after the proposed 60-day cut-off date for inclusion in that plan year's annual reporting submission. If a state passes a benefit requirement after the annual submission deadline that is in addition to EHB and requires defrayal, the state should defray the cost of that benefit in spite of it not being captured as part of the annual report submitted to HHS for that submission year. The annual reporting requirement should function as an additional, but complementary step to those already in place at § 155.170.

b. States' EHB-Benchmark Plan Options

We proposed May 7, 2021 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year pursuant to § 156.111(a), and the deadline for states to notify us that they wish to permit between-category substitution for the 2023 plan year. We also made some clarifications to § 156.111(b)(2) regarding scope of benefits. We are finalizing these deadlines as proposed and confirming the scope of benefit clarifications.

In the 2019 Payment Notice, we stated that we believe states should have additional choices with respect to benefits and affordable coverage. Therefore, we finalized options for states to select new EHB-benchmark plans starting with the 2020 plan year. Under § 156.111(a), a state may modify its EHB-benchmark plan by: (1) Selecting the EHB-benchmark plan that another state used for the 2017 plan year; (2) Replacing one or more EHB categories of benefits in its EHB-benchmark plan used for the 2017 plan year with the same categories of benefits from another state's EHB-benchmark plan used for the 2017 plan year; or (3) Otherwise selecting a set of benefits that would become the state's EHB-benchmark plan.

Under any of these three options, the EHB-benchmark plan also has to meet additional standards, including EHB scope of benefit requirements under § 156.111(b). These requirements include providing a scope of benefits that is equal to, or greater than, to the extent any supplementation is required to provide coverage within each EHB category, the scope of benefits provided under a typical employer plan. Section 156.111(b)(2) defines a typical employer plan as either (1) one of the selecting state's 10 base-benchmark plan options established at § 156.100 from which the state was able to select for the 2017 plan year; or (2) the largest health insurance plan by enrollment in any of the five largest large group health insurance products by enrollment in the selecting state, as product and plan are defined at § 144.103, provided that: (a) The product has at least 10 percent of the total enrollment of the five largest large group health insurance products by enrollment in the selecting state; (b) the plan provides minimum value; (c) the benefits are not excepted benefits; and (d) the benefits in the plan are from a plan year beginning after December 31, 2013. The state's EHB-benchmark plan must also satisfy the generosity standard at § 156.111(b)(2)(ii), which specifies that a state's EHB-benchmark plan must not exceed the generosity of the most generous among a set of comparison plans, including the EHB-benchmark plan used by the state in 2017, and any of the state's base-benchmark plan options for the 2017 plan year, supplemented as necessary.

Additionally, states must document meeting these requirements through an actuarial certification and associated actuarial report from an actuary who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies. We published the ''Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with § 156.111(b)(2)(i) and (ii)'' (example methodology guidance), alongside the 2019 Payment Notice.[134] We finalized that the current EHB-benchmark plan selection would continue to apply for any year for which a state does not select a new EHB-benchmark plan from among these options.

The 2019 Payment Notice stated that we would propose EHB-benchmark plan submission deadlines in the HHS annual Notice of Benefit and Payment Parameters. Accordingly, we proposed May 7, 2021 as the deadline for states to submit the required documents for the state's EHB-benchmark plan selection for the 2023 plan year. We emphasized that this deadline would be firm, and that states should optimally have one of their points of contact who has been predesignated to use the EHB Plan Management Community reach out to us using the EHB Plan Management Community well in advance of the deadline with any questions. Although not a requirement, we recommended states submit applications at least 30 days prior to the submission deadline to ensure completion of their documents by the proposed deadline. We also reminded states that they must complete the required public comment period and submit a complete application by the deadline. We solicited comment on the proposed deadline.

In the 2019 Payment Notice, we also finalized a policy through which states may opt to permit issuers to substitute benefits between EHB categories. In the preamble to that rule, we stated that the deadline applicable to state selection of a new benchmark plan would also apply to this state opt-in process. Therefore, we proposed May 7, 2021, as the deadline for states to notify us that they wish to permit between-category substitution for the 2023 plan year. States wishing to make such an election must do so via the EHB Plan Management Community. We solicited comment on the proposed deadline.

We also reiterated the scope of benefits requirements at § 156.111(b)(2). We finalized the definition of a typical employer plan to establish the minimum level of benefits for the state's EHB-benchmark plan selection and to ensure plans that meet EHB standards are equal in scope to a typical employer plan as required under section 1302(2)(A) of the PPACA, and a generosity standard to establish the

[134] Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-Example-Acceptable-Methodology-for-Comparing-Benefits.pdf.*

maximum level of benefits for a state's EHB-benchmark plan selection.

The generosity standard at § 156.111(b)(2)(ii) balances our goal of promoting state flexibility with the need to preserve coverage affordability by minimizing the opportunity for a state to select EHB in a manner that would make coverage unaffordable for patients and increase federal costs. As such, we clarified for states that when selecting an updated EHB-benchmark plan from the available options listed at § 156.111(a), the new EHB-benchmark plan may not exceed the generosity of the most generous among the set of comparison plans listed at § 156.111(b)(2)(ii) even by a *de minimis* amount, and that states must clearly demonstrate in their actuarial report to HHS how the state's updated EHB-benchmark plan satisfies the generosity test. In other words, the generosity of the state's updated EHB-benchmark plan may not exceed a 0.0 percentage point actuarial increase above the most generous among the set of comparison plans listed at § 156.111(b)(2)(ii).

Finally, we clarified that the typical employer plan and generosity standard requirements are two separate tests that an EHB-benchmark plan must satisfy. However, we recognized that there may be some instances in which it may be difficult to design an EHB-benchmark plan that satisfies both standards. Therefore, we reminded states that, as we stated in the example methodology guidance,[135] states should consider using the same plan as the comparison plan for both tests, to the extent possible, to help minimize burden and to mitigate against any potential conflict caused by applying each test with a different comparison plan.

Comment: Multiple commenters agreed with the proposed submission deadlines.

Response: We are finalizing the deadlines as proposed. The deadline for state submission of EHB-benchmark plan changes and to notify HHS that the state will allow between-category benefit substitution for the 2023 plan year is May 7, 2021.

Comment: Some commenters asked for further clarification on the generosity standard when states chose to select a new EHB-benchmark plan. Others did not agree with the generosity standard. One commenter noted that states could interpret the requirement for a proposed EHB-benchmark plan not to exceed the generosity of the comparison plan to allow a *de minimis* difference in actuarial value. Another commenter stated that the 2019 Payment Notice did not sufficiently emphasize that a state could not exceed the generosity standard.

Response: As provided at § 156.111(e)(2)(ii), the actuary's certification and report must affirm that the state's proposed EHB-benchmark plan does not exceed the generosity of the most generous of the plans listed at § 156.111(b)(2)(ii)(A) and (B). Furthermore, ''does not exceed the generosity'' means that changes to the EHB-benchmark plan cannot result in an increase in generosity beyond that reference plan, no matter how *de minimis.* Finally, when a state selects a new EHB-benchmark plan, the state must, among other requirements, provide an actuarial certification and an associated actuarial report from an actuary, who is a member of the American Academy of Actuaries, in accordance with generally accepted actuarial principles and methodologies, that affirms compliance with the generosity standard, consistent with § 156.111(e)(2).

Comment: Several comments were out of the scope of the proposals and pertained to EHB benchmark policy in general. Some commenters noted opposition to the policy previously finalized at § 156.111 in the 2019 Payment Notice. Commenters stated that HHS should ensure that states strictly comply with the requirement to provide public notice and comment on the proposed benchmark plan, including by providing detailed information about proposed changes and the actuarial report that the state must submit to HHS. They also suggested that we implement a federal notice and comment process for state benchmark plan changes. Another commenter noted that the comment period should allow commenters a significant amount of time to respond to the proposal, while another commenter stated that states should notify interested stakeholders when proposing changes to the benchmark. One commenter suggested allowing states to add additional coverage of habilitative services, outside of the process at § 156.111. One commenter urged us to implement a notice and comment process when a state wishes to permit between-category benefit substitution.

Response: As these comments do not pertain to the proposals, we will take them into consideration for future rulemaking. As stated in the 2019 Payment Notice, we expect states to use a reasonable public comment period.[136] As a best practice, we encourage states to use the public comment process delineated in any applicable state administrative procedure law or regulations. States must submit a complete application to HHS by the deadline, which means that the state public comment period must have concluded prior to submitting the application to HHS, so that the state can consider public comments prior to submitting the final application.

4. Essential Health Benefits Package (§ 156.130)

a. Premium Adjustment Percentage (§ 156.130)

We proposed to update the annual premium adjustment percentage using the most recent estimates and projections of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) from the NHEA, which are calculated by the CMS Office of the Actuary. For the 2021 benefit year, the premium adjustment percentage will represent the percentage by which this measure for 2020 exceeds that for 2013.

Section 1302(c)(4) of the PPACA directs the Secretary to determine an annual premium adjustment percentage, a measure of premium growth that is used to set the rate of increase for three parameters detailed in the PPACA: (1) The maximum annual limitation on cost sharing (defined at § 156.130(a)); (2) the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code (defined at § 155.605(d)(2)); and (3) the employer shared responsibility payment amounts under section 4980H(a) and (b) of the Code (see section 4980H(c)(5) of the Code). Section 1302(c)(4) of the PPACA and § 156.130(e) provide that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013, and the regulations provide that this percentage will be published in the annual HHS notice of benefit and payment parameters.

The 2015 Payment Notice[137] and 2015 Market Standards Rule[138] established a methodology for estimating the average per capita premium for purposes of calculating the premium adjustment percentage for the 2015 benefit year and beyond.

[135] Example of an Acceptable Methodology for Comparing Benefits of a State's EHB-benchmark Plan Selection in Accordance with 45 CFR 156.111(b)(2)(i) and (ii), available at *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Final-Example-Acceptable-Methodology-for-Comparing-Benefits.pdf.*

[136] 83 FR at 17017.

[137] 79 FR 13743.

[138] 79 FR 30240.

Beginning with the 2015 benefit year, the premium adjustment percentage was calculated based on the estimates and projections of average per enrollee employer-sponsored insurance premiums from the NHEA. In the proposed 2015 Payment Notice, we proposed that the premium adjustment percentage be calculated based on the projections of average per enrollee private health insurance premiums. Based on comments received, we finalized the 2015 Payment Notice to instead use per enrollee employer-sponsored insurance premiums in the methodology for calculating the premium adjustment percentage. We chose employer-sponsored insurance premiums because they reflected trends in health care costs without being skewed by individual market premium fluctuations resulting from the early years of implementation of the PPACA market reforms. We adopted this methodology in subsequent Payment Notices for the 2016 through 2019 benefit years, but noted in the 2015 Payment Notice that we may propose to change our methodology after the initial years of implementation of the market reforms, once the premium trend is more stable.

In the 2020 Payment Notice, we adopted a modification of the premium measure that we use to calculate the premium adjustment percentage. This premium measure captures increases in individual market premiums in addition to increases in employer-sponsored insurance premiums for purposes of calculating the premium adjustment percentage. Specifically, we calculate the premium measures for 2013 and 2020 as private health insurance premiums minus premiums paid for Medicare supplement (Medigap) insurance and property and casualty insurance, divided by the unrounded number of unique private health insurance enrollees, excluding all Medigap enrollees.

This premium measure is an adjusted private individual and group market health insurance premium measure, which is similar to NHEA's private health insurance premium measure. NHEA's private health insurance premium measure includes premiums for employer-sponsored insurance; ''direct purchase insurance,'' which includes individual market health insurance purchased directly by consumers from health insurance issuers, both on and off the Exchanges and Medigap insurance; and the medical portion of accident insurance (''property and casualty'' insurance). The measure we used in the 2020 Payment Notice is published by NHEA and includes NHEA estimates and projections of employer-sponsored insurance and direct purchase insurance premiums, but we excluded Medigap and property and casualty insurance from the premium measure since these types of coverage are not considered primary medical coverage for individuals who elect to enroll. We used per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) so that the premium measure would more closely reflect premium trends for all individuals primarily covered in the private health insurance market since 2013, and we anticipated that the change to use per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) would additionally reduce Federal PTC expenditures if the Department of the Treasury and the IRS adopted the same premium measure. The Department of the Treasury and the IRS have since adopted the premium growth measure provided in the 2020 Payment Notice for purposes of the indexing adjustments under section 36B of the Code.[139]

We proposed to continue to use the NHEA private health insurance premium measure (excluding Medigap and property and casualty insurance) for the 2021 benefit year. As such, we proposed that the premium adjustment percentage for 2021 be the percentage (if any) by which the most recent NHEA projection of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2020 ($6,759) exceeds the most recent NHEA estimate of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) for 2013 ($4,991).[140] Using this formula, the proposed premium adjustment percentage for the 2021 benefit year was 1.3542376277 ($6,759/$4,991), which represents an increase in private health insurance (excluding Medigap and property and casualty insurance) premiums of approximately 35.4 percent over the period from 2013 to 2020. We sought comments on the proposed premium adjustment percentage.

After reviewing public comments, we are finalizing the premium adjustment percentage at the proposed value of 1.3542376277, based on the NHEA data available at the time of proposal, for the 2021 benefit year. The following is a summary of the public comments we received on the premium adjustment percentage.

Comment: We received a few comments regarding the timing of NHEA data updates that we use to calculate the premium adjustment percentage index (PAPI) and associated payment parameters. For the 2020 Payment Notice, these data were updated between the proposed and final rules, and in order to reflect the most recent data available, we updated the value of the premium adjustment percentage in the final 2020 Payment Notice accordingly. Some commenters expressed concern that updates to the NHEA data between the proposed and final rules could lead to unpredictability in benefit design and pricing. They recommended that even if NHEA data are updated between the proposed and final rules, we should finalize the premium adjustment percentage using the NHEA data that was available when the proposed rule was published.

Response: We understand some commenters' concern that issuers require the payment parameters associated with the NHEA data as early as possible prior to rate submissions to develop benefit designs and pricing. In light of these comments, we clarify that for the 2021 benefit year and beyond, we are finalizing payment parameters that depend on NHEA data, including the premium adjustment percentage and required contribution percentage, based on the data that are available as of the publication of the proposed rule for that benefit year, to increase the predictability of benefit design. These payment parameters include the premium adjustment percentage, the maximum annual limitation on cost sharing, the reduced maximum annual limitations on cost sharing for silver plan variations, and the required contribution percentage. We are finalizing a premium adjustment percentage for the 2021 benefit year at 1.3542376277, as proposed.

Comment: All commenters on this proposal expressed concern with the rate of increase in the PAPI and related payment parameters. Many commenters specifically opposed the use of a premium measure that includes individual market premium changes, on

[139] See Revenue Procedure 2019–29, 2019–32 IRB 620. *https://www.irs.gov/pub/irs-drop/rp-19-29.pdf.*

[140] The 2013 and 2020 per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance) figures used for this calculation were published on February 20, 2019. The series used in the determinations of the adjustment percentages can be found in Table 17 on the CMS website, which can be accessed by clicking the ''NHE Projections 2018–2027—Tables'' link located in the Downloads section at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html.* A detailed description of the NHE projection methodology is also available on the CMS website.

the grounds that the use of that measure would lead to more rapid increases in consumer costs than the ESI-only premium measure utilized to calculate the PAPI prior to the 2020 benefit year. Commenters expressed concerns that more rapid increases in the premium adjustment percentage would lead to lower enrollment. We also received two comments suggesting caps to the PAPI such that, if we maintain the current measure, we should cap the PAPI to a maximum 3 percent annual increase or that we should revise the calculation to allow for a few years of transition between the ESI-only premium measure and premium measures that include individual market premiums.

Response: As stated earlier in this preamble, we are finalizing the proposed value of the premium adjustment percentage, using the measure of premium growth that accounts for individual market health insurance premiums, as well as employer-sponsored insurance that we finalized in the 2020 Payment Notice, based on the data available at the time of the proposal. We believe that a measure that incorporates employer-sponsored insurance as well as individual market premiums is an appropriate, comprehensive measure of premium growth as discussed in the 2020 Payment Notice.[141] As such, we will continue to calculate the premium adjustment percentage using NHEA projections of per enrollee premiums for private health insurance (excluding Medigap and property and casualty insurance).

(1) Maximum Annual Limitation on Cost Sharing for Plan Year 2021

We proposed to increase the maximum annual limitation on cost sharing for the 2021 benefit year based on the proposed value calculated for the premium adjustment percentage for the 2021 benefit year. Under § 156.130(a)(2), for the 2021 calendar year, cost sharing for self-only coverage may not exceed the dollar limit for calendar year 2014 increased by an amount equal to the product of that amount and the premium adjustment percentage for 2021. For other than self-only coverage, the limit is twice the dollar limit for self-only coverage. Under § 156.130(d), these amounts must be rounded down to the next lowest multiple of $50.

Using the premium adjustment percentage of 1.3542376277 for 2021 as proposed, and the 2014 maximum annual limitation on cost sharing of $6,350 for self-only coverage, which was published by the IRS on May 2, 2013,[142] we proposed that the 2021 maximum annual limitation on cost sharing would be $8,550 for self-only coverage and $17,100 for other than self-only coverage. This represents an approximately 4.9 percent increase above the 2020 parameters of $8,150 for self-only coverage and $16,300 for other than self-only coverage. We solicited comment on this proposal.

After reviewing public comments, we are finalizing the maximum annual limitation on cost sharing values at $8,550 for self-only coverage and $17,100 for other than self-only coverage, as proposed. The following is a summary of the public comments we received on the maximum annual limitation on cost sharing.

Comment: Some commenters requested that HHS work with the IRS to align the maximum annual limitation on cost sharing we publish based on the PAPI and the maximum out-of-pocket value the IRS publishes regarding high-deductible health plans (HDHPs). These commenters are concerned that differences between the two maximum out-of-pocket values would prevent issuers from offering HDHPs that will allow individuals to contribute to health savings accounts (HSAs) as bronze plans.

Response: We recognize that the different requirements published by the IRS and by HHS may result in some issuers being unable to offer HSA-eligible HDHPs, in accordance with sections 223(c) and (g) of the Code, within the actuarial value range for bronze metal level plans. IRS and HHS are required to follow separate statutes for the maximum annual limitation on cost sharing. The calculation for the maximum annual limitation on cost sharing published by HHS is mandated by section 1302(c)(1) of the PPACA and depends on the premium adjustment percentage defined by section 1302(c)(4) of the PPACA as a measure of growth in average per capita premiums. The annual updates to the HDHP maximum out-of-pocket published by the IRS, however, are mandated by section 223(g) of the Code and depend on a cost-of-living adjustment defined as a measure of growth in the Chained Consumer Price Index for all Urban Consumers by section 1(f)(3) of the Code. HHS will continue to adhere to the calculation of the maximum annual limitation on cost sharing mandated by the PPACA.

b. Reduced Maximum Annual Limitation on Cost Sharing (§ 156.130)

We proposed to continue to use the method we established in the 2014 Payment Notice for determining the appropriate reductions in the maximum annual limitation on cost sharing for cost-sharing plan variations to serve enrollees at three ranges of household income below 250 percent of the federal poverty level (FPL). We are finalizing the reductions in the maximum annual limitation on cost sharing as proposed.

Sections 1402(a) through (c) of the PPACA direct issuers to reduce cost sharing for EHBs for eligible individuals enrolled in a silver-level QHP. In the 2014 Payment Notice, we established standards related to the provision of these CSRs. Specifically, in part 156, subpart E, we specified that QHP issuers must provide CSRs by developing plan variations, which are separate cost-sharing structures for each eligibility category that change how the cost sharing required under the QHP is to be shared between the enrollee and the Federal Government. At § 156.420(a), we detailed the structure of these plan variations and specified that QHP issuers must ensure that each silver-plan variation has an annual limitation on cost sharing no greater than the applicable reduced maximum annual limitation on cost sharing specified in the annual HHS notice of benefit and payment parameters. Although the amount of the reduction in the maximum annual limitation on cost sharing is specified in section 1402(c)(1)(A) of the PPACA, section 1402(c)(1)(B)(ii) of the PPACA states that the Secretary may adjust the cost-sharing limits to ensure that the resulting limits do not cause the AV of the health plans to exceed the levels specified in section 1402(c)(1)(B)(i) of the PPACA (that is, 73 percent, 87 percent, or 94 percent, depending on the income of the enrollee).

As we proposed, the 2021 maximum annual limitation on cost sharing would be $8,550 for self-only coverage and $17,100 for other than self-only coverage. We analyzed the effect on AV of the reductions in the maximum annual limitation on cost sharing described in the statute to determine whether to adjust the reductions so that the AV of a silver plan variation will not exceed the AV specified in the statute. In the proposed rule, we described our analysis for the 2021 plan year and our proposed results.

[141] See 84 FR 17454 at 17540.

[142] See Revenue Procedure 2013–25, 2013–21 IRB 1110. *http://www.irs.gov/pub/irs-drop/rp-13-25.pdf.*

(1) Analysis for Determining the Reduced Maximum Annual Limitation on Cost Sharing

Consistent with our analysis in the 2014 through 2020 Payment Notices, we developed three test silver level QHPs, and analyzed the impact on AV of the reductions described in the PPACA to the proposed estimated 2021 maximum annual limitation on cost sharing for self-only coverage ($8,550). The test plan designs are based on data collected for 2020 plan year QHP certification to ensure that they represent a range of plan designs that we expect issuers to offer at the silver level of coverage through the Exchanges. For 2021, the test silver level QHPs included a PPO with typical cost-sharing structure ($8,550 annual limitation on cost sharing, $2,650 deductible, and 20 percent in-network coinsurance rate); a PPO with a lower annual limitation on cost sharing ($6,800 annual limitation on cost sharing, $3,000 deductible, and 20 percent in-network coinsurance rate); and an HMO ($8,550 annual limitation on cost sharing, $4,375 deductible, 20 percent in-network coinsurance rate, and the following services with copayments that are not subject to the deductible or coinsurance: $500 inpatient stay per day, $500 emergency department visit, $30 primary care office visit, and $55 specialist office visit). All three test QHPs meet the AV requirements for silver level health plans.

We then entered these test plans into the draft version of the 2021 AV Calculator [143] and observed how the reductions in the maximum annual limitation on cost sharing specified in the PPACA affected the AVs of the plans. We found that the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 100 and 150 percent of FPL (⅔ reduction in the maximum annual limitation on cost sharing), and 150 and 200 percent of FPL (⅔ reduction), would not cause the AV of any of the model QHPs to exceed the statutorily specified AV levels (94 and 87 percent, respectively).

In contrast, the reduction in the maximum annual limitation on cost sharing specified in the PPACA for enrollees with a household income between 200 and 250 percent of FPL (½ reduction), would cause the AVs of two of the test QHPs to exceed the specified AV level of 73 percent. As a result, we proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 200 and 250 percent of FPL be reduced by approximately ⅕, rather than ½, consistent with the approach taken for benefit years 2017 through 2019. We further proposed that the maximum annual limitation on cost sharing for enrollees with a household income between 100 and 200 percent of FPL be reduced by approximately ⅔, as specified in the statute, and as shown in Table 4.

The proposed reductions in the maximum annual limitation on cost sharing must adequately account for unique plan designs that may not be captured by our three model QHPs. We also noted that selecting a reduction for the maximum annual limitation on cost sharing that is less than the reduction specified in the statute would not reduce the benefit afforded to enrollees in the aggregate because QHP issuers are required to further reduce their annual limitation on cost sharing, or reduce other types of cost sharing, if the required reduction does not cause the AV of the QHP to meet the specified level.

In prior years we found, and we continue to find, that for individuals with household incomes of 250 to 400 percent of FPL, without any change in other forms of cost sharing, the statutory reductions in the maximum annual limitation on cost sharing will cause an increase in AV that exceeds the maximum 70 percent level in the statute. As a result, we did not propose to reduce the maximum annual limitation on cost sharing for individuals with household incomes between 250 and 400 percent of FPL. We solicited comment on this analysis and the proposed reductions in the maximum annual limitation on cost sharing for 2021.

We note that for 2021, as described in § 156.135(d), states are permitted to submit for HHS approval state-specific datasets for use as the standard population to calculate AV. No state submitted a dataset by the September 1, 2019 deadline.

TABLE 4—REDUCTIONS IN MAXIMUM ANNUAL LIMITATION ON COST SHARING FOR 2021

Eligibility category	Reduced maximum annual limitation on cost sharing for self-only coverage for 2021	Reduced maximum annual limitation on cost sharing for other than self-only coverage for 2021
Individuals eligible for CSRs under § 155.305(g)(2)(i) (100–150 percent of FPL)	$2,850	$5,700
Individuals eligible for CSRs under § 155.305(g)(2)(ii) (151–200 percent of FPL)	2,850	5,700
Individuals eligible for CSRs under § 155.305(g)(2)(iii) (201–250 percent of FPL)	6,800	13,600

We received no comments on the reductions in the maximum limitations on cost sharing apart from those already discussed in this preamble. As such, we are finalizing the 2021 values as proposed (reproduced in Table 4).

c. Cost-Sharing Requirements (§ 156.130)

We proposed to revise § 156.130(h) to provide that, notwithstanding any other provision on the annual limitation on cost sharing, and to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers to enrollees for specific prescription drugs are permitted, but not required, to be counted toward the annual limitation on cost sharing. We also proposed to interpret the definition of cost sharing to exclude expenditures covered by direct drug manufacturer support. We are generally finalizing the policy as proposed with a minor revision to the title of the regulatory provision to reflect its application to all forms of direct support provided by drug manufacturers, which include coupons for specific prescription drugs. However, we are not finalizing the proposed interpretation of the definition of cost sharing to exclude these amounts from that term.

[143] Available at *https://www.cms.gov/cciio/resources/regulations-and-guidance/index.*

In the 2020 Payment Notice at § 156.130(h)(1), we finalized that, for plan years beginning on or after January 1, 2020, notwithstanding any other provision of § 156.130, and to the extent consistent with applicable state law, amounts paid toward cost sharing using any form of direct support offered by drug manufacturers to enrollees to reduce or eliminate immediate out-of-pocket costs for specific prescription brand drugs that have an available and medically appropriate generic equivalent are not required to be counted toward the annual limitation on cost sharing. In that rule, we expressed concern that market distortion can exist when a consumer selects a higher-cost brand name drug when an equally effective generic drug is available.

Since finalizing § 156.130(h)(1) in that rule, we received feedback indicating confusion about whether it requires plans and issuers to count the value of all forms of direct support provided by drug manufacturers, including drug manufacturers' coupons, toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available, particularly with regard to large group market and self-insured group health plans. On August 26, 2019, HHS and the Departments of Labor and the Treasury released FAQ Part 40,[144] acknowledging the confusion among stakeholders and the possibility that the requirement could create a conflict with certain rules for HDHPs that are intended to allow eligible individuals to establish an HSA.

Specifically, Q&A–9 of IRS Notice 2004–50 [145] states that the provision of drug discounts will not disqualify an individual from being an eligible individual if the individual is responsible for paying the costs of any drugs (taking into account the discount) until the deductible under the HDHP is satisfied. Thus, Q&A–9 of IRS Notice 2004–50 requires an HDHP to disregard drug discounts and other manufacturer and provider discounts when determining if the deductible for an HDHP has been satisfied, and only allows amounts actually paid by the individual to be taken into account for that purpose. Therefore, an issuer or sponsor of an HDHP could be put in the position of complying with either the requirement under the 2020 Payment Notice for limits on cost sharing in the case of direct support provided by drug manufacturers for a brand name drug with no available or medically appropriate generic equivalent or the IRS rules for minimum deductibles for HDHPs, but potentially being unable to comply with both rules simultaneously.[146]

Accordingly, in FAQ Part 40, we explained that we intended to undertake rulemaking in the HHS Notice of Benefit and Payment Parameters for 2021, in consultation with the Departments of Labor and the Treasury to address the conflict, and that until the 2021 Payment Notice is issued and effective, the Departments will not initiate an enforcement action if an issuer of group or individual health insurance coverage or a group health plan excludes the value of direct support provided by drug manufacturers from the annual limitation on cost sharing, including in circumstances in which there is no medically appropriate generic equivalent available.

In the proposed rule, we proposed to revise § 156.130(h) in its entirety to provide that, notwithstanding any other provision of the annual limitation on cost sharing regulation, and to the extent consistent with applicable state law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers to enrollees for specific prescription drugs are permitted, but not required, to be counted toward the annual limitation on cost sharing. Under the proposal, plans and issuers would have the flexibility to determine whether to include or exclude dollar amounts of direct support provided by drug manufacturers from the annual limitation on cost sharing, regardless of whether a generic equivalent is available, when otherwise consistent with applicable requirements.

We also proposed to interpret the definition of cost sharing to exclude expenditures covered by drug manufacturer coupons, without proposing any changes to the regulatory definition of cost sharing under § 155.20. Under the proposed interpretation, the value of the direct support provided by drug manufacturers would not be required to count towards the annual limitation on cost sharing.

Section 1302(c)(3)(A) of the PPACA defines the term cost sharing to include: (1) Deductibles, coinsurance, copayments, or similar charges; and (2) any other expenditure required of an insured individual which is a qualified medical expense [147] with respect to EHB covered under the plan. Section 1302(c)(1) of the PPACA states that the cost sharing incurred under a health plan shall not exceed the annual limitation on cost sharing. We explained that, under the proposed interpretation, direct support provided by drug manufacturers, including coupon amounts, would be viewed as reducing the costs incurred by an enrollee under the health plan because they would reduce the amount that the enrollee is required to pay in order to obtain coverage for the drug. The value of the coupon would not be considered a cost incurred by or charged to the enrollee; thus, we explained its value would not be required to count toward the annual limitation on cost sharing.

Under this proposed interpretation, and to the extent consistent with applicable state law, we sought to provide issuers of non-grandfathered individual and group market coverage, and all non-grandfathered group health plans subject to section 2707(b) of the PHS Act, flexibility to determine whether to include or exclude amounts of direct support provided by drug manufacturers from the annual limitation on cost sharing, regardless of whether a medically appropriate generic equivalent is available.[148] The proposal would enable issuers and group health plans to continue longstanding practices with regard to how and whether direct drug manufacturer support accrues towards an enrollee's annual limitation on cost sharing.[149]

As noted, the proposal would also afford issuers of non-grandfathered individual and group market coverage, and all non-grandfathered group health plans subject to section 2707(b) of the PHS Act, the same opportunity as under the current § 156.130(h)(1) to incentivize generic drug usage by excluding the amounts of direct drug manufacturer support for brand name drugs from the annual limitation on cost sharing when a medically appropriate generic equivalent is available. We

[144] Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf.*

[145] 2004–2 C.B. 196, available at *https://www.irs.gov/pub/irs-drop/n-04-50.pdf.*

[146] FAQs About Affordable Care Act Implementation Part 40. August 26, 2019. Available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-40.pdf* and *https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-40.*

[147] As defined in section 223(d)(2) of the Code.

[148] We note that an issuer or group health plan that elects to credit direct drug manufacturer support amounts toward the minimum deductible of an HDHP could disqualify an individual from making HSA contributions, pursuant to Q&A–9 of Notice 2004–50.

[149] The annual limitation on cost sharing under section 1302(c)(1) of the PPACA is applied to non-grandfathered group health plans by section 2707(b) of the PHS Act, which is incorporated by reference into ERISA and the Code. Therefore, we generally refer to both issuers and group health plans when describing the policy regarding the annual limitation on cost sharing in this section of the preamble.

stated that we expect issuers and group health plans to be transparent with enrollees and prospective enrollees regarding whether the value of direct drug manufacturer support accrues to the annual limitation on cost sharing as such policies would affect enrollees' out-of-pocket liability under their plans. We also stated we would expect issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits.

We received many comments on this proposal.

Comment: Some commenters supported the proposed policy, noting that the policy would give health insurance issuers and group health plans increased flexibility to address the cost of brand name drugs and lower the cost of health insurance overall. Others supported the proposal's deference to state law, regulations, and guidance on whether drug manufacturer support accrues towards the annual limitation on cost sharing. One commenter recommended that the regulation text be revised to require that all drug manufacturer financial assistance be treated the same way, whether provided directly or through a surrogate organization.

Numerous commenters and individuals opposed permitting insurers to exclude direct support from drug manufacturers from amounts enrollees have paid toward the annual limitation on cost sharing. These commenters urged HHS not to finalize the proposal, and to leave the policy established in the 2020 Payment Notice. These commenters asserted that the proposal is in direct opposition to the administration's stated goals of reducing drug prices for patients. Additionally, they expressed concern that patient costs would increase dramatically, which could lead to greater non-adherence to medications and ultimately impact the life and health of patients.

Response: For the reasons stated in the proposed rule, and as further described in responses to comments in this subsection of the preamble, we are generally finalizing this policy as proposed, except we are making a non-substantive change to the title of the regulatory provision to ''Use of direct support offered by drug manufacturers'' and are not finalizing the proposed interpretation of the definition of cost sharing to exclude expenditures covered by direct drug manufacturer support.

We agree with commenters who supported the provision of the policy that states it is only effective to the extent consistent with state law. As finalized, § 156.130(h) provides states with the flexibility to promulgate rules that would require direct drug manufacturer support amounts to be counted by health insurance issuers towards the annual limitation on cost sharing. To the extent states want to require health insurance issuers to count direct drug manufacturer support amounts towards the annual limitation on cost sharing, they can do so when such action would be consistent with other applicable laws and rules (for example, federal non-discrimination requirements). At the same time, however, states also have flexibility to promulgate rules that would mandate exclusion of such amounts from the annual limitation on cost sharing.

We appreciate commenters' concerns that the proposal could raise out-of-pocket costs for consumers who use brand name drugs. However, we believe the impact of such costs may be limited if issuers that currently allow these amounts to be counted toward enrollees' deductibles or their annual limitation on cost sharing continue their current behavior, which we believe will be the case. [150] As stated in the proposed rule, the flexibility provided under this policy will enable issuers and group health plans to continue longstanding practices with regard to how and whether direct drug manufacturer support accrues towards an enrollee's annual limitation on cost sharing. Prior to the 2020 Payment Notice, federal rules did not explicitly state whether issuers and group health plans had the flexibility to determine how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing. While the policy finalized in the 2020 Payment Notice may have caused confusion, FAQ Part 40, released in August 2019, provided issuers and group health plans with sufficient notice that issuers and group health plans may choose to maintain their existing plan designs for plan year 2020. This final rule, combined with FAQ Part 40, ensures that issuers and group health plans need not make changes to how they have historically handled direct drug manufacturer support amounts. Issuers and group health plans will continue to have flexibility, subject to state law and other applicable requirements (if any), to determine if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing. Longstanding practices of including these amounts towards the annual limitation on cost sharing can continue. Although, consistent with the Administration's efforts to combat high and rising out-of-pocket costs for prescription drugs, we continue to encourage issuers to find innovative methods to address the market distortion that occurs when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug. This includes, to the extent consistent with state law and other applicable requirements, leveraging the flexibility to exclude direct drug manufacturer support amounts from the annual limitation on cost sharing, given the market distortive effects such support can cause. We do not expect any significant increases in patient costs or non-adherence to medications if issuers choose to continue their current behavior. Therefore, we believe the impact to consumers will be minimal if issuers choose to continue their current behavior.

While we believe it is unlikely that issuers will choose to change their longstanding practices, we acknowledge the possibility that some issuers or group health plans may make changes to their plan designs to exclude direct drug manufacturer support amounts from the annual limitation on cost sharing. In these limited circumstances, consumers enrolled in such plans may see changes to their plan design, such as changes to formulary designs or cost-sharing structures, which may increase or decrease their out-of-pocket costs for a specific prescription drug. Given the multitude of variables and considerations that are out of HHS's control, we cannot project this burden with sufficient certainty. For issuers and group health plans that do make changes to their longstanding practices, we continue to encourage transparency with regard to changes in how direct drug manufacturer support amounts count towards the annual limitation on cost sharing. For example, we encourage issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits. If we find that such transparency is not provided, HHS may consider future rulemaking to require that issuers provide this information in plan documents and collateral material. We also remind issuers that when determining if and how to factor in direct drug

[150] In fact, no comments submitted by the health insurance industry on this policy in the 2021 Payment Notice proposed rule expressed a desire to change their current practices.

manufacturer support amounts towards the annual limitation on cost sharing, such policies must apply in a uniform, non-discriminatory manner.[151] Lastly, while we did not propose and are not finalizing policies regarding indirect drug manufacturer support of specific drugs, we do intend to continue to monitor the impact of such support.

Comment: Some commenters supported the policy, stating that it ensures the viability of HSAs that may be paired with HDHPs. Opposing commenters expressed concern that HHS's rationale for choosing not to maintain and enforce the rule as finalized in the 2020 Payment Notice is based on a misinterpretation of Q&A 9 of IRS Notice 2004–50 and that no conflict exists. Several commenters questioned whether the scenario described in Q&A 9 of IRS Notice 2004–50 referenced in the proposed rule applies to direct drug manufacturer support. One commenter noted that a ''discount card'' is separate and distinct from a drug maker coupon, traditionally used in lieu of health insurance, and therefore, was excluded from the calculation of annual deductibles when the IRS issued Notice 2004–50. This commenter also noted that copay assistance from a drug maker has traditionally counted toward annual deductibles and out-of-pocket limits, and therefore, it is highly unlikely that the IRS was referring to drug manufacturers' coupons in its notice.

Many commenters requested that HHS clarify that the rule does not conflict with rules relating to HDHPs with HSAs. Many commenters also noted that the 2020 Payment Notice could not conflict with IRS Notice 2004–50 because it is explicitly described as ''guidance on Health Savings Accounts,'' and therefore, does not carry the force of law. One commenter noted that in section 223(c)(2) of the Code, which defines the term ''high deductible health plan,'' that there was no mention in the statute of precisely who must bear the cost of the established deductible, nor any requirement that assistance with cost sharing, from any party, be excluded from the deductible.

Another commenter was concerned that health plans could misinterpret these statements to mean that HHS is directing them to exclude manufacturer assistance from patient cost-sharing limits, which could accelerate a trend toward ''accumulator adjustment programs,'' which are utilization management tools pharmacy benefit managers and health plans may use that exclude copay assistance from counting toward a patient's deductible or annual limitation on cost sharing.

Response: As explained in FAQ Part 40, since publication of the 2020 Payment Notice, the Departments received feedback indicating there was confusion about whether the HHS policy finalized in the 2020 Payment Notice required plans and issuers to count the value of drug manufacturers' coupons toward the annual limitation on cost sharing, other than in circumstances in which there is a medically appropriate generic equivalent available, particularly with regard to large group market and self-insured group health plans. The Departments considered the information provided by stakeholders and agreed that the federal standards regarding the application of drug manufacturers' coupons to the annual limitation on cost sharing was ambiguous. FAQ Part 40 also explained that the Departments would not initiate an enforcement action if an issuer of group or individual health insurance coverage or a group health plan excludes the value of direct support provided by drug manufacturers from the annual limitation on cost sharing. In the proposed rule and this final rule, we seek to clarify the HHS policy and address the confusion, including the potential conflict, identified by stakeholders.

Since its enactment, section 223 of the Code has provided that individuals covered by an HDHP may not have medical expenses paid by other coverage prior to satisfying the deductible and remain eligible to contribute to an HSA (with certain limited exceptions, such as preventive care or disregarded coverage). There is no requirement that individuals covered by an HDHP exclusively pay for medical expenses they incur before meeting the deductible (and so, for example, family members may provide assistance as a gift to the individual, which may include paying for medical expenses on behalf of the individual). However, the HDHP is not permitted to credit the deductible in a manner that does not reflect the actual cost of medical care to the individual.

Whether or not this principle is directly applicable to a particular arrangement, it is consistent with the guidance provided in IRS Notice 2004–50. If a third party involved in the provision of a service or product that resulted in the medical expense, such as a drug manufacturer, has arranged for a rebate or discount for the individual tied to the individual incurring the medical expense, whether via a drug discount card or a drug coupon, the true economic cost to the individual is the net amount incurred. Accordingly, to meet the requirements of section 223 of the Code, an HDHP may only take into account that net amount when determining whether the individual has satisfied the deductible. Therefore, a conflict between the HHS policy finalized in the 2020 Payment Notice and the provisions of section 223 of the Code and IRS guidance may exist for issuers who elect to include drug manufacturer support amounts towards the consumer's deductible and annual limitation on cost sharing if the consumer is enrolled in an HDHP coupled with an HSA. In addition, stakeholders expressed confusion about these issues and the possibility that the HHS policy on the annual limitation on cost sharing could create a conflict with certain IRS rules. For example, stakeholders raised questions related to certain administrative issues related to how to determine and apply the net amount to the deductible when an individual receives this type of payment. The Department of the Treasury and the IRS continue to review the comments from stakeholders on the IRS rules on HDHPs to determine if additional guidance would assist in lowering plan burdens while still ensuring the deductible is applied in compliance with the requirements of section 223 of the Code. In this rule, we clarify that the HHS policy on the annual limitation on cost sharing is intended to provide maximum flexibility and allow issuers to avoid this type of conflict for those situations where it may arise.

Under the policy finalized in this rule, issuers have flexibility, when consistent with state law, to determine if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing, subject to applicable requirements such as federal non-discrimination laws.

Finally, HHS further clarifies that, under the policy finalized in this rule, issuers and group health plans remain free to continue longstanding policies with regard to how direct drug manufacturer support accrues towards accumulators. We do not require and are not directing issuers and group health plans to any specific practice with regards to how these amounts are treated with respect towards accumulators. However, recognizing the market distortion effects related to direct drug manufacturer support amounts when consumers select a higher-cost brand name drug over an equally effective, medically appropriate generic drug and as part of our efforts

[151] See, for example, 45 CFR 146.121, 147.104(e), 147.110, 156.125, and 156.225, as applicable.

to combat the high and rising out-of-pocket costs for prescription drugs, we encourage issuers and group health plans to consider the flexibility to exclude these amounts from the annual limitation on cost sharing as one tool that could be used to address these concerns.

Comment: Multiple commenters expressed concern about our interpretation of the term ''cost sharing.'' Most commenters found the interpretation of cost sharing in the proposed rule to be inconsistent with the definition of ''cost sharing'' in 45 CFR 155.20, which provides that ''cost sharing means any expenditure required by or on behalf of an enrollee with respect to essential health benefits.'' Commenters argued that drug manufacturer coupons offered on behalf of plan enrollees fall within the definition of cost sharing. One commenter noted the proposed rule failed to acknowledge that many other forms of patient assistance exist beyond direct drug manufacturer support, such as crowdfunding amounts, durable medical equipment (DME) manufacturer support, and waived medical debt, and thus failed to explain why the proposal singles out direct drug manufacturer assistance, or to explain how the policy, more broadly applied, would impact these other types of assistance.

Response: After consideration of comments, we are not finalizing the proposed interpretation to exclude expenditures covered by drug manufacturer coupons and other drug manufacturer direct support from the definition of cost sharing at 45 CFR 155.20. Excluding such amounts from the federal definition of cost sharing would be inconsistent with the flexibility we are seeking to provide to issuers in this rulemaking and could be seen as a barrier for issuers who want to include these amounts towards a consumer's annual limitation on cost sharing when otherwise consistent with applicable federal and state requirements.

As some commenters noted, drug manufacturer coupons offered to plan enrollees can be interpreted as falling within the existing definition of cost sharing. More specifically, ''cost sharing,'' as defined at section 1302(c)(3)(A) of PPACA and implemented at § 155.20, are expenditures required by or on behalf of an enrollee with respect to EHB, and include deductibles, coinsurance, copayments or similar charges. The value of the direct drug manufacturer support can be considered part of the overall charges incurred by the enrollee as the consumer cannot obtain the drug without providing the full amount owed. For example, if a consumer is responsible for a $50 co-pay for a brand name drug, the consumer cannot obtain the drug at the point of sale without providing the full $50 (whether with $50 cash, or $30 cash with the $20 coupon). At the same time, however, as stated in the proposed rule, the value of the direct drug manufacturer support could be viewed as not representing costs incurred by or charged to enrollees. Instead, such amounts could be viewed as representing a reduction, by drug manufacturers, in the amount that the enrollee is required to pay at the point of sale in order to obtain the drug. We have therefore determined that the term ''cost sharing'' is subject to interpretation regarding whether these amounts fall under this definition. To provide maximum flexibility for states and issuers to decide if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing, we are not finalizing the proposed interpretation to exclude such amounts from the definition of cost sharing.

For issuers who elect to include these amounts towards a consumer's annual limitation on cost sharing, the value of direct drug manufacturer support would be considered part of the overall charges incurred by the enrollee. For issuers who elect to not count these amounts towards the consumer's annual limitation on cost sharing, the value of the direct drug manufacturer support would be considered a reduction in the amount that the enrollee incurs or is required to pay. As we explained above, when determining if and how to factor in direct drug manufacturer support amounts towards the annual limitation on cost sharing, issuers must apply such policies in a uniform, non-discriminatory manner. In addition, issuers should be clear and transparent in communications with enrollees and prospective enrollees regarding whether the value of drug manufacturer support accrues to the annual limitation on cost sharing. We encourage issuers to prominently include this information on websites and in brochures, plan summary documents, and other collateral material that consumers may use to select, plan, and understand their benefits.

We also disagree with comments that the proposed rule did not adequately explain the policy or the rationale for tailoring this policy to direct support provided by drug manufacturers. We explained in the proposed rule that the flexibility afforded under this policy was proposed specifically to address market distortion caused by direct support, including coupons, from drug manufacturers. As we explained in the 2020 Payment Notice proposed rule, we recognize that copayment support may help enrollees by encouraging adherence to existing medication regimens, particularly when copayments may be unaffordable to many patients.[152] However, the availability of a coupon or other direct support may cause physicians and enrollees to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices which can distort the market and the true cost of drugs. Such direct support from drug manufacturers can add significant long-term costs to the health care system. In some cases, this direct support may be increasing overall drug costs and can lead to unnecessary spending by issuers, which is passed on to all patients in the form of increased premiums and reduced coverage of other potentially useful health care interventions. Further, the Administration has identified high and rising out-of-pocket costs for prescription drugs, among other issues, as a challenge to consumers. For these reasons, we pursued a policy that was focused on direct drug manufacturer support. We currently have no evidence that the other types of support identified by the commenter (for example, crowdfunding amounts, waived medical debt, or support toward the purchase of DME) has similar distortive effects on the market as manufacturer support for brand name prescription drugs.[153] Further, we are unaware of any DME providers that provide financial incentives to compete with 'generic' versions of their product. Thus, we did not propose and are not finalizing cost sharing policies regarding such amounts, but will monitor them and their potential impact on the market for potential future rulemaking.

Comment: Several commenters appreciated the recommendation that issuers and group health plans consider adopting the practice of excluding any value an enrollee may obtain from a prescription drug manufacturer's cost-sharing assistance program and should

[152] See 84 FR 227 at 290–291.

[153] HHS previously identified concerns with respect to cost-sharing support from hospitals, other healthcare providers and other commercial entities. See, for example, *https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/downloads/third-party-qa-11-04-2013.pdf.* We also continue to monitor these practices and their impact on the market for potential further action, if necessary.

disclose this practice on all websites, brochures, plan documents and other collateral materials. However, numerous commenters expressed concern that putting the onus on issuers and group health plans to inform the consumer about any policy to not count direct drug manufacturer support towards the annual limitation on cost sharing limit is inadequate. These commenters recommended that HHS require that issuers and group health plans clearly communicate to enrollees in their summaries of benefits and coverage and in their summary plan descriptions that direct drug manufacturer support does not count toward their deductibles or out-of-pocket maximums. One commenter opposed placing a new notice requirement on issuers and group health plans. An additional commenter noted that any efforts aimed at supporting transparency must also include a requirement that drug manufacturers fully disclose all direct payments they make on behalf of plan enrollees.

Response: We agree with commenters that it is important for issuers and group health plans to be clear and transparent with consumers regarding whether direct drug manufacturer support amounts will count towards the annual limitation on cost sharing, especially when such amounts will not be counted towards the annual limitation on cost sharing. This information may be essential for a consumer in deciding between plans. However, we did not propose such a requirement in the proposed rule and are not finalizing such a requirement in this rule. We intend to continue to monitor this issue, including how issuers disclose such information and may propose further rulemaking to impose robust disclosure requirements if we find that enrollees are not provided sufficient information on these practices. Further, while we encourage drug pricing transparency among drug manufacturers, we did not propose a requirement that drug manufacturers fully disclose all direct payments that are made on behalf of plan enrollees, and therefore this issue is outside of the scope of this rule.

5. Requirements for Timely Submission of Enrollment Reconciliation Data (§ 156.265)

In the Establishment of Exchanges and Qualified Health Plans; Exchange Standards interim final rule,[154] we established standards for the collection and transmission of enrollment information. At § 156.265(f), we set forth standards on the enrollment reconciliation process, specifying that issuers must reconcile enrollment with the Exchange no less than once a month. Issuers in Exchanges using the Federal platform, that is, FFEs and SBE–FP, currently update data through ongoing processes collectively referred to as Enrollment Data Alignment, which includes 834 transactions, the monthly enrollment reconciliation cycle, and two dispute processes (enrollment disputes and payment disputes) that are used to make enrollment updates that cannot be handled through monthly reconciliation. Issuers offering plans through State Exchanges update Exchange data through processes designed by the State Exchange.

Although the regulations in § 156.265 require issuers to reconcile enrollment with the Exchange monthly, they do not specify standards for the format or quality of these data exchanges, such as the manner in which enrollment updates must be reflected in updates of previously submitted enrollment data, or the timeframe in which issuers should report data updates and data errors to the Exchange. If QHP issuers fail to make or report enrollment updates accurately and timely, the accuracy of payment, the accuracy of enrollment data that the Exchange has available to address consumer questions, and the accuracy of the data reported to consumers on their IRS Forms 1095–A, Health Insurance Marketplace Statement, after the end of the coverage year could be affected. For example, if an issuer does not regularly update its enrollment data to reflect retroactive enrollment changes throughout the year, and instead submits large volumes of changes to the Exchange well after the plan year has ended, these late changes may trigger the mailing of corrected Forms 1095–A to consumers after tax season, creating consumer burden and confusion.

To more explicitly state requirements for issuers in the Exchanges, we proposed amending § 156.265(f) to require an issuer to include in its enrollment reconciliation submission to the Exchange the most recent enrollment information that is available and that has been verified to the best of its knowledge or belief. We also proposed to amend § 156.265(g) to direct QHP issuers to update their enrollment records as directed by the Exchange, and to inform the Exchange if any such records contain errors, within 30 days. We believe these amendments will encourage more timely reconciliation and error reporting, resulting in an improved consumer experience. We stated in the proposed rule that, for SBE–FPs, references in this section to the ''Exchange'' should be understood to mean HHS, as administrator of the Federal platform. We sought comments on these proposed amendments.

After reviewing public comments, we are finalizing amendments to the enrollment reconciliation data submission requirements in § 156.265 as proposed to require an issuer to include in its enrollment reconciliation submission to the Exchange the most recent enrollment information that is available. HHS looks forward to working with issuers on improving the reconciliation process to promote the exchange of timely and accurate data between QHP issuers and Exchanges.

Below, we summarize public comments received on these proposals.

Comment: Several commenters supported the proposal stating it will help improve the enrollment reconciliation process allowing both QHPs and Exchanges to have timely and accurate data.

Response: HHS agrees with these comments and is finalizing the policy as proposed.

Comment: One commenter proposed changes to § 156.265(g)(1) and (2). This commenter asked that HHS change the word ''confirm'' to ''verify'' in § 156.265(g)(1). The commenter was concerned that use of the word ''confirm'' could be misunderstood as referring to the Confirmation/Effectuation ASC X12 Benefit Enrollment and Maintenance (834) file. This commenter also suggested that HHS change the word ''describe'' in § 156.265(g)(2) to ''resolve for'' as ''describe'' does not convey that an issuer has the responsibility to make any necessary enrollment updates in issuer systems and electronically send corresponding enrollment information to update Exchange records.

Response: HHS agrees with the recommendation regarding § 156.265(g)(1) and will amend it to avoid any potential misunderstanding. HHS does not agree with the suggested change to (g)(2). The suggested ''resolve for'' edit implies that it is entirely within the issuer's control. While the issuer needs to report the problem, resolving it is a joint process that involves both the issuer and the Exchange. However, to address the issuer's concern, we are adding the language ''and resolved assigned updates'' to § 156.265(f) to make it clear that the issuer is responsible for resolving assigned updates in its own system during reconciliation.

Comment: One commenter asked HHS to provide additional clarification on issuer responsibilities to send updates

[154] See 77 FR 18309 at 18425.

to the Exchange within 30 days of an enrollment dispute. Another commenter recommended that issuers continue submitting monthly files as part of the enrollment reconciliation process, but should not be penalized for failure to report all errors or changes within 30 days.

Response: QHP issuers should make their best effort to actively monitor their enrollment data for accuracy in real time and to report all known data errors and changes to the Exchange within 30 days. If QHP issuers fail to make or report enrollment updates accurately and timely, the accuracy of payment, the accuracy of enrollment data that the Exchange has available to address consumer questions, and the accuracy of the data reported to consumers on their IRS Form 1095-As after the end of the coverage year could be affected. HHS notes that some issuers currently review enrollment and payment data for errors after the plan year has ended, leading to late payment and Form 1095–A corrections, and therefore, we are making this change to clarify that issuers have a responsibility to actively review their data on an ongoing basis and report corrections timely to HHS. HHS intends to monitor compliance with this requirement as a risk factor for targeting issuers for payment audits.

6. Promoting Value-Based Insurance Design

In this section of the proposed rule, we sought to promote a consumer-driven health care system in which consumers are empowered to select and maintain health care coverage of their choosing. We proposed to offer QHP issuers options to assist them design value-based insurance plans that would empower consumers to receive high value services at lower cost.

In the 2017, 2018, and 2019 Payment Notices, we sought comment on ways in which HHS can foster market-driven programs that can improve the management and costs of care and that provide consumers with quality, person-centered coverage. We also sought comment on how we may encourage value-based insurance design within the individual and small group markets and ways to support issuers in using cost sharing to incentivize more cost-effective consumer behavior. We solicited comments on how HHS can better encourage these types of plan designs, and whether any existing regulatory provisions or practices discourage such designs.

We also previously noted our interest in value-based insurance designs that: Focus on cost effective drug tiering structures; address overused, higher cost health services; provide innovative network design that incentivizes enrollees to use higher quality care; and promote use of preventive care and wellness services. In response to these comment solicitations, we received many comments supporting HHS's efforts to explore ways to encourage innovations and value-based insurance design.

In the proposed rule, we stated that we are pursuing strategies that will assist in the uptake and offering of value-based insurance design by QHP issuers. Specifically, we outlined a ''value-based'' model QHP that contains consumer cost-sharing levels aimed at driving utilization of high value services and lowering utilization of low value services when medically appropriate.

Currently, under our rules, issuers have considerable discretion in the design of cost-sharing structures, subject to certain statutory AV requirements, non-discrimination provisions,[155] and other applicable laws such as the MHPAEA (section 2726 of the PHS Act). We did not propose any changes to this flexibility. We are providing additional specificity around value-based design and how issuers could opt to incorporate such design into their QHPs. Offering a value-based insurance design QHP would be voluntary and issuers are encouraged to select services and cost sharing that work best for their consumers.

Borrowing from work provided by the Center for Value-based Insurance Design at the University of Michigan[156] (the Center), Table 5 lists high value services and drugs that an issuer may want to consider offering with lower or zero cost sharing. Table 5 also includes a list of low value services that issuers should consider setting at higher consumer cost sharing. High value services are those that most people will benefit from and have a strong clinical evidence base demonstrating appropriate care. The high value services and drugs identified in Table 5 are supported by strong clinical effectiveness evidence. Low value services are those services in which the majority of consumers would not derive a clinical benefit. The Center considered services that have been identified by other aligned efforts, such as the Choosing Wisely initiative, the Value-based Insurance Design Health Task Force on Low Value Care, the Oregon Public Employee's Benefits Board, SmarterCare CA, and the Washington State Health Authority.[157] The Center's research has shown that a silver level of coverage base plan could alter the cost sharing as we proposed in Table 5 of the proposed rule and could achieve a zero impact on plan premiums, while incentivizing the consumer to seek more appropriate care.

TABLE 5—HIGH AND LOW VALUE SERVICES AND DRUG CLASSES

High Value Services with Zero Cost Sharing
Blood pressure monitors (hypertension)
Cardiac rehabilitation
Glucometers and testing strips (diabetes)
Hemoglobin a1c testing (diabetes)
INR testing (hypercoagulability)
LDL testing (hyperlipidemia)
Peak flow meters (asthma)
Pulmonary rehabilitation
High Value Generic Drug Classes with Zero Cost Sharing
ACE inhibitors and ARBs
Anti-depressants
Antipsychotics
Anti-resorptive therapy
Antiretrovirals
Antithrombotics/anticoagulants
Beta blockers
Buprenorphine-naloxone
Glucose lowering agents
Inhaled corticosteroids
Naloxone
Rheumatoid arthritis medications
Statins
Thyroid-related
Tobacco cessation treatments
High Value Branded Drug Classes with Reduced Cost Sharing
Anti-TNF (tumor necrosis factor)
Hepatitis C direct-acting combination
Pre-exposure prophylaxis for HIV (PrEP) [1]
Specific Low Value Services Considered
Proton beam therapy for prostate cancer
Spinal fusions
Vertebroplasty and kyphoplasty
Vitamin D testing
Commonly Overused Service Categories with Increased Cost sharing
Outpatient specialist services
Outpatient labs

[155] We note that issuers are also subject to federal civil rights laws, including Title VI of the Civil Rights Act. Section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the PPACA, and conscience and religious freedom laws.

[156] For more information, please see information about the VBID–X project available at *http://vbidcenter.org/initiatives/vbid-x/* and resulting white paper, available at *http://vbidcenter.org/wp-content/uploads/2019/07/VBID-X-Final-Report_White-Paper-7.13.19.pdf.*

[157] Additional information on data sources considered by the Center, please see: *https://www.choosingwisely.org/; http://vbidhealth.com/low-value-care-task-force.php; https://www.oregon.gov/oha/pebb/pages/index.aspx; https://www.iha.org/our-work/insights/smart-care-california; https://www.hca.wa.gov.*

TABLE 5—HIGH AND LOW VALUE SERVICES AND DRUG CLASSES—Continued

High-cost imaging
X-rays and other diagnostic imaging
Outpatient surgical services
Non-preferred branded drugs

[1] Per 26 CFR 54.9815–2713, 29 CFR 2590.715–2713, and 45 CFR 147.130, non-grandfathered group health plans and non-grandfathered health insurance coverage in the group or individual markets, including QHP issuers in the individual market, will be required to cover PrEP without imposing any cost-sharing requirements for plan or policy years beginning on or after June 11, 2020, in a manner consistent with the U.S Preventive Services Task Force (USPSTF) final recommendation at *https://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/prevention-of-human-immunodeficiency-virus-hiv-infection-pre-exposure-prophylaxis.*

For issuers in Exchanges using the Federal platform, HHS is not currently offering preferential display on *HealthCare.gov* for QHPs that include value-based insurance design. However, we are considering ways in which consumers could easily identify a ''value-based'' QHP. We solicited comments on ways in which these ''value-based'' QHPs could be identified to consumers on *HealthCare.gov*, how best to communicate their availability to consumers, how best to demonstrate how the cost-sharing structures affect different consumers, and how to assist consumers in selecting a value-based QHP if it is an appropriate option.

We also solicited comment on how HHS could collect information from issuers in Exchanges using the Federal platform to indicate that their QHP includes value-based insurance design. This could include collecting the information from the issuer, instructing issuers to include ''value-based'' in the plan name, or establishing HHS-adopted criteria that an issuer would have to meet in order to be labeled value-based.

We also solicited comment on principles that HHS could adopt to establish what constitutes a value-based plan, perhaps establishing minimum standards, as well as obstacles to implementation. We are interested in additional ways in which HHS could provide operational assistance to issuers offering value-based QHPs. We discussed that we understand that some states require the use of standardized plan designs and may not be able to certify QHPs with alternative cost-sharing structures. We solicited comment from states that believe their cost-sharing laws would not allow for this type of plan design.

Lastly, we solicited comment on other value-based insurance design activities HHS should pursue in the future, including applicable models for stand-alone dental plans.

Comment: The majority of comments received were in support of HHS using value-based insurance design as a tool to make coverage more affordable and to encourage consumers to seek cost-effective care. Commenters supported the approach outlined in the proposed rule as it would allow QHP issuers to maintain flexibility while incrementally introducing value-based insurance design options for Exchange enrollees. Others noted that some issuers are already offering some of the proposed cost-sharing options. A few commenters questioned the proposed approach noting that using cost sharing as a tool to influence consumer behavior could potentially introduce discriminatory benefit design or unfairly disadvantage consumers with certain chronic conditions.

Commenters offered numerous suggestions to modify the options included in the proposed rule. Specifically, commenters suggested alternative value-based approaches that would not require varying consumer cost sharing, such as providing incentives to issuers or providers to support cost effective care delivery. Several commenters supported making ''value-based'' plans required for QHP issuers to achieve greater standardization across QHPs. Others requested that HHS defer to states to develop specific value-based plan designs as states are in the best position to determine the needs of their population. Many commenters offered specific suggestions to the services identified in Table 5, either requesting additional services be added or identifying specific services be removed, most commonly outpatient services or non-preferred branded drugs.

Response: We appreciate the support for the options outlined in the proposed rule and are finalizing the options as proposed. We note that the option to provide varying cost sharing for any of the services identified in Table 5 is at the discretion of the issuer. As we noted in the proposed rule, issuers have considerable discretion in the design of cost-sharing structures, subject to certain statutory AV requirements, non-discrimination provisions,[158] and other applicable laws such as the MHPAEA (section 2726 of the PHS Act). We did not propose any changes to this flexibility. We believe that maintaining issuer flexibility will allow for issuers to experiment with different cost-sharing structures that best meet their enrollee's needs. We are not requiring issuers to offer value-based plans required. We expect that value-based plans utilizing the cost sharing suggested in Table 5 would be among many different plan designs offered by QHP issuers to meet the needs of consumers and acknowledge that QHP issuers may not offer these designs exclusively. We share concerns with commenters that varying cost sharing may not meet the needs of all consumers and encourage issuers to offer QHPs that meet the needs of a heterogenetic population. For this reason, we will not be pursuing or requiring the development of a value-based standardized option.

While we believe that states have the primary role in assessing the needs of their population, we also acknowledge that some states may not have the resources or desire to develop value-based plan options. The designs offered in this preamble are offered in such a fashion as to encourage issuers to engage in value-based plan design without stifling innovation or intruding upon state activities to do the same.

Comment: Commenters offered numerous comments on consumer understanding of the concept of value-based plans and how best to potentially identify ''value-based'' QHPs. Most commenters were concerned that consumers may not understand the differences between value-based plans and non-value-based plans without significant investment in education, communication, and direct assistance. Because of this, some recommended that no changes be made to *HealthCare.gov* to identify value-based plans until more research and education on best practices on how to communicate the concept of value to consumers is complete. Other commenters suggested search functionalities on *HealthCare.gov* should be enhanced to facilitate the identification of value-based plans and to allow for consumers to search for value-based services at a granular level and for pre-deductible services. Other commenters suggested that *HealthCare.gov* include static educational information for consumers and include a visual designation for consumers to easily identify QHPs with value-based cost sharing. Others stated value-based plans should be offered preferential display and be easily identified by consumers. We did not receive many specific comments on how to best demonstrate how the cost-sharing structures affect different

[158] We note that issuers are also subject to federal civil rights laws, including Title VI of the Civil Rights Act. Section 504 of the Rehabilitation Act, the Age Discrimination Act, section 1557 of the PPACA, and conscience and religious freedom laws.

consumers or how to assist consumers in selecting a value-based plan, if appropriate, with many commenters suggesting HHS engage with outside stakeholders or adopt recommendations produced by other entities to the extent they are available. Other consumers requested that price and quality data be displayed alongside a value-based indicator.

Response: At this time, we are evaluating options on how best to identify value-based plans on *HealthCare.gov* and currently have no specific plans to introduce an indicator for the 2021 plan year as we have yet to develop criteria or minimum standards as to what would constitute a value-based plan, as discussed further below. As we previously noted, we also will not implement preferential display at this time. We agree that consumers will need to be educated on how to evaluate differing cost-sharing structures, how those cost-sharing structures will impact different consumers, and how best to direct certain consumers to value-based plans, if appropriate. We will consider the work of external groups in this area and as well as our own consumer testing. We will consider our operational priorities in evaluating other suggested changes to *HealthCare.gov* in the future.

Comment: Commenters suggested modifying the QHP issuer application materials to collect from the issuer whether or not the QHP was ''value-based,'' however many were not supportive of publicly labelling plans on *HealthCare.gov* as ''value-based'' as ''value'' can be interpreted differently by different consumers. Other commenters appeared supportive of HHS exploring standards for QHP issuers to meet in order to be designated as value-based. Commenters also noted that issuer tools to design plans, such as the actuarial value calculator may need to be modified in order to accommodate value-based plans. Some states indicated that they were modifying their existing standardized plans to accommodate the cost-sharing options in Table 5. Commenters also supported exploring adoption of value-based approaches by stand-alone dental plans.

Response: At this time, we will consider options to establish criteria for identifying value-based plans in future rulemaking. We will also consider the impact of value-based insurance design on the actuarial value calculator, if necessary. We will continue to work with states that are implementing similar approaches to ensure that we share best practices and lessons learned with value-based option adoption.

Lastly, we will continue to explore opportunities for stand-alone dental plans to adopt value-based design.

After reviewing the public comments, we are finalizing the options as proposed.

7. Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

Under existing § 156.270(b)(1), issuers have been required to send termination notices, including the termination effective date and reason for termination, to enrollees only for terminations due to (1) loss of eligibility for QHP coverage, (2) non-payment of premiums, and (3) rescission of coverage. For this purpose, we considered a termination of coverage of a consumer whose enrollment would violate the anti-duplication provision of section 1882 of the Social Security Act (the Act) to be a termination because the enrollee is no longer eligible for QHP coverage under § 155.430(b)(2)(i), and therefore, issuers are required to send a termination notice under § 156.270(b)(1) when the consumer's coverage is non-renewed.[159]

However, there are a number of scenarios where issuers were not clearly required to send termination notices, including enrollee-initiated terminations, the death of the enrollee, the enrollee changing from one QHP to another during an annual open enrollment period or special enrollment period, and terminations for dual enrollment when an enrollee has asked the Exchange to end QHP coverage when found in other coverage, such as through Medicare PDM. We proposed to amend § 156.270(b)(1) to require QHP issuers to send to enrollees a termination notice for all termination events described in § 155.430(b), regardless of who initiated the termination. We are finalizing this provision as proposed.

The original version of § 156.270 required a termination notice when an enrollee's coverage was terminated ''for any reason,'' [160] with a 30-day advance notice requirement. This requirement was eventually replaced with the previous requirement this rule revises. As bases for termination in § 155.430(b)(2) were expanded, § 156.270 was not updated in parallel. Although we recommended that issuers send termination notices whenever an enrollee's coverage is terminated, questions arose from issuers regarding when termination notices were required. Updating our regulations to require issuers to send termination notices to enrollees for all termination events, regardless of who initiated the termination, will help streamline issuer operations and reduce confusion. This change will also help promote continuity of coverage by ensuring that enrollees are aware that their coverage is ending, as well as the reason for its termination and the termination effective date, so that they can take appropriate action to enroll in new coverage, if eligible. We solicited comments on this proposal.

Comment: All commenters who weighed in on this proposal supported it. Commenters stated that this proposal would avoid member confusion and/or unnecessary QHP inquiries and promote continuity of coverage. For example, enrollees don't currently receive written confirmation of a termination they initiated; commenters stated that it is important for the enrollee to have in writing the actual termination date for their records, in case of miscommunication with the issuers about the preferred date or to later dispute an inaccurate Form 1095–A, and to ensure they take appropriate steps to re-enroll in coverage without a gap, if eligible.

Response: We agree with commenters and believe this change will help streamline issuer operations and reduce confusion. It will also help promote continuity of coverage by ensuring that enrollees are aware that their coverage is ending, as well as the reason for their termination, and their termination effective date, so that they can take appropriate action to enroll in new coverage, if eligible.

After reviewing the public comments, we are finalizing this provision as proposed.

8. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice,[161] we established provisions related to confirmation and dispute of payment and collection reports. These provisions were written under the assumption that issuers would generally be able to provide these confirmations or disputes automatically to HHS. However, we found that many issuers prefer to

[159] See 3.4.8 Medicare Enrollment and Non-renewals of the 2019 Federally-facilitated Exchanges (FFEs) and Federally-facilitated Small Business Health Options Program (FF–SHOP) Enrollment Manual at *https://www.regtap.info/uploads/library/ENR_EnrollmentManualForFFEandFF-SHOP_v1_5CR_092519.pdf.*

[160] Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers; Final Rule and Interim Final Rule, March 27, 2012 (77 FR 18310).

[161] See 78 FR 65045 at 65080.

research payment errors and use enrollment reconciliation and disputes to update their enrollment and payment data, and are unable to complete this research and provide confirmation or dispute of their payment and collection reports within 15 days, as currently required under § 156.1210. In addition, because the FFE typically reflects enrollment reconciliation updates 1 to 2 months after they have occurred, issuers attempting to comply with the 15-day deadline submit disputes that are no longer necessary after the reconciliation updates have been processed.

Therefore, we proposed to amend § 156.1210(a) to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow issuers more time to research, report, and correct inaccuracies through other channels. The longer timeframe also allows for the processing of reconciliation updates, which may resolve potential disputes.

We also proposed to remove the requirement at § 156.1210(a) that issuers actively confirm payment accuracy to HHS each month, as well as the language in § 156.1210(b) regarding late filed discrepancies. Instead, we proposed to amend § 156.1210(b) to require an annual confirmation from issuers that the amounts identified in the most recent payment and collections report for the coverage year accurately reflect applicable payments owed by the issuer to the Federal Government and the payments owed to the issuer by the Federal Government, or that the issuer has disputed any identified inaccuracies, after the end of each payment year, in a form and manner specified by HHS. Under the proposed approach, issuers would also have an opportunity as part of the annual confirmation process to notify HHS of disputes related to identified inaccuracies. In the proposed rule, we explained that the changes are based on our experience with current enrollment and payment operations, which include frequent updates to enrollment and payment data throughout the year that we believe make monthly confirmation unnecessarily burdensome. We also explained that we believed that the late filed discrepancy process in § 156.1210(c) was unnecessary and duplicative of the payment process modifications proposed in § 156.1210 and the adjustments to the enrollment process proposed in § 156.265(f).

We also explained that HHS intends to work cooperatively with issuers that make a good faith effort to comply with these procedures. We noted that issuers could demonstrate that they are working in good faith cooperatively with HHS by sending regular and accurate enrollment reconciliation files and timely enrollment disputes throughout the applicable enrollment calendar, submitting payment disputes within the 90-day dispute window, making timely and regular changes to enrollment reconciliation and dispute files to correct past errors, and by reaching out to HHS and responding timely to HHS outreach to address any issues identified.

We sought comments on these proposed amendments to § 156.1210. After reviewing public comments, we are finalizing the amendments as proposed to lengthen the time to report payment inaccuracies from 15 days to 90 days to allow issuers more time to research, report, and correct inaccuracies through other channels. We are also finalizing the amendments to § 156.1210(b) and (c) as proposed, to require issuers to provide an annual confirmation after the end of the payment year, in a form and manner specified by HHS and to remove the language that has become duplicative regarding discrepancies to be addressed in future reports. HHS intends to continue working with issuers on potential further improvements to the payment and collections reports process.

Comment: Several commenters supported these amendments saying they appreciate HHS's interest in removing unnecessary reporting requirements to reduce administrative burden for issuers, as well as HHS's intention to work cooperatively with issuers that make a good faith effort to comply with these requirements. These commenters also supported the proposed change from a 15 day to 90 day reporting timeframe and appreciate the additional time to report payment inaccuracies as this better accounts for monthly billing cycles. One commenter recommended that the annual certification process occur after March following the applicable benefit year to account for the 90-day window for reporting payment inaccuracies.

Response: We appreciate the comments and are finalizing the amendments to § 156.1210 as proposed. We also note that we intend to conduct the annual certification process under § 156.1210(b) after the final April enrollment reconciliation file is issued. Additional details on the form and manner for submission of this annual confirmation will be provided in future guidance.

F. Part 158—Issuer Use of Premium Revenue: Reporting and Rebate Requirements

1. Reporting Requirements Related to Premiums and Expenditures (§ 158.110)

We proposed to amend § 158.110(a) to clarify the requirement that expenses for functions outsourced to or services provided by other entities retained by an issuer must be reported consistently with how expenses must be reported when such functions are performed directly by the issuer. Such entities include third-party vendors, other health insurance issuers, and other entities, whether affiliated or unaffiliated with the issuer.

In the preamble to the proposed rule, we identified several technical guidance documents [162] that HHS released to address specific issues and circumstances related to the reporting of third-party expenses for MLR purposes. The guidance generally specifies that the administrative cost and profit component of payments to third-party vendors may not be included in an issuer's incurred claims or QIA, except in the case of capitation payments to clinical providers or to third-party vendors for the provision of clinical services directly to enrollees through the vendors' own employees. The guidance also generally specifies that payments to third-party vendors to perform administrative functions on behalf of the issuer must be reported as a non-claims administrative expense. In order to consolidate and clarify the MLR treatment of payments to third-party vendors and other entities, we proposed to revise § 158.110(a) to capture the requirement that expenses for functions outsourced to or services provided by other entities retained by an issuer must be reported consistently with how expenses must be reported when incurred directly by the issuer. We solicited comments on this proposal.

After considering the public comments, we are finalizing the amendment to § 158.110(a) as proposed.

Comment: Several commenters supported the proposal and agreed that it would be beneficial to clarify the regulation to ensure that issuers report expenses for functions outsourced to or services provided by other entities retained by the issuers in the same manner as expenses that issuers incur

[162] See May 13, 2011 CCIIO Technical Guidance (CCIIO 2011–002) Q&As #8, #11, #12 and #14, available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/mlr-guidance-20110513.pdf.* Also see July 18, 2011 CCIIO Technical Guidance (CCIIO 2011–004) Q&A #19, available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/20110718_mlr_guidance.pdf.*

directly. One commenter opposed the proposal because of concern that issuers may be required to report confidential and proprietary information that is specific to a third-party vendor. One commenter asked HHS to clarify whether this provision will encompass risk-based payments made by health plans to contracted providers. Another commenter requested that we delay the applicability date of the proposed amendment to give large group issuers additional time to renew outsourced contracts.

Response: With respect to the comment regarding disclosure of confidential and proprietary information, we note that nothing in the existing MLR regulations and guidance or the amendments to § 158.110(a) finalized in this rule requires an issuer to report confidential and proprietary information specific to a third-party vendor or other entity it retains, as the expenses for functions outsourced to or services provided by such entities are reported only in the aggregate, generally combined with the issuer's non-outsourced expenses, and allocated to the applicable state and market. With respect to the question regarding payments to risk-bearing providers, we clarify that the amendments to § 158.110(a) do not modify the February 10, 2012 CCIIO Technical Guidance (CCIIO 2012–001) [163] Q&As ##20–22. That guidance clarified that issuers may include in incurred claims payments to certain clinical (but not pricing) risk-bearing entities such as Accountable Care Organizations (ACOs), provided certain conditions are met, except that payments to such entities for administrative functions performed on behalf of the issuer may not be included in incurred claims. Finally, regarding the request to delay the applicability date for this amendment, we acknowledge the commenter's concern but note that the proposal codifies, clarifies, and aligns with the approach outlined in existing guidance. Therefore, we are not modifying the applicability date and the amendment will be applicable as of the effective date for this final rule.

2. Reimbursement for Clinical Services Provided to Enrollees (§ 158.140)

We proposed to amend § 158.140(b)(1)(i) to require issuers to deduct from incurred claims not only prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer and any prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer, typically a pharmacy benefit manager (PBM). In the proposed rule, we explained that the phrase ''price concession,'' when used in this context, is intended to capture any time an issuer or an entity that provides pharmacy benefit management services to the issuer receives something of value related to the provision of a covered prescription drug (for example, manufacturer rebate, incentive payment, direct or indirect remuneration, etc.) regardless from whom the item of value is received (for example, pharmaceutical manufacturer, wholesaler, retail pharmacy, vendor, etc.).

The existing regulatory framework in § 158.140(b)(1)(i) and (b)(3)(i) through (iii) did not clearly address the situation where the administrative costs and profits related to the provision of pharmacy benefits are comprised, in whole or in part, of a portion or all of the prescription drug rebates and other price concessions that the issuer allows the entity providing pharmacy benefit management services to retain. Consequently, enrollees failed to receive the benefit of prescription drug rebates and price concessions to the extent these are retained by an entity other than the issuer and issuers faced an unlevel playing field based on the manner in which they chose to compensate entities providing pharmacy benefit management services. The existing regulations also did not clearly address situations where the issuer received a price concession related to the provision of pharmacy benefits other than a rebate.

Therefore, we proposed to revise § 158.140(b)(1)(i) to require adjustments that must be deducted from incurred claims to include not only prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer, and any prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer that are associated with administering the issuer's prescription drug benefits. We explained that the proposed amendments would additionally align more closely with the MLR provisions that apply to the Medicare Advantage organizations and Part D sponsors and Medicaid managed care organizations,[164] both of which require that the full amount of prescription drug rebates and price concessions be deducted from incurred claims. We further proposed that these amendments would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022). We solicited comments on all aspects of these proposals.

After considering the public comments, we are finalizing the amendment to § 158.140(b)(1)(i) as proposed to require adjustments that must be deducted from incurred claims to include not only prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer, and any prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer that are associated with administering the issuer's prescription drug benefits. However, in response to comments, we are delaying the applicability date for these amendments to the 2022 MLR reporting year (MLR reports filed in 2023).

We are also updating the regulatory text to clarify that, consistent with the policy outlined in the proposed rule,[165] the amendment to § 158.140(b)(1)(i) requires issuers to subtract from incurred claims prescription drug rebates and other price concessions when received and retained by an issuer ''and'' an entity providing pharmacy benefit management services.

Comment: Most commenters supported the proposal and agreed that implementing these amendments would more accurately reflect an issuer's incurred claims that are included in the MLR rebate and calculation and align with the requirements that have been implemented in the Medicare and Medicaid MLR programs. Some commenters expressed confidence that the amendment would benefit enrollees either by lowering premiums or increasing MLR rebates, and some commenters further urged HHS to pursue robust enforcement of the

[163] Available at *https://www.cms.gov/CCIIO/Resources/Files/Downloads/2012-02-10-guidance-mlr-ipas.pdf.*

[164] See the Medicare Advantage program and Prescription Drug Benefit program May 23, 2013 final rule (78 FR 31284), as amended by the April 16, 2018 final rule (83 FR 16440); and the Medicaid managed care May 6, 2016 final rule (81 FR 27497) and the CMCS May 15, 2019 information bulletin available at *https://www.medicaid.gov/federal-policy-guidance/downloads/cib051519.pdf.*

[165] Namely, that the policy reflected in the amendment to § 158.140(b)(1)(i) requires issuers to deduct from incurred claims prescription drug rebates and other price concessions not only when received and retained by the issuer but also when received and retained by an entity providing pharmacy benefit management services to the issuer. See 85 FR 7088 at 7139 (February 6, 2020).

proposed requirements. A few commenters opposed the proposal, expressing concerns that it would reduce the allowable administrative costs and disadvantage PBM contracts that do not pass all prescription drug rebates and price concessions to issuers, that the amounts for prescription drug rebates and other price concessions retained by PBMs and similar entities are not readily available to issuers, and that amounts that an issuer allows the PBM to retain do not represent an issuer's expense.

Response: As explained in the proposed rule, we believe the existing regulatory framework provided an unfair advantage to issuers with PBM contracts that did not pass all prescription drug rebates and price concessions to issuers, since the regulation currently only requires issuers to deduct from incurred claims prescription drug rebates received by the issuer. This allowed such issuers to inflate incurred claims in the MLR calculation, and thus improperly increase the allowable administrative costs, relative to financially identically situated issuers who choose to compensate entities providing pharmacy management benefit services by paying a fee or inflated pharmacy reimbursement amount. Further, as discussed in the proposed rule, it is our view that allowing an entity providing pharmacy benefit management services to retain some or all of the prescription drug rebates and other price concessions that an issuer could have otherwise received is a form of compensation provided by the issuer to the entity for services that the entity performs for the issuer, and therefore is an administrative cost of the issuer. An issuer that does not outsource pharmacy benefit management services to another entity would perform such services itself, exclude such expenses from incurred claims, and report the expenses as an administrative cost. Issuers that do not outsource these services and directly negotiate prescription drug rebates for enrollees' drug utilization would also deduct from incurred claims the full amount of these rebates (as there would be no other entity retaining such amounts). Therefore, we view these amendments as a way to level the playing field among issuers, promote uniform MLR reporting, and ensure that enrollees receive the benefit of these rebates and price concessions. We also appreciate the comments urging HHS to pursue robust enforcement of the amendments and will continue to conduct enforcement activities in the MLR oversight process, which would include review of compliance with these requirements (once effective). Lastly, we proposed that the amendment would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022) precisely in order to enable issuers to make any adjustments to their contracts with entities providing pharmacy benefit management services that may be necessary to ensure that issuers are able to obtain the information required for accurate reporting and compliance with federal MLR requirements. As detailed below, we are finalizing a later applicability date in response to comments to provide more time for issuers to update their respective contracts, as may be necessary.

Comment: A number of commenters, including both some that supported and some that opposed the proposal, requested that HHS define ''price concessions'' more narrowly to align with the definitions in section 1150A of the Act, as added by the PPACA, which requires PBMs to report certain prescription benefit information to HHS and that excludes certain types of fees paid to PBMs by drug manufacturers or issuers. These commenters additionally requested that HHS codify the definition of prescription drug rebates and other price concessions in the regulation and recommended that HHS do so through separate rulemaking.

Response: We appreciate these comments and will consider codifying the definition of prescription drug rebates and other price concessions through separate rulemaking in advance of the applicability date for these new reporting requirements. In addition, in light of these comments, and the delayed applicability date discussed below, we are not finalizing a definition of ''price concession'' in this rulemaking.

Comment: Several commenters requested that HHS delay the applicability date for these amendments until the 2022 reporting year (MLR reports filed in 2023) in order to allow additional time for issuers to negotiate contracts with entities providing pharmacy benefit management services, as well as to allow additional time for HHS to consider alternative definitions for the term ''price concessions''. Some commenters noted that some issuers have already executed contracts with PBMs and other entities to perform pharmacy benefit management services for 2021, such that the proposed applicability of the 2021 reporting year (MLR reports filed in 2022) may not provide sufficient time to update those contracts and allow an issuer to come into compliance with the proposed new requirements.

Response: We acknowledge the practical considerations raised by the commenters, including with respect to the timing of contracts, and agree with commenters' recommendation to delay the applicability date of these amendments to the 2022 reporting year (MLR reports filed in 2023). This additional time will also allow us to further consider the suggested alternative definition for ''price concession''.

3. Activities That Improve Health Care Quality (§ 158.150)

We proposed to amend § 158.150(b)(2)(iv)(A)(*5*) to clarify that issuers in the individual market may include the cost of certain wellness incentives [166] as QIA expenses in the MLR calculation, in the same manner as is currently permitted in the group market.[167] The proposal reflected the fact that issuers in the individual market are currently permitted to offer participatory wellness programs, provided such programs are consistent with applicable state law and available to all similarly situated individuals,[168] and that some issuers in participating states may additionally offer health-contingent wellness programs under the wellness program demonstration project that HHS announced on September 30, 2019.[169] We proposed that this amendment would be applicable beginning with the 2021 MLR reporting year (reports due by July 31, 2022). We solicited comments on this proposal.

After reviewing the public comments, we are finalizing this amendment as proposed.

Comment: We received numerous comments regarding the proposed amendment to explicitly allow all issuers in the individual market to

[166] For this purpose, the term ''wellness incentive'' has the same meaning as the term ''reward'' in § 146.121(f)(1)(i).

[167] Under section 2705(j) of the PHS Act and 45 CFR 146.121(f), health-contingent and participatory wellness programs are permitted in the group market. HHS previously recognized that participatory wellness programs in the individual market do not violate section 2705 and are therefore permitted, provided that such programs are consistent with applicable state law and available to all similarly situated individuals enrolled in the individual health insurance coverage. See 78 FR at 33167. In addition, section 2705(l) of the PHS Act authorizes the Secretary to establish a 10-state wellness program demonstration project under which issuers may offer non-discriminatory wellness programs in the individual market.

[168] See the Incentives for Nondiscriminatory Wellness Programs in Group Health Plans; Final Rule; 78 FR 33158 at 33167 (June 3, 2013).

[169] *https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/Wellness-Program-Demonstration-Project-Bulletin.pdf.*

include certain wellness incentives as QIA in the MLR calculation. Some commenters supported the proposal because it would align the treatment of wellness programs in the group and individual markets and encourage issuers to offer wellness programs in the individual market. While the majority of commenters on this proposal expressed opposition, most of these commenters cited concerns about wellness programs themselves, such as concerns about their effectiveness and potential to discriminate, rather than concerns regarding the proposed amendment to the MLR rules.

Response: We appreciate commenters' general concerns about wellness programs, but note that we did not propose and are not making any changes to the rules regarding wellness programs.[170] Instead, the amendment to § 158.150(b)(2)(iv)(A)(*5*) is specific to the treatment of expenses of certain wellness activities for MLR reporting purposes.

We believe this amendment is appropriate and necessary as it ensures that the MLR rules are interpreted consistently across the individual and group markets, and therefore, would increase consumer choice and access to participatory wellness programs that are currently allowed in the individual market and any health-contingent wellness programs that may be available in a state that is approved to participate in the wellness program demonstration project.

4. Other Non-Claims Costs (§ 158.160)

In the proposed rule, we proposed to amend § 158.160(b)(2), to conform with the proposed amendments to § 158.140(b)(1)(i), by requiring issuers to report the prescription drug rebates received by the issuer, as well as any price concessions received and retained by the issuer, and any prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer that are associated with administering the issuer's prescription drug benefits, as non-claims costs.

After reviewing the public comments, we are finalizing this requirement as proposed, except that the requirement will not apply to the prescription drug rebates and other price concessions received by the issuer. We are also delaying the applicability date of this amendment to the 2022 reporting year (MLR reports filed in 2023) to align with the applicability date of the amendments to § 158.140(b)(1)(i).

Comment: Several commenters pointed out that the proposal inadvertently required issuers to report prescription drug rebates and other price concessions as an administrative cost regardless of whether they are received and retained by the issuer or by the entity providing pharmacy benefit management services. The commenters noted that to the extent such amounts are received and retained by the issuer, they do not represent an administrative fee paid by the issuer to the entity providing pharmacy benefit management services, and that adding these amounts to non-claims cost may cause them to be double-counted in the administrative costs reported by the issuer.

Response: We agree with the commenters that reporting the prescription drug rebates and other price concessions received and retained by the issuer as non-claims costs may result in double-counting in MLR reports, since issuers would already report these amounts in non-claims costs to the extent the funds are used for administrative expenses. Therefore, we are finalizing this requirement as proposed, except that the requirement will not apply to the prescription drug rebates and other price concessions received by the issuer and will have a delayed applicability date, as detailed above.

IV. Collection of Information Requirements

This final rule contains information collection requirements (ICRs) that are subject to review by OMB. A description of these provisions is given in the following paragraphs with an estimate of the annual burden, summarized in Table 8. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (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 solicited public comment on each of the required issues under section 3506(c)(2)(A) of the PRA for the following information collection requirements.

A. Wage Estimates

To derive wage estimates, we generally used data from the Bureau of Labor Statistics to derive average labor costs (including a 100 percent increase for fringe benefits and overhead) for estimating the burden associated with the ICRs.[171] Table 65 in this final rule presents the mean hourly wage, the cost of fringe benefits and overhead, and the adjusted hourly wage.

As indicated, employee hourly wage estimates have been adjusted by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly across employers, and because methods of estimating these costs vary widely across studies. Nonetheless, there is no practical alternative, and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

TABLE 6—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES

Occupation Title	Occupational code	Mean hourly wage ($/hr.)	Fringe benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Chief Executive*	11–1011	$96.22	$96.22	$192.44
General and Operations Manager	11–1021	59.56	59.56	119.12
Compensation and Benefits Manager	11–3111	63.87	63.87	127.74
Lawyer	23–1011	69.34	69.34	138.68

[170] See 45 CFR 147.121 and 147.110.

[171] See May 2018 Bureau of Labor Statistics, Occupational Employment Statistics, National Occupational Employment and Wage Estimates. Available at *https://www.bls.gov/oes/current/oes_stru.htm.*

TABLE 6—ADJUSTED HOURLY WAGES USED IN BURDEN ESTIMATES—Continued

Occupation Title	Occupational code	Mean hourly wage ($/hr.)	Fringe benefits and overhead ($/hr.)	Adjusted hourly wage ($/hr.)
Legal Support Worker	23–2099	34.34	34.34	68.68

* Chief executive wage is used to estimate the state official wages.

B. ICRs Regarding Notice Requirement for Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors (§ 146.145(b)(3)(viii)(E))

In § 146.145(b)(3)(viii)(E), we require that an excepted benefit HRA offered by a non-Federal governmental plan sponsor must provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the plan, and a description or summary of the benefits. This notice must be provided on an annual basis no later than 90 days after the first day of the excepted benefit HRA plan year (or, if a participant is not eligible to participate at the beginning of the plan year, no later than 90 days after the employee becomes a participant in the excepted benefit HRA).

We estimate that for each excepted benefit HRA sponsored by a non-Federal governmental plan, a compensation and benefits manager will need 1 hour (at $127.74 per hour) and a lawyer will need 0.5 hours (at $138.68 per hour) to prepare the notice. The total burden for an HRA plan sponsor will be 1.5 hours with an equivalent cost of approximately $197. This burden will be incurred the first time the non-Federal governmental plan sponsor provides an excepted benefit HRA.

In subsequent years, if there are changes in benefits, we estimate that a compensation and benefits manager will need 0.5 hours (at $127.74 per hour) and a lawyer will need 0.25 hours (at $138.68 per hour) to update the notice. The total burden for an HRA plan sponsor will be 0.75 hours with an equivalent cost of approximately $99. If there are no changes in benefits, the burden to update the notice in subsequent years is expected to be minimal and therefore is not estimated.

We estimate that approximately 901 state and local government entities will offer excepted benefit HRAs each year.[172] The total burden to prepare the notices will be approximately 1,352 hours with an equivalent cost of approximately $177,569. We estimate that approximately 10 percent of state and local government entities will make substantive changes to benefits each year and the total annual burden to update the notices will be approximately 68 hours with an equivalent cost of approximately $8,879.

Non-Federal governmental sponsors of excepted benefit HRAs must provide the notice to eligible participants every year. We estimate that sponsors will provide printed copies of these notices to approximately 193,715 eligible participants annually.[173] We anticipate that the notices will be approximately 1-page long, and the cost of materials and printing will be $0.05 per notice. It is assumed that these notices will be provided along with other benefits information with no additional mailing cost. We assume that approximately 54 percent of notices will be provided electronically and approximately 46 percent will be provided in print along with other benefits information. Therefore, state and local government entities providing excepted benefit HRAs to their employees will print approximately 89,109 notices at a cost of approximately $4,455 annually.

The total burden to prepare and send the notices in the first year will be approximately $182,000. In subsequent years, these employers will incur a cost of $8,879 to update the notices and printing and materials costs of approximately $4,455 annually. The average annual burden over 3 years will be 496 hours with an equivalent annual cost of $65,109, and an average annual total cost of $69,565.

TABLE 7—ANNUAL BURDEN AND COSTS

Year	Estimated number of non-federal governmental employers offering HRAs	Estimated number of notices to all eligible participants	Total annual burden (hours)	Total estimated labor cost	Total estimated printing and materials cost
2020	901	193,715	1,352	$177,569	$4,455
2021	901	193,715	68	8,879	4,455
2022	901	193,715	68	8,879	4,455
3 year Average	901	193,715	496	65,109	4,455

We did not receive any comments on the burden estimates. A summary of comments and response on whether the notice should be provided annually is included previously in the preamble.

C. ICRs Regarding Special Enrollment Periods (§ 155.420)

We are amending § 155.420(d)(1)(ii) to codify that qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year will be eligible for the special enrollment period available to qualified individuals and dependents who are enrolled in any non-calendar year group health plan or individual health insurance coverage. This special enrollment period is subject to pre-enrollment eligibility verification for individuals who are newly enrolling in

[172] HHS assumes that only 1 percent of state and local government entities will offer excepted benefit HRAs.

[173] HHS assumes that excepted benefit HRAs will be offered to all employees of state and local government entities that offer excepted benefit HRAs. This is an upper bound and actual number of eligible participants is likely to be lower if excepted benefit HRAs are offered to only some employee classes.

coverage through the Exchange, and to plan category limitations for Exchange enrollees who use the special enrollment period to change to a different QHP. While the FFEs make every effort to verify an individual's special enrollment period eligibility through automated electronic means, including when it is verifying eligibility on behalf of SBE–FPs, the FFEs currently cannot electronically verify whether an individual has a non-calendar year plan year QSEHRA. Therefore, qualifying individuals will be required to provide supporting documentation within 30 days of plan selection to confirm their special enrollment period triggering event, which is the end date of their QSEHRA. Acceptable documents may include a dated letter from their employer stating when their QSEHRA plan year ends or a copy of the notice that their employer provided them with to comply with section 9831(d)(4) of the Code.[174]

We estimate that this policy will result in relatively few additional consumers being required to submit documents to verify their eligibility to enroll through the proposed special enrollment period on Exchange, because this group consists of a subset of consumers with a QSEHRA whose QSEHRA renews on a non-calendar year plan year basis. Within that group, only those who are not already enrolled in individual market health insurance coverage in order to meet their QSEHRA's requirement to have MEC and who wish to change plans mid-calendar year will be required to submit documents to confirm special enrollment period eligibility. Additionally, because changing plans mid-calendar year will generally result in these consumers' deductibles and other cost-sharing accumulators re-setting we anticipate that few consumers will opt to do so, and that there will only be a minimal increase in burden.

We solicited comment on whether or not this is the case; we received broad support for the proposal, and did not receive any comments that disagreed with or suggested that we should revise our estimate in the proposed rule that relatively few additional consumers would be required to submit documents to verify their eligibility to enroll through the proposed special enrollment period on Exchange.

[174] Per IRS Notice 2017–67, this notice must include the date on which the QSEHRA is first provided to the eligible employee. Therefore, it is likely that in some cases it will also include or imply the QSEHRA end date.

D. ICRs Regarding Quality Rating Information Display Standards for Exchanges (§§ 155.1400 and 155.1405)

At §§ 155.1400 and 155.1405, we codify the flexibility for State Exchanges that operate their own eligibility and enrollment platforms to customize the display of quality rating information for their QHPs. The burden related to the proposed requirements was previously approved under OMB control number 0938–1312 (Establishment of an Exchange by a State and Qualified Health Plans PRA (CMS–10593)); the approval expired in August 2019; however, we are in the process of reinstating this information collection. The associated 60-day **Federal Register** notice published on February 25, 2020 (85 FR 10701). We do not anticipate that the flexibility we are codifying for State Exchanges that operate their own eligibility and enrollment platforms regarding the display of quality rating information for their QHPs would increase burden, as State Exchanges have the choice to pursue (or not pursue) this flexibility.

E. ICRs Regarding State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We are finalizing as proposed § 156.111(f) that specifies the type of information states are required to submit to HHS by the annual submission deadline in a form and manner specified by HHS. For a reporting package to be complete, states will need to submit an annual report that complies with each requirement listed at § 156.111(f)(1) through (6). If a state does not submit an annual reporting package by the annual submission deadline, HHS will identify which benefits are in addition to EHB for the applicable plan year in the state. We are also finalizing the proposed reporting schedule, such that states will be required to notify HHS for the first year of reporting by July 1, 2021, of any benefits in addition to EHB that QHPs are required to cover in plan year 2021 or after plan year 2021 by state action taken by May 2, 2021 (60 days prior to the annual submission deadline).

HHS will provide the template(s) to states that states are required to use for reporting the required information proposed in § 156.111(f)(1) through (6). Those templates, including the certification form, are available for review as part of the information collection we are amending under OMB control number: 0938–1174 (Essential Health Benefits Benchmark Plans (CMS–10448)), publishing alongside this final rule. We intend to post state submission of these documents on the EHB website prior to the end of the plan year during which the reporting takes place. If the state does not notify HHS of its state-required benefits that are in addition to EHB in accordance with the requirements at § 156.111(f), HHS will complete a similar document for the state and post it to the CMS website.

As we did not receive any comments that specifically contested the estimated state burden associated with the annual reporting requirement and no comments regarding the estimated number of states that we anticipate will annually report to HHS versus the number we anticipate will opt to have HHS identify which benefits are in addition to EHB for the applicable plan year in the state, we are finalizing these estimates below.

We continue to anticipate that the majority of states will choose to annually report to HHS under this policy, as states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of QHP coverage of those benefits. Because we believe the information we are requiring that states report to HHS as part of this annual reporting should already be readily accessible to states, we estimate that approximately ten states will not report and the remaining states will annually report to HHS by the annual reporting submission deadline. Therefore, we estimate that approximately forty-one (41) states will respond to the information collection requirements associated with the finalized annual reporting policy.

For the first year in which the annual reporting will take place, states will be required to include a comprehensive list of all state-required benefits applicable to QHPs in the individual and/or small group markets under state mandates that were imposed on or before December 31, 2011 and that were not withdrawn or otherwise no longer effective before December 31, 2011, as well as those state mandates that were imposed after December 31, 2011, regardless of whether the state believes such state-required benefits require defrayal in accordance with § 155.170. Each annual reporting cycle thereafter, the state will only need to update the content in its report to add any new state benefit requirements, and to indicate whether state benefit requirements previously reported to HHS have been amended or repealed. Information in states' initial reports must be accurate as of a day that is at least 60 days prior to the first reporting submission deadline set by HHS. As such, we estimate that the burden estimates for states in the first

year of annual reporting will be higher than in each subsequent year.

Although we estimate a higher burden in the first year of annual reporting of state-required benefits, states are already expected to identify which state-required benefits are in addition to EHB and to defray the cost of QHP coverage of those benefits in accordance with § 155.170. Because we believe the information we are requiring states report to HHS should be readily accessible to states, we estimate that it will require a legal support worker 25 hours (at a rate of $68.68) to pull and review all mandates, transfer this information into the HHS provided template, and validate the information in the first year of annual reporting. We estimate that it will require a general and operations manager 3 hours (at a rate of $119.12) to then review the completed template and submit it to HHS in the first year of annual reporting. We estimate that it will require a state official 2 hours (at a rate of $192.44) in the first year of annual reporting to review and sign the required document(s) for submission on behalf of the state, to confirm the accuracy of the submission. The information will be submitted to HHS electronically at minimal cost. Therefore, we estimate that the burden for each state to meet this reporting requirement in the first year will be 30 hours, with an equivalent cost of approximately $2,459, with a total first year burden for all 41 states of 1,230 hours and an associated total first year cost of approximately $100,829.

Because the first year of annual reporting is intended to set the baseline list of state-required benefits which states will update as necessary in future annual reporting cycles, we believe the burden associated with each annual reporting thereafter will be lower than the first year. We estimate that for each annual reporting cycle after the first year it will require a legal support worker 10 hours (at a rate of $68.68) to transfer the information about state-required benefits into the HHS provided template and validate the information. We estimate that it will require a general and operations manager 2 hours (at a rate of $119.12) to review the completed template and submit it to HHS each year after the first annual reporting. We estimate that it will require a state official 1 hour (at a rate of $192.44) to review and sign the required document(s) for submission on behalf of the state, to confirm the accuracy of the submission. Therefore, we estimate that the burden for each state to meet the annual reporting requirement each year after the first year of annual reporting will be 13 hours with an equivalent cost of approximately $1,117, with a total annual burden for all 41 states of 533 hours and an associated total annual cost of approximately $45,817. The average annual burden over 3 years will be approximately 765 hours with an equivalent average annual cost of approximately $64,154.

We are amending the information collection currently approved under OMB control number: 0938–1174 (Essential Health Benefits Benchmark Plans (CMS–10448)) to include this burden.

F. ICRs Regarding Termination of Coverage or Enrollment for Qualified Individuals (§ 156.270)

The collection of information titled, ''Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers'' (OMB control number 0938–1341 (CMS–10592)) already accounts for burden estimates for QHP issuers to provide notice to an enrollee if the enrollee's coverage in a QHP is terminated. Consequently, we are not making any changes under the aforementioned control number. Since we are not making any changes to the submission process or burden, we are not making any changes under the aforementioned control number.

G. ICRs Regarding Medical Loss Ratio (§§ 158.110, 158.140, 158,150, and 158.160)

We are finalizing our proposal to amend § 158.110(a) to clarify that issuers must report for MLR purposes expenses for functions they outsource to or services provided by other entities, consistent with how issuers must report directly incurred expenses. We are also finalizing our proposal to amend § 158.140(b)(1)(i) to require issuers to deduct from incurred claims not only the prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer and any prescription drug rebates and other price concessions received and retained by an entity that provides pharmacy benefit management services to the issuer (including drug price negotiation services) that are associated with administering the issuer's prescription drug benefits. We are further amending § 158.160(b)(2) to require that the prescription drug rebates and other price concessions received and retained by an entity that provides pharmacy benefit management services to the issuer must be reported as a non-claims cost. Finally, we are finalizing our proposal to amend § 158.150(b)(2)(iv)(A)(*5*) to explicitly allow issuers in the individual market to include the cost of certain wellness incentives as QIA in the MLR calculation. We do not anticipate that implementing any of these provisions will require significant changes to the MLR annual reporting form or significantly change the associated burden. The burden related to this information collection is currently approved under OMB control number 0938–1164 (Medical Loss Ratio Annual Reports, MLR Notices, and Recordkeeping Requirements (CMS–10418)).

H. Summary of Annual Burden Estimates for Requirements

TABLE 8—ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Regulation section(s)	OMB control number	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Labor cost of reporting ($)	Total cost ($)
§ 146.145(b)(3)(viii)(E)	0938–1361	901	193,715	0.003	496	65,109	69,565
§ 156.111	0938–1174	41	41	18.7	765	64,154	64,154
Total		942	193,756		1,261	129,263	133,719

Note: There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 8.

V. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes standards related to the risk adjustment program for the 2021 benefit year, clarifications and improvements to the RADV program, as well as certain modifications that will promote transparency, innovation in the private sector, reduce burden on stakeholders, and improve program integrity. This rule finalizes additional standards related to eligibility redetermination, special enrollment periods, state selection of EHB-benchmark plan and annual reporting of state-required benefits, premium adjustment percentage, termination of coverage, excepted benefit HRAs, the MLR program, and FFE and SBE–FP user fees.

B. Overall Impact

We have examined the impacts 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 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any 1 year).

Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) Having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as ''economically significant''); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order. A RIA must be prepared for major rules with economically significant effects ($100 million or more in any 1 year), and a ''significant'' regulatory action is subject to review by OMB. HHS has concluded that this rule is likely to have economic impacts of $100 million or more in at least 1 year, and therefore, is expected to be economically significant under Executive Order 12866. Therefore, HHS has provided an assessment of the potential costs, benefits, and transfers associated with this rule. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

The provisions in this final rule aim to ensure taxpayer money is more appropriately spent and that states have flexibility and control over their insurance markets. They will reduce regulatory burden, reduce administrative costs for issuers and states, and may lower net premiums for consumers. Through the reduction in financial uncertainty for issuers and increased affordability for consumers, these provisions are expected to increase access to affordable health coverage. Although there is still some uncertainty regarding the net effect on premiums, we anticipate that the provisions of this final rule will help further HHS's goal of ensuring that all consumers have access to quality and affordable health care and are able to make informed choices, that the insurance market offers choices, and that states have more control and flexibility over the operation and establishment of Exchanges.

Affected entities, such as states, will incur costs related to the EHB reporting requirement, defrayal of the cost of state-required benefits; implementation of new special enrollment period requirements; and non-Federal governmental plan sponsors offering excepted benefit HRAs will incur expenses associated with providing a notice. Issuers will experience a net increase in rebates paid to consumers due to the amendments to the MLR requirements. In accordance with Executive Order 12866, HHS believes that the benefits of this regulatory action justify the costs.

C. Impact Estimates of the Payment Notice Provisions and Accounting Table

In accordance with OMB Circular No. A–4, Table 9 depicts an accounting statement summarizing HHS's assessment of the benefits, costs, and transfers associated with this regulatory action.

This final rule implements standards for programs that will have numerous effects, including providing consumers with access to affordable health insurance coverage, reducing the impact of adverse selection, and stabilizing premiums in the individual and small group health insurance markets and in an Exchange. We are unable to quantify all benefits and costs of this final rule. The effects in Table 9 reflect qualitative impacts and estimated direct monetary costs and transfers resulting from the provisions of this final rule for health insurance issuers and consumers. The annual monetized transfers described in Table 9 include an increase in risk adjustment user fee transfers and the potential net increase in rebates from

issuers to consumers due to the amendments to MLR requirements.

We are finalizing the risk adjustment user fee of $0.25 PMPM for the 2021 benefit year to operate the risk adjustment program on behalf of states,[175] which we estimate to cost approximately $60 million in benefit year 2021, an increase of $10 million from that estimated for the 2020 benefit year. We are also finalizing the FFE user fee rate at 3.0 percent of premiums and the SBE–FP user fee rate at 2.5 percent of premiums, which are the same as the user fee rates for the 2020 benefit year.

TABLE 9—ACCOUNTING TABLE

Benefits:				
Qualitative: • Greater market stability resulting from updates to the risk adjustment methodology. • Increase in consumers' understanding of their excepted benefit HRA offer. • Strengthened program integrity related to provisions to terminate QHP coverage for Exchange enrollees who have become deceased during a plan year and via processing voluntary terminations on behalf of Medicare, Medicaid/CHIP, if applicable, BHP, dual enrollees via PDM. • More plan options for Exchange enrollees newly ineligible for CSRs, resulting in increased continuous coverage and associated benefit to risk pools. • Streamlined Exchange operations by eliminating certain prospective coverage effective date rules and retroactive payment rules for special enrollment periods.				
Costs	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Annualized Monetized ($/year)	−$54.57	2019	7	2020–2024
	−51.51	2019	3	2020–2024
Quantitative: • Costs incurred by sponsors of non-Federal governmental plans and states to comply with provisions related to notice requirement for excepted benefit HRAs and reporting related to state mandated benefits, as detailed in the Collection of Information Requirements section, estimated to be approximately $182,000 in 2020, approximately $105,200 in 2021 and approximately $59,000 from 2022 onwards. • Reduction in potential costs to Exchanges since they will not be required to conduct random sampling as a verification process for enrollment in or eligibility for employer-based insurance when the Exchange reasonably expects that it will not obtain sufficient verification data, estimated to be one-time savings of $48.5 million in 2020 and annual savings of $99 million in 2020 and 2021. • Regulatory familiarization costs of approximately $169,500 in 2020.				
Qualitative: • Increased costs due to increases in providing medical services (if health insurance enrollment increases). • Potentially minor costs to Exchanges and DE partners to update the application and logic to account for new plan options for Exchange enrollees newly ineligible for CSRs and enrollees covered by a non-calendar plan year QSEHRA. • Potential reduction in costs to issuers due to elimination of duplicative coverage as part of PDM. • Potential reduction in costs to consumers due to PDM noticing efforts to notify enrollees of duplicative coverage and risk for tax liability. • Potential costs to the Exchanges and consumers to comply with the new special enrollment period requirements. • Potential reduction in burden for Exchanges and issuers to comply with the special enrollment period prospective coverage effective dates.				
Transfers	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
Federal Annualized Monetized ($/year)	$7.7	2019	7	2020–2024
	7.9	2019	3	2020–2024
Other Annualized Monetized ($/year)	10.2	2019	7	2020–2024
	10.6	2019	3	2020–2024
Quantitative: • Federal Transfers: Increase in risk adjustment user fee transfers from issuers to the federal government by $10 million starting in 2021, compared to that estimated for the prior benefit year.				

[175] As noted earlier in this final rule, no state has elected to operate the risk adjustment program for the 2021 benefit year; therefore, HHS will operate the program for all 50 states and the District of Columbia.

Transfers	Estimate (million)	Year dollar	Discount rate (percent)	Period covered
• Other Transfers: Net increase in transfers from health insurance issuers to consumers in the form of rebates of $18.2 million per year starting in 2022 MLR reporting year, due to amendments to the MLR requirements.				
Qualitative: • Potential decreases in premiums and PTCs associated with adjustments to MLR. • Potential decrease in APTC and CSR payments due to reduction in duplicative coverage and retroactive termination of coverage to the date of death as part of PDM and more accurate defrayal of costs for state mandated benefits. • Transfer of costs from issuers to states to the extent that a state will newly defray the cost of state-required benefits it should have already been defraying.				

This RIA expands upon the impact analyses of previous rules and utilizes the Congressional Budget Office's (CBO) analysis of the PPACA's impact on Federal spending, revenue collection, and insurance enrollment. The PPACA ends the transitional reinsurance program and temporary risk corridors program after the benefit year 2016. Therefore, the costs associated with those programs are not included in Table 9 or 10. Table 10 summarizes the effects of the risk adjustment program on the Federal budget from FYs 2020 through 2024, with the additional, societal effects of this final rule discussed in this RIA. We do not expect the provisions of this final rule to significantly alter CBO's estimates of the budget impact of the premium stabilization programs that are described in Table 10.

In addition to utilizing CBO projections, HHS conducted an internal analysis of the effects of its regulations on enrollment and premiums. Based on these internal analyses, we anticipate that the quantitative effects of the provisions in this rule are consistent with our previous estimates in the 2020 Payment Notice for the impacts associated with the APTCs, the premium stabilization programs, and FFE and SBE–FP user fee requirements.

TABLE 10—ESTIMATED FEDERAL GOVERNMENT OUTLAYS AND RECEIPTS FOR THE RISK ADJUSTMENT AND REINSURANCE PROGRAMS FROM FISCAL YEAR 2020–2024, IN BILLIONS OF DOLLARS [1]

Year	2020	2021	2022	2023	2024	2020–2024
Risk Adjustment and Reinsurance Program Payments	5	6	6	6	7	30
Risk Adjustment and Reinsurance Program Collections	5	6	6	6	7	30

[1] Reinsurance collections ended in FY 2018 and outlays in subsequent years reflect remaining payments, refunds, and allowable activities.
Note: Risk adjustment program payments and receipts lag by one quarter. Receipt will fully offset payments over time.
Source: Congressional Budget Office. *Net Federal Subsidies Associated With Health Insurance Coverage, 2020 to 2030: Table From CBO's March 2020 Baseline.* March 6, 2020. Available at *https://www.cbo.gov/about/products/baseline-projections-selected-programs#6.*

1. Notice Requirement for Excepted Benefit HRAs Offered by Non-Federal Governmental Plan Sponsors (§ 146.145(b)(3)(viii)(E))

In § 146.145(b)(3)(viii)(E), we require that an excepted benefit HRA offered by a non-Federal governmental plan sponsor must provide, on an annual basis, a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps or other limits on benefits under the plan, and a description or summary of the benefits. This notice will provide employees with clear information regarding excepted benefit HRAs offered by their employers. Excepted benefit HRAs sponsored by non-Federal governmental entities will incur costs to provide the notice as detailed previously in the Collection of Information Requirements section.

2. Early Retiree Reinsurance Program (Part 149)

The provision to remove the regulations at part 149 of title 45 governing the ERRP will not have any direct regulatory impact since the ERRP sunset as of January 1, 2014. However, removing the regulations will reduce the volume of Federal regulations.

3. Risk Adjustment

The risk adjustment program is a permanent program created by section 1343 of the PPACA that collects charges from issuers with lower-than-average risk populations and uses those funds to make payments to issuers with higher-than-average risk populations in the individual, small group, and merged markets (as applicable), inside and outside the Exchanges. We established standards for the administration of the risk adjustment program in subparts A, B, D, G, and H of part 153.

If a state is not approved to operate, or chooses to forgo operating its own risk adjustment program, HHS will operate risk adjustment on its behalf. For the 2021 benefit year, HHS will operate a risk adjustment program in every state and the District of Columbia. As described in the 2014 Payment Notice, HHS's operation of risk adjustment on behalf of states is funded through a risk adjustment user fee. For the 2021 benefit year, we have used the same methodology that we finalized in the 2020 Payment Notice to estimate our administrative expenses to operate the program. Risk adjustment user fee costs for the 2021 benefit year are expected to increase from the prior 2020 benefit year estimates of approximately $50 million to approximately $60 million. We estimate that the total cost for HHS to

operate the risk adjustment program on behalf of states and the District of Columbia for 2021 will be approximately $60 million, and the risk adjustment user fee will be $0.25 PMPM. Because of the increase in costs estimated for the 2021 benefit year, we expect the final risk adjustment user fee for the 2021 benefit year to increase transfers from issuers of risk adjustment covered plans to the Federal Government by $10 million.

Additionally, to use risk adjustment factors that reflect more recent treatment patterns and costs, we will recalibrate the HHS risk adjustment models for the 2021 benefit year by using more recent claims data to develop updated risk factors, as part of our continued assessment of modifications to the HHS-operated risk adjustment program for the individual and small group (and merged) markets. We will discontinue our reliance on MarketScan® data to recalibrate the risk adjustment models, and adopt an approach of using the 3 most recent years of available enrollee-level EDGE data for recalibration of the risk adjustment models for the 2021 benefit year and beyond. We believe that the approach of blending (or averaging) 3 years of separately solved coefficients will provide stability within the risk adjustment program and minimize volatility in changes to risk scores from the 2020 benefit year to the 2021 benefit year due to differences in the datasets' underlying populations. We will also incorporate the proposed HCC changes beginning with the 2021 benefit year risk adjustment models to transition from the ICD–9 to ICD–10 codes. We do not expect these changes to affect the absolute value of risk adjustment transfers, or impact issuer burden beyond what we previously estimated in the 2020 Payment Notice.

4. Risk Adjustment Data Validation (§§ 153.350 and 153.630)

We are making changes to the RADV methodology for identifying outliers, which results in adjustments to transfers under § 153.350. Beginning with the 2019 benefit year of RADV, we will consider issuers to be outliers only if they have 30 or more HCCs recorded on EDGE for any HCC group in which their failure rate appears anomalous. As only a very small number of issuers will be affected by this change, and those affected already have small total plan liability risk scores for the affected HCC groups due to their low HCC counts, we expect the total reduction of burden to issuers to be small. Projections based on 2017 benefit year RADV adjustments estimate an overall 0.7 percent reduction in absolute RADV transfer adjustments across all issuers for benefit years to which this change may apply.

We are also finalizing that the 2019 benefit year RADV will serve as a second pilot year for the purposes of prescription drug data validation in addition to the 2018 benefit year RADV. This second pilot year will provide HHS and issuers with 2 full years of experience with the data validation process for prescription drugs before adjusting transfers. We do not expect this to affect the magnitude of RADV adjustments to risk adjustment transfers, or to impact issuer burden or administrative costs beyond what we previously estimated in the 2020 Payment Notice.

5. Verification Process Related to Eligibility for Insurance Affordability Programs (§ 155.320)

We are finalizing the policy that HHS will not take enforcement action against Exchanges that do not perform random sampling as required by § 155.320(d)(4), when the Exchange does not reasonably expect to obtain sufficient verification data as described in § 155.320(d)(2)(i) through (iii), for plan years 2020 and 2021. In the 2019 Payment Notice final rule, we discussed the burden associated with sampling based in part on the alternative process used for the Exchanges. HHS incurred approximately $750,000 in costs to design and operationalize a study in 2016 and the study indicated that $353,581 of APTC was potentially incorrectly granted to individuals who inaccurately attested to their enrollment in or eligibility for a qualifying eligible employer-sponsored plan. We placed calls to employers to verify 15,125 cases but were only able to verify 1,948 cases. A large number of employers either could not be reached or were unable to verify a consumer's information, resulting in a verification rate of approximately 13 percent. The sample-size involved in the 2016 study did not represent a statistically significant sample of the target population and did not fulfill all regulatory requirements for sampling under paragraph (d)(4)(i) of § 155.320.

We estimate that the overall one-time cost of implementing sampling would have been approximately $8 million for the Exchanges using the Federal platform, and between $2 million and $7 million for other Exchanges, depending on their enrollment volume and existing infrastructure. Therefore, we estimate that the average per-Exchange cost of implementing sampling that resembles the approach taken by the Exchanges using the Federal platform would have been approximately $4.5 million for State Exchanges that operate their own eligibility and enrollment platform, for a total cost of $58.5 million for the 13 State Exchanges that operate their own eligibility and enrollment platform (operating in 12 States and the District of Columbia). However, we are aware that 4 State Exchanges that operate their own eligibility and enrollment platform have already incurred costs to implement sampling and estimate that they have incurred one-time costs of approximately $4.5 million per Exchange with a total of $18 million and will only experience savings related to recurring costs. Therefore, the one-time savings for Exchanges using the Federal platform and the remaining State Exchanges that operate their own eligibility and enrollment platform will be approximately $48.5 million.

We estimate the annual costs to conduct sampling on a statistically significant sample size of approximately 1 million cases to be approximately $8 million for the Exchanges using the Federal platform and $7 million on average for each State Exchange that operates its own eligibility and enrollment platform. This estimate includes operational activities such as noticing, inbound and outbound calls to the Marketplace call center, and adjudicating consumer appeals. The total annual cost to conduct sampling would have been $91 million for 13 State Exchanges. Therefore, the total annual cost for the Exchanges using the Federal platform and the 13 State Exchanges that operate their own eligibility and enrollment platform would have been $99 million. We estimated that relieving Exchanges of the requirement to conduct sampling for plan years 2020 and 2021 will result in annual savings of approximately $99 million. We solicited comment on this estimate.

We received no public comments on these proposed cost savings, and therefore, we are finalizing as proposed.

6. Eligibility Redetermination During a Benefit Year (§ 155.330)

We are amending § 155.330(e)(2)(i)(D) to clarify that the Exchanges will not redetermine eligibility for APTC/CSRs for Medicare, Medicaid/CHIP, and, if applicable, BHP for dual enrollees who provide written consent for Exchanges to end their QHP coverage prior to terminating the coverage. We anticipate that this will benefit dual enrollees, as processing a voluntary termination mitigates the risk for future tax liability for APTC/CSRs paid inappropriately during months of overlapping coverage. It will also streamline the termination

process. Additionally, we believe this provision will safeguard consumers against being enrolled in unnecessary or duplicative coverage. This provision may reduce burden on Exchanges by allowing them to streamline their PDM operations since eligibility redeterminations for APTC/CSRs are not necessary when processing a voluntary termination of coverage for a dual enrollee who has permitted the Exchange to do so, and will provide Exchanges with more flexibility in their operations.

We solicited comment on the impacts of the proposal. We received no public comments on costs or anticipated burden on states with regard to the proposed changes. Therefore, we are finalizing as proposed.

We further amend § 155.330(e)(2)(i)(D) by adding new language that clarifies when the Exchange identifies deceased enrollees via PDM, the Exchange will follow the process outlined in § 155.430(d)(7) and terminate coverage retroactively to the date of death, without the need to redetermine the eligibility of the deceased enrollee. We believe this change will reduce the amount of time a deceased enrollee remains in QHP coverage while receiving APTC/CSRs. Additionally, we believe this provision will not increase burden on State Exchanges that operate their own eligibility and enrollment platform because we believe these changes merely clarify the operational process when conducting checks for deceased enrollees and would not impose new requirements on State Exchanges that operate their own eligibility and enrollment platform. Additionally, this provision may help streamline Exchanges' PDM operations, as eligibility redeterminations are not necessary when termination of coverage is for a deceased enrollee, and will provide Exchanges with more flexibility in their operations.

We solicited comment on the impacts of the proposal. We received no public comments on costs or anticipated burden on states with regard to the proposed changes. Therefore, we are finalizing as proposed.

7. Special Enrollment Periods (§ 155.420)

a. Exchange Enrollees Newly Ineligible for CSRs

We are amending § 155.420(a)(4) to allow enrollees who qualify for a special enrollment period due to becoming newly ineligible for CSRs to change to a QHP one metal level higher or lower, but delaying to January 2022 the effective date for this modification to allow Exchanges more time to implement the change. We anticipate that this will benefit applicable enrollees and dependents by providing them with additional flexibility to change to a plan better suited to their needs based on changes to their premiums and/or cost-sharing requirements. In some cases, this change may help enrollees to maintain continuous coverage for themselves and for their dependents when they otherwise would have no longer been able to afford higher premiums or increased cost-sharing requirements of their current silver-level plan. This provision may also provide some benefit to the individual market risk pool by making it easier for those affected to maintain continuous coverage in spite of potentially significant changes in their out-of-pocket health care costs. Regardless, we believe that this change will not have a negative impact on the individual market risk pool, because most applicable enrollees will seek to change coverage based on financial rather than health needs. However, this provision will impose a small cost to Exchanges that have implemented plan category limitations, because it will require a change to application and plan selection system logic to permit applicable enrollees and dependents to change to gold or bronze level plans after having previously restricted them to silver level plans. We solicited comments on the extent to which Exchanges would experience burden due to the change, and regarding potential burden on FFE Direct Enrollment and Enhanced Direct Enrollment partners, as well as more generally on the impact of the proposal.

Several commenters supported providing State Exchanges with flexibility related to implementing special enrollment period policy changes because they often necessitate resource-intensive work. However, a wide range of commenters supported this proposal because they believed it would reduce burden on affected Exchange enrollees by allowing them to change their QHP selection based on a change to their financial circumstances. Some of these commenters noted that this change could allow some enrollees to maintain coverage who otherwise would not have been able to do so, which supports our belief that this provision may have a small but positive impact on the individual market risk pool. Therefore, while we are aware that this change will likely impose burden on State Exchanges required to implement it, we believe that the benefit of finalizing it will outweigh the cost and that delaying the effective date for this modification will give Exchanges sufficient time to incorporate it into their development priorities and allocate resources accordingly.

b. Special Enrollment Period Limitations for Enrollees Who Are Dependents

We believe that the new provision in § 155.420(a)(4)(iii)(C) will not impose burden on Exchanges, because it will streamline the rules at § 155.420(a)(4) by ensuring that all existing enrollees are treated in the same way, and therefore, may simplify implementation. We also anticipate that it will help mitigate confusion on the part of issuers, Exchanges, and consumers by clarifying that the 2017 Market Stabilization Rule's intent was to apply the same limitations to dependents who are currently enrolled in Exchange coverage that it applies to current, non-dependent Exchange enrollees.

However, we solicited comment from Exchanges on whether this is the case, and if not, on the costs that the proposal would impose in terms of updates to application system logic, as well as potential consumer burden based on the number of enrollees who might be affected by this type of plan category limitation.

Several commenters expressed support for this proposal based on its simplification of current regulations. However, several commenters opposed this proposal based on their belief that a parent or guardian should be able to re-evaluate their household's QHP selection based on metal level when newly enrolling in Exchange coverage with currently-enrolled dependents. Additionally, similar to the other plan category limitation-related proposal, we did not receive comments that specifically contradicted our understanding that this change would impose some limited burden on Exchanges, but several commenters cited strong support for providing State Exchanges with flexibility related to implementing special enrollment period policy changes because they often necessitate resource-intensive work. Some of these commenters also voiced strong opposition to plan category limitations more generally. While we are sensitive to State Exchange concerns about the cost of implementing changes to system logic, we believe that the benefit of this provision in terms of simplifying plan category limitation rules and ensuring that these rules work as intended will outweigh the cost.

c. Special Enrollment Period Prospective Coverage Effective Dates

Our revision to transition special enrollment periods previously following regular effective date rules to instead be effective on the first of the month following plan selection in Exchanges using the Federal platform will improve long-term operational efficiency through standardization for issuers and the Exchanges using the Federal platform, while reducing consumer confusion and minimizing gaps in coverage. We do not expect issuers to incur substantial new costs by aligning these effective dates, as issuers routinely effectuate coverage on the first of the month following plan selection or faster.

Additionally, because billing is tied to effective dates, transitioning to these more expedited effective dates in the Exchanges using the Federal platform will simplify issuer billing practices. Operationalizing the aligned prospective effective dates may reduce system errors and related casework, as well as confusion for consumers, issuers, and caseworker and call center staff based on different rules applying for different scenarios. Also, we believe eliminating the requirement that Exchanges demonstrate that all of their participating QHP issuers agree to effectuate coverage in a shorter timeframe will reduce burden for both issuers and Exchanges. We did not receive comments on this analysis.

d. Special Enrollment Period Retroactive Coverage Effective Dates

We are eliminating the special rule for retroactive effective dates after an enrollment has been pended due to special enrollment period verification and to simplify applicability of retroactive effective date and binder payment rules to clarify the ability of consumers effectuating enrollments with retroactive effective dates to select prospective coverage by paying only one month's premium. This will improve long-term operational efficiency for issuers and Exchanges, while reducing confusion for consumers, issuers, and caseworker and call center staff based on different rules for different scenarios. We do not expect issuers to incur new costs in streamlining applicability of the retroactive effective date rule. Under previous § 155.400(e)(1)(iii), issuers already received transactions for retroactive coverage and assigned coverage effective dates either retroactively or prospectively based on consumer payments. This change will simply eliminate the complexity for an issuer to have to determine the appropriate binder payment rule to apply to an enrollment with a retroactive effective date when issuers receive only 1 month's premium. Finally, because issuers, not Exchanges using the Federal platform, are responsible for assigning effective dates based on premium payments received under this policy, Exchanges using the Federal platform will not incur costs based on this change. We did not receive comments on this analysis.

e. Enrollees Covered by a Non-Calendar Year Plan Year QSEHRA

We are amending § 155.420(d)(1)(ii) to codify the special enrollment period available to qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year. We expect that this will impose some burden on Exchanges and off-Exchange individual health insurance issuers that implement pre-enrollment eligibility verification for special enrollment periods due to related updates to the application and the need to train staff that reviews documents from applicants to verify special enrollment period eligibility. However, we believe that this burden will be limited because the ''non-calendar year plan year special enrollment period'' is already subject to pre-enrollment eligibility verification, and because individuals who qualify may already be enrolled in Exchange coverage, and therefore, not subject to pre-enrollment eligibility verification. We also anticipate that this provision will impose limited burden on FFE Enhanced Direct Enrollment partners, because required changes for these partners will be limited to updating application question wording.

Additionally, while this provision will provide QSEHRA participants an opportunity to change their individual health insurance plan, we believe that uptake will be limited as most eligible employees will likely not want to change to a new QHP during the QHP's plan year because such a change would result in their deductibles and other accumulators re-setting. Similarly, we believe that burden on issuers related to adverse selection will be limited due to low uptake because of the disadvantages to enrollees of changing their coverage during its plan year, and because the special enrollment period at § 155.420(d)(1)(ii) is subject to plan category limitations per § 155.420(a)(4)(iii). We solicited comments on this proposal, including from Exchanges, on implementation burden and costs.

Commenters generally expressed support for this proposal, and we did not receive comments that this change would create burden for State Exchanges or other key stakeholders.

8. Effective Dates for Terminations (§ 155.430)

As discussed earlier in the preamble to § 155.430, this provision will align the provision for termination after an enrollee experiences a technical error that does not allow her to terminate her coverage or enrollment through the Exchange with all other enrollee-initiated termination effective date rules under § 155.430. Specifically, at the option of the Exchange, the enrollee will no longer have to provide 14-days advance notice before the termination becomes effective. Exchanges and issuers are not expected to incur new costs by aligning these termination dates, as Exchanges and issuers are both well acquainted with same-day termination transactions. Further, similar to the 2019 updates to § 155.430(d)(2), this provision will retain State Exchange flexibility to choose whether to implement this change. Operationalizing the aligned termination dates might reduce system errors and related casework, as well as confusion for consumers, issuers, and caseworker and call center staff based on contradictory rules for different scenarios.

9. Quality Rating Information Display Standards for Exchanges (§§ 155.1400 and 155.1405)

We are amending §§ 155.1400 and 155.1405 to codify the flexibility for State Exchanges that operate their own eligibility and enrollment platforms, to customize the display of quality rating information on their websites. We expect that this will impose minimal burden on State Exchanges. In particular, these State Exchanges have the choice to pursue this flexibility or to display the quality rating information assigned for each QHP as provided by HHS. Further, a few State Exchanges during the display pilot have already chosen to display quality rating information with some state-specific customizations to incorporate additional state or local information or to modify the names of the QRS quality ratings.

10. FFE and SBE–FP User Fees (§ 156.50)

For 2021, we considered two alternative proposals. First, we proposed to maintain the FFE and the SBE–FP user fee rates at current levels, 3.0 and 2.5 percent of premiums, respectively. Alternatively, we considered and solicited comment on reducing the user fee rates below the 2020 benefit year levels. If the user fees

are lowered below the 2020 benefit year levels, FFE and SBE–FP user fee transfers from issuers to the Federal Government would be lower compared to those estimated for the prior benefit year.

We are finalizing the FFE user fee rate at 3.0 percent of premiums and the SBE–FP user fee rate at 2.5 percent of premiums, which are the same as the user fee rates for the 2020 benefit year. Therefore, there will be no change in user fee transfers.

11. State Selection of EHB-Benchmark Plan for Plan Years Beginning on or After January 1, 2020 (§ 156.111)

We are amending § 156.111(d) and adding a new paragraph (f) to require states to annually report to HHS any state-required benefits in addition to EHB in accordance with § 155.170 that are applicable to QHPs in the individual and/or small group markets. As finalized, if the state does not report to HHS its state-required benefits considered to be in addition to EHB by the annual reporting submission deadline, HHS will identify which benefits are in addition to EHB for the state for the applicable plan year. We also specify at § 156.111(f)(1) through (6) the type of documentation states will be required to submit as part of the annual reporting, which among other requirements will need to be signed by a state official with authority to make the submission on behalf of the state, to confirm the accuracy of the submission.

Comment: Many commenters stated that an annual reporting requirement would be an additional administrative burden on states, the type the Administration instructed agencies to reduce to the maximum extent permitted by law and duplicate the burden states already bear as the entities responsible for identifying which mandates require defrayal. To ease burden, one commenter recommended that HHS leverage the existing reporting related to EHB rather than creating a new, duplicative report. For example, one commenter stated that HHS making determinations in the states' place about which state-required benefits are in addition to EHB conflicts with Executive Order 13865, ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients,'' which directs HHS ''to the maximum extent permitted by law, provide relief from any provision or requirement of the PPACA that would impose a fiscal burden on any State. . . .'' [176] Commenters also expressed concerned that the annual reporting requirement will be so burdensome that it will discourage states from adopting changes to provide additional health benefits to consumers or even deter states from updating their EHB-benchmark plan.

Response: We recognize that requiring states to annually report to HHS will require that states submit additional paperwork to HHS on an annual basis. However, because states are already required under § 155.170 to identify which state-required benefits are in addition to EHB and to defray the cost of those benefits, we believe any burden experienced by states will be minimal and that this reporting requirement will be complementary to the process the state should already have in place for tracking and analyzing state-required benefits. Additionally, states may opt not to report this information and instead let HHS make this determination for them.

We also believe any such burden is justified to ensure that HHS is not paying APTC for portions of premium attributable to non-EHB. We continue to be concerned that there are states not defraying the costs of their state-required benefits in addition to EHB in accordance with Federal requirements. For such states, the burden may be higher to meet the annual reporting requirement to the extent it requires the state to begin tracking, analyzing, and identifying state-required benefits for purposes of determining whether defrayal is required. However, we believe the annual reporting requirement is necessary to help states be diligent about their framework for determining which mandates are in addition to EHB in accordance with § 155.170 and to partner with HHS on improving program integrity. This requirement properly aligns with Federal requirements for defraying the cost of state-mandated benefits, will generally improve transparency with regard to the types of benefit requirements states are enacting, and will provide the necessary information to HHS for increased oversight over whether states are appropriately determining which state-required benefits require defrayal and whether QHP issuers are properly allocating the portion of premiums attributable to EHB for purposes of calculating PTCs.

We acknowledge that some states may already be appropriately identifying which state-required benefits are in addition to EHB, and that these states may have already developed an effective process for defraying the cost of these state-required benefits. However, we believe many other states are not doing so, and that this annual reporting policy will assist in achieving greater compliance with § 155.170 in all states, and therefore, broadly strengthen program integrity. Furthermore, we disagree that requiring already compliant states to annually report would be disruptive or unnecessarily burdensome given that the information included in the annual reports should already be readily accessible to states, especially already compliant states. We believe any burden will be limited to the completion of the HHS templates, validation of that information, and submission of the templates to HHS. These costs have been discussed previously in the Collection of Information Requirements section. We also believe standardizing the form and manner of the report and the data elements required (rather than allowing states to determine the form and manner of reporting) is important for consistency year after year and for ensuring HHS has the information necessary to adequately oversee state compliance with § 155.170.

We do not anticipate these requirements will add any new burden on non-reporting states as they will be relying on HHS to make these determinations and fill out these templates for them. Because we are also finalizing that HHS's identification of which benefits are in addition to EHB in non-reporting states will become part of the definition of EHB for the applicable state for the applicable year, this may require states to defray more benefits than the state currently defrays or anticipated having to defray. In this scenario, we acknowledge the annual reporting requirement may generate additional costs for a state that defers the task of identifying state-mandated benefits that require defrayal to HHS in order to properly align the state with Federal requirements regarding defrayal.

To the extent that this provision will cause a state to newly defray the cost of state-required benefits, this will represent a transfer of costs from the issuer to the state, as the issuer might have been previously covering the costs of benefits for which the state should have been defraying. In the event that the annual reporting requirement causes states to newly identify state-required benefits as being in addition to EHB that were previously being incorrectly

[176] Executive Order 13865, ''Reducing Regulatory Burdens Imposed by the Patient Protection and Affordable Care Act & Improving Healthcare Choice To Empower Patients,'' 82 FR 26885, 26886 (June 12, 2017) *available at https://www.govinfo.gov/content/pkg/FR-2017-06-12/pdf/2017-12130.pdf.*

covered as part of EHB, this may decrease the amount of PTC for enrollees in the state as the percent of premium allocable to EHB will be reduced.

We again emphasize that section 36B(b)(3)(D) of the Code specifies that the portion of the premium allocable to state-required benefits in addition to EHB shall not be taken into account in determining a PTC. As such, we believe any burden resulting from the finalized annual reporting requirement is necessary to ensure that the federal government is not paying APTC for portions of premiums attributable to non-EHB in violation of this provision.

12. Provisions Related to Cost Sharing (§ 156.130)

The Affordable Care Act provides for the reduction or elimination of cost sharing for certain eligible individuals enrolled in QHPs offered through the Exchanges. This assistance is intended to help many low- and moderate-income individuals and families obtain health insurance.

We are finalizing the reductions in the maximum annual limitation on cost sharing for silver plan variations as proposed. Consistent with our analysis in previous Payment Notices, we developed three model silver level QHPs and analyzed the impact on their AVs of the reductions described in the PPACA to the estimated 2021 maximum annual limitation on cost sharing for self only coverage of $8,550. We do not believe the changes to the maximum annual limitation on cost sharing or the reductions in this parameter for silver plan variations will result in a significant economic impact.

We are also finalizing the premium adjustment percentage for the 2021 benefit year at the proposed value of 1.3542376277, based on the NHEA data available at the time of proposal. Section 156.130(e) provides that the premium adjustment percentage is the percentage (if any) by which the average per capita premium for health insurance coverage for the preceding calendar year exceeds such average per capita premium for health insurance for 2013. The annual premium adjustment percentage sets the rate of increase for three parameters detailed in the Affordable Care Act: The annual limitation on cost sharing (defined at § 156.130(a)), the required contribution percentage used to determine eligibility for certain exemptions under section 5000A of the Code, and the assessable payments under sections 4980H(a) and 4980H(b). In response to comments, we have finalized the premium adjustment percentage, required contribution percentage, and related parameters based on the NHEA data that were available as of the publication of the proposed rule. This approach differs from the approach taken by HHS in the 2020 Payment Notice, wherein we updated the premium adjustment percentage based on updates to the NHEA data that took place between the publication of the proposed rule and the publication of the final rule.

We are finalizing the 2021 premium adjustment percentage as proposed without updates to reflect the most recent NHEA data available as of the publication of the proposed rule in order to increase the transparency and predictability of premium adjustment percentage and related parameters for stakeholders.

We believe that the premium adjustment percentage of 1.3542376277 based on average per enrollee private health insurance premiums (excluding Medigap and property and casualty insurance), and as calculated based on NHEA data available as of the publication of the proposed rule, is well within the parameters used in the modeling of the Affordable Care Act, and we do not expect that these finalized values will alter CBO's May 2018 baseline estimates of the budget impact beyond the changes described in the 2020 Payment Notice.

13. Cost-Sharing Requirements and Drug Manufacturers Support (§ 156.130)

We are revising § 156.130(h) in its entirety to state, notwithstanding any other provision of the annual limitation on cost sharing regulation, and to the extent consistent with state law, amounts of direct support offered by drug manufacturers to enrollees for specific prescription drugs towards reducing the cost sharing incurred by an enrollee using any form are not required to be counted toward the annual limitation on cost sharing. We believe that this will impose minimal burden, as it reflects the longstanding practice of health insurance issuers and group health plans determining whether drug manufacturer direct support to enrollees for specific prescription drugs counts toward the annual limitation on cost sharing.

Comment: Some commenters expressed concerns that consumers would experience higher health care utilization and greater overall health care costs.

Response: While we appreciate concerns that the proposal may raise out-of-pocket costs for consumers, we believe the impact of such costs will be limited as issuers and group health plans were provided with sufficient notice that longstanding plan designs need not change for plan year 2020 with regard to how direct drug manufacturer support amounts count towards the annual limitation on cost sharing. By finalizing this policy, issuers and group health plans may continue their longstanding practices with regard to how and whether direct drug manufacturer support accrues towards an enrollee's annual limitation on cost sharing. This, combined with FAQ Part 40 released in August 2019, should prevent or mitigate changes to how issuers and group health plans have historically handled direct drug manufacturer support amounts. Therefore, we anticipate that there will be minimal overall disruption to consumers.

14. Requirements for Timely Submission of Enrollment Reconciliation Data (§ 156.265)

In the Establishment of Exchanges and Qualified Health Plans; Exchange Standards interim final rule,[177] we established standards for the collection and transmission of enrollment information. At § 156.265(f), we set forth standards on the enrollment reconciliation process, specifying that issuers must reconcile enrollment with the Exchange no less than once a month. Although the regulations in § 156.265 require issuers to reconcile enrollment with the Exchange monthly, they do not specify standards for the format or quality of these data exchanges, such as the manner in which enrollment updates must be reflected in updates of previously submitted enrollment data, or the timeframe in which issuers should report data updates and data errors to the Exchange. To clarify these procedures, we are amending § 156.265(f) to require a QHP issuer to include in its enrollment reconciliation submission to the Exchange the most recent enrollment information that is available and that has been verified to the best of its knowledge or belief. We are also amending § 156.265(g) to direct a QHP issuer to update its enrollment records as directed by the Exchange (or for QHP issuers in SBE–FPs, the Federal platform), and to inform the Exchange (or for QHP issuers in SBE–FPs, the Federal platform) if any such directions are in error within 30 days. In SBE–FPs, references in this section to the Exchange should be understood to mean HHS, as administrator of the Federal platform. We believe these amendments will encourage more timely reconciliation and error reporting, resulting in an improved consumer

[177] See 77 FR 18309 at 18425.

experience. However, because we believe that issuers are already routinely conducting verifications of internal enrollment data at various points in the year, we do not believe that these clarifying standards on the process for submitting enrollment and reconciliation data will materially impact issuer burden, beyond what we estimated in the Exchange Establishment rules.

15. Dispute of HHS Payment and Collections Reports (§ 156.1210)

In the 2014 Payment Notice,[178] we established provisions related to confirmation and dispute of payment and collection reports. These provisions were written under the assumption that issuers would generally be able to provide these confirmations or disputes automatically to HHS. We are amending § 156.1210 by lengthening the time to report payment errors from 15 days to 90 days to allow issuers the option of researching, reporting, and correcting errors through other channels. We believe this change will slightly reduce issuer burden compared to what was previously estimated in the 2014 Payment Notice.

16. Medical Loss Ratio (§§ 158.110, 158.140, 158.150, and 158.160)

We are amending § 158.110(a) to clarify that for MLR purposes, issuers must report expenses for functions outsourced to or services provided by other entities consistently with how issuers must report directly incurred expenses. We do not expect this amendment to impact issuer burden as it does not fundamentally change the existing requirements. We are also amending § 158.140(b)(1)(i) to require issuers to deduct from incurred claims not only the prescription drug rebates received by the issuer, but also any price concessions received and retained by the issuer, as well as any prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services (including drug price negotiation services) to the issuer. We are making conforming amendments to § 158.160(b)(2) to require such amounts to be reported as non-claims costs when received and retained by an entity providing pharmacy benefit management services. While there does not exist comprehensive public data on the amount, prevalence, or retention rate for prescription drug rebates and other price concessions retained by PBMs or other entities providing pharmacy benefit management services, based on data from the 2017 MLR reporting year, including the data from issuers who receive and report prescription drug rebates, we estimate that this requirement may increase rebate payments from issuers to consumers by $18.4 million per year. Since issuers generally prefer to set premium rates at a level that avoids rebates, and consequently potential rebate increases create a downward pressure on premiums, this requirement is also likely to lead to reductions in PTC transfers (which are a function of the premium rate for the second lowest-cost silver plan applicable to a consumer, the premium rate for the plan purchased by the consumer, and the consumer's income level) from the Federal Government to certain consumers in the individual market. Additionally, we are amending § 158.150(b)(2)(iv)(A)(*5*) to explicitly allow issuers in the individual market to include the cost of certain wellness incentives as QIA in the MLR calculation. Based on data from the 2017 MLR reporting year, we estimate that this provision may decrease rebate payments from issuers to consumers by $0.2 million per year.

We are finalizing these proposals as proposed, except that we are delaying the applicability date of the amendments to §§ 158.140(b)(1)(i) and 158.160(b)(2) until the 2022 MLR reporting year (MLR reports filed in 2023), and modifying the amendment to § 158.160(b)(2) to only apply to the prescription drug rebates and price concessions received and retained by an entity providing pharmacy benefit management services to the issuer.

Comment: One commenter stated that the amendment to § 158.140(b)(1)(i) requiring issuers to deduct from incurred claims the prescription drug rebates and other price concessions received and retained by an entity providing pharmacy benefit management services to the issuer would increase, rather than decrease, premiums because ''retained rebates as currently reported under MLR reduce *actual* plan administrative expenses [and t]he administrative fees paid to PBMs that replace the retained rebates would also be subtracted, resulting in the same net effect.''

Response: We respectfully disagree with the commenter's assessment. We note that the regulation, both before and after the amendment to § 158.140(b)(1)(i), does not allow administrative fees paid by an issuer directly to a PBM or a similar entity to be included in incurred claims. However, prior to the amendment to § 158.140(b)(1)(i), an issuer was able to include in incurred claims compensation provided by an issuer to a PBM for administrative or other services by allowing the PBM to retain part or all of the prescription drug rebates and other prices concessions. Because the amendment to § 158.140(b)(1)(i) requires issuers to subtract such prescription drug rebates and other prices concessions from incurred claims, the amendment will result in lower MLRs for some issuers and will lead such issuers to lower premiums or pay higher MLR rebates to enrollees.

17. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that this rule will be reviewed by all affected issuers, states, non-Federal governmental entities offering excepted benefit HRAs, and some individuals and other entities that commented on the proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed the proposed rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we consider the number of affected entities and past commenters to be a fair estimate of the number of reviewers of this final rule.

We are required to issue a substantial portion of this rule each year under our regulations and we estimate that approximately half of the remaining provisions would cause additional regulatory review burden that stakeholders do not already anticipate. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule, excluding the portion of the rule that we are required to issue each year.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $109.36 per hour, including overhead and fringe benefits.[179] Assuming an average reading speed, we estimate that it would take approximately 1 hours for the staff to review the relevant portions

[178] See 78 FR 65045 at 65080.

[179] *https://www.bls.gov/oes/current/oes_nat.htm.*

of this final rule that causes unanticipated burden. We assume that approximately 1,550 entities will review this final rule. For each entity that reviews the rule, the estimated cost is approximately $109.36. Therefore, we estimate that the total cost of reviewing this regulation is approximately $169,508 ($109.36 × 1,550 reviewers).

D. Regulatory Alternatives Considered

In developing the policies contained in this rule, we considered numerous alternatives to the presented proposals. Below we discuss the key regulatory alternatives that we considered.

For the amendment to part 146, we considered not proposing a requirement that a notice be provided to individuals with an offer of an excepted benefit HRA from a non-Federal governmental plan. However, we believe that a notice will provide these consumers with important information about their excepted benefit HRA.

Instead of deleting the regulations in part 149, governing the ERRP, we considered taking no action and leaving the regulations in place. We believe that it serves the public interest to reduce the volume of federal regulations when doing so will not compromise the effectiveness of federal programs, nor detract from the government's ability to implement laws or oversee funds appropriated for that purpose. Since the ERRP has been fully implemented, and has no ongoing functions, costs, or obligations, repealing the regulations will not impair the government's ability to implement the program or oversee the funds appropriated for that purpose.

In finalizing the risk adjustment model recalibration in part 153, we considered whether to add an additional sex and age category for enrollees age 65 and over as part of our recalibration of the HHS models, due to our proposal to stop using MarketScan® data. However, upon finding different trends in the age 65 and over population, as discussed in the preamble, we did not propose to add these additional categories.

In regards to the proposed changes to § 155.320, we considered taking no action to modify the requirement that when an Exchange does not reasonably expect to obtain sufficient verification data related to enrollment in or eligibility for employer sponsored coverage that the Exchange must select a statistically significant random sample of applicants and attempt to verify their attestation with the employer listed on their Exchange application. However, based on HHS's experience conducting sampling, this manual verification process requires significant resources for a low return on investment, as using this method HHS identified only a small population of applicants who received APTC/CSR payments inappropriately. We ultimately determined that a verification process for employer-sponsored coverage should be one that is evidence or risk-based and that not taking enforcement action against Exchanges that do not conduct random sampling was appropriate as we anticipate future rulemaking is necessary to ensure that Exchanges have more flexibility for such verifications.

Regarding the changes to §§ 155.330 and 155.430, we considered taking no action to clarify Exchange operations regarding processing voluntary terminations for Exchange enrollees who provide written consent to permit the Exchange to end QHP coverage if they are later found to also be enrolled in Medicare via PDM. We ultimately determined however that these revisions were necessary to clarify that eligibility need not be redetermined as part of terminations at the request of enrollees resulting from Medicare PDM.

Additionally, we considered taking no action and proceeding with terminating coverage following an eligibility determination when the Exchange conducts periodic checks for deceased enrollees rather than retroactively terminating back to the date of death. However, we determined that the revisions will clarify that eligibility need not be redetermined prior to terminating deceased enrollee coverage retroactively to the date of death.

We considered taking no action regarding the proposal to add a new § 155.420(a)(4)(ii)(B) in order to allow enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP to change to a QHP one metal level higher or lower if they elect to change their QHP enrollment. However, based on questions and concerns from Navigators and other enrollment assisters, as well as from agents and brokers, the current policy likely prevents some enrollees from maintaining continuous coverage for themselves and for their dependents due to a potentially significant change to their out-of-pocket costs. Under the provision, an enrollee impacted by an increase to his or her monthly premium payment may change to a bronze-level plan, while an enrollee who has concerns about higher copayment or coinsurance cost-sharing requirements may change to a gold-level plan. HHS believes that this policy will likely have minimal impact on the individual market risk pool because most applicable enrollees will be seeking to change coverage based on changes to their financial circumstances rather than ongoing or emerging health needs.

We also considered making no changes regarding our proposal to clarify the 2017 Market Stabilization Rule's intent to apply the same limitations to dependents who are currently enrolled in Exchange coverage that it applies to current, non-dependent Exchange enrollees. As discussed in the proposed rule, preamble language from the 2017 Market Stabilization Proposed Rule explains that the requirement at § 155.420(a)(4)(iii) would extend to enrollees who are on an application where a new applicant is enrolling in coverage through a special enrollment period, using general terms to convey that restrictions should apply to enrollees and newly-enrolling individuals regardless of the dependent or parent or guardian status of a new enrollee. However, because this intended aspect of the limitation is not articulated in regulation, we were concerned that the rule's current wording would cause confusion among issuers, consumers, and Exchanges. Additionally, this change is consistent with HHS's goal to establish equivalent treatment for all special enrollment period eligible enrollees, and with the policy goal of preventing enrollees from changing plans in the middle of the coverage year based on ongoing or newly emerging health issues.

In proposing and finalizing that special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection in Exchanges using the Federal platform, we considered whether we could implement this change through subregulatory guidance, since for many of these special enrollment periods, Exchanges have discretion under § 155.420(b)(2)(i), (iv), and (v) to provide an effective date on the first of the month following plan selection, or under § 155.420(b)(3) to ensure that coverage is effective on an appropriate date based on the circumstances of the special enrollment period. However, Exchange discretion is not available under current regulations for several special enrollment periods that use regular effective dates; that is, HHS could not apply faster effective dates in the Exchanges using the Federal platform without regulatory changes for certain special enrollment periods. These are the special enrollment periods available under § 155.420(d)(6)(i), (ii), and (v); (d)(8); and (d)(10). Only applying faster effective dates for some, but not all, special enrollment periods that currently use regular effective date rules would not accomplish our goals of

standardization and improving long-term operational efficiency. We believe this regulatory change is necessary to align all prospective special enrollment periods under one effective date rule.

In proposing and finalizing aligning retroactive effective date and binder payment rules under § 155.400(e)(1)(iii), we considered eliminating both § 155.400(e)(1)(v) (as we proposed), but revising, rather than eliminating, § 155.420(b)(5). Previously, section 155.420(b)(5) provided that if a consumer's enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, and the assigned effective date would require the consumer to pay 2 or more months of retroactive premium to effectuate coverage or avoid cancellation, the consumer has the option to choose a coverage effective date that is no more than 1 month later than had previously been assigned. However, we determined that revising this provision would cause more confusion than standardizing retroactive effective date and binder payment rules under § 155.400(e)(1)(iii). Instead, we are finalizing the proposed amendment to § 155.400(e)(1)(iii) to state more explicitly that any consumer who can effectuate coverage with a retroactive effective date, including those whose enrollment is delayed until after special enrollment period verification, would also have the option to effectuate coverage with the applicable prospective coverage.

Through this change, a consumer can choose to only pay for 1 month of coverage by the applicable deadline, notwithstanding the retroactive effective date that the Exchange otherwise would be required to ensure. Even though very few consumers wait more than a few days for HHS to review their special enrollment period verification documents and provide a response (as discussed in the preamble of the proposed rule), we want to ensure that those few consumers whose coverage is delayed by at least 1 month due to special enrollment period verification would have the same options as any other consumers who are eligible to receive coverage with a retroactive effective date.

As described in the HRA rule,[180] HHS included consumers who are newly provided a QSEHRA in the class of persons eligible for a new special enrollment period established for qualified individuals, enrollees, and dependents who newly gain access to an individual coverage HRA. We also expressed our intent to treat a QSEHRA with a non-calendar year plan year as a group health plan for the limited purpose of the non-calendar year plan year special enrollment period, and to codify this interpretation in future rulemaking. Our goal is to ensure employees and their dependents with a non-calendar year plan year QSEHRA have the same opportunity to change individual health insurance coverage outside of the individual market open enrollment period as those who are enrolled in a non-calendar year plan year individual coverage HRA.

In finalizing the annual reporting of state-required benefits in addition to EHB, we considered a variety of alternatives, including withdrawing the proposal altogether. We also considered instead issuing a toolkit or guidance for states to assist with identifying state-required benefits in addition to EHB and properly defraying the cost of those benefits in accordance with § 155.170. However, we do not believe that either of these options would alone offer HHS direct insight into the frequency with which states require benefits in addition to EHB to be covered and whether states are properly defraying the costs of state-required benefits in addition to EHB. Therefore, we are finalizing the annual reporting policy as proposed, except for a minor revision at § 156.111(d)(2). However, to address comments regarding the lack of clarity around the current defrayal policy, we will also take steps to engage with states to clarify this policy before the first annual submission deadline. Through this state engagement, we hope to provide additional technical assistance that helps ensure state understanding when a state-benefit requirement is in addition to EHB and requires defrayal, provides examples, and explains how a state could operationalize the defrayal process pursuant to federal requirements at § 155.170. We believe additional outreach to states prior to the first annual reporting submission deadline of July 1, 2021, will strengthen state understanding of defrayal policy ahead of the first year of implementation of the annual reporting requirement in plan year 2021.

We also considered revising the policy such that Exchanges would again be the entity responsible for identifying which additional state-required benefits, if any, are in addition to EHB instead of the state. However, as noted previously in the 2017 Payment Notice, we changed the policy to make the state the entity responsible for identifying state-required benefits in addition to EHB instead of the Exchange because we believe states are generally more familiar with state-required benefits. We also considered revising § 155.170 to make HHS the entity responsible for identifying which state-required benefits are in addition to EHB in every state such that HHS would always identify which mandates require defrayal, but the QHP issuers would still be responsible for quantifying the costs for these additional mandates and reporting them to the state, at which point the state would be expected to make payments directly to the enrollee or the QHP issuer. However, because we still believe states are generally most familiar with state-required benefits and, because we support state flexibility, we believe that states should remain the entity responsible for identifying state-required benefits in addition to EHB. We believe the annual reporting policy we are finalizing is consistent with this goal of state flexibility and acknowledges state expertise, as it would not shift the authority from the state to HHS as the entity responsible for identifying whether a mandate is in addition to EHB unless the state does not submit an annual report to HHS or does not do so in the form and manner specified by HHS, in which case only then would HHS identify which state-required benefits are in addition to EHB for the state.

In proposing and finalizing amendments to § 156.270(b)(1) to require QHP issuers to send to enrollees a termination notice for all termination events, we considered whether to revert to the original language in the first iteration of § 156.270, which required a termination notice when an enrollee's coverage was terminated ''for any reason.'' However, because the termination notice requirement is triggered under this paragraph ''[i]f a QHP issuer terminates an enrollee's coverage or enrollment in a QHP through the Exchange . . . ,'' we were concerned that this could be read to require termination notices for issuer-initiated terminations only. To be clear that we are proposing to require termination notices for the full range of termination events described under § 155.430(b), including those initiated by an enrollee, our amendments instead refer broadly to the reasons listed in § 155.430(b) rather than identifying each termination reason under that section.

For the amendments to § 158.150, we considered making no change to the current regulation that does not explicitly allow issuers in the individual market to include the cost of certain wellness incentives as QIA in the MLR calculation. However, we believe that finalizing the changes to this section will ensure that it is

[180] 84 FR 28888.

interpreted consistently across the individual and group markets. We also believe that finalizing the changes to this section will generally increase consumer choice and access to wellness programs, including any health-contingent wellness programs that may be available in a state that is approved to participate in the wellness program demonstration project.

E. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), (5 U.S.C. 601, *et seq.*), requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule will not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as (1) a proprietary firm meeting the size standards of the Small Business Administration (SBA), (2) a not-for-profit organization that is not dominant in its field, or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity''. HHS uses a change in revenues of more than 3 to 5 percent as its measure of significant economic impact on a substantial number of small entities.

In this rule, we finalize standards for the risk adjustment and RADV programs, which are intended to stabilize premiums and reduce incentives for issuers to avoid higher-risk enrollees. Because we believe that insurance firms offering comprehensive health insurance policies generally exceed the size thresholds for ''small entities'' established by the SBA, we do not believe that an initial regulatory flexibility analysis is required for such firms.

We believe that health insurance issuers and group health plans would be classified under the North American Industry Classification System code 524114 (Direct Health and Medical Insurance Carriers). According to SBA size standards, entities with average annual receipts of $41.5 million or less would be considered small entities for these North American Industry Classification System codes. Issuers could possibly be classified in 621491 (HMO Medical Centers) and, if this is the case, the SBA size standard would be $35 million or less.[181] We believe that few, if any, insurance companies underwriting comprehensive health insurance policies (in contrast, for example, to travel insurance policies or dental discount policies) fall below these size thresholds. Based on data from MLR annual report [182] submissions for the 2017 MLR reporting year, approximately 90 out of 500 issuers of health insurance coverage nationwide had total premium revenue of $41.5 million or less. This estimate may overstate the actual number of small health insurance companies that may be affected, since over 72 percent of these small companies belong to larger holding groups, and many, if not all, of these small companies are likely to have non-health lines of business that will result in their revenues exceeding $41.5 million. Only 10 of these 90 potentially small entities, three of them part of larger holding groups, are estimated to experience a change in rebates under the amendments to the MLR provisions of this final rule in part 158. Therefore, we believe that the MLR provisions of this final rule will not affect a substantial number of small entities.

We believe that a small number of non-Federal government jurisdictions with a population of less than 50,000 will offer employees an excepted benefit HRA, and therefore, will be subject to the proposed notice requirement in part 146. Therefore, we do not believe that an initial regulatory flexibility analysis is required for such firms.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis 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 604 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 and has fewer than 100 beds. This rule will not affect small rural hospitals. Therefore, the Secretary has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a proposed rule that includes any Federal mandate that may result in expenditures in any 1 year by a state, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. In 2020, that threshold is approximately $156 million. Although we have not been able to quantify all costs, we expect the combined impact on state, local, or Tribal governments and the private sector to be below the threshold.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a final rule that imposes substantial direct costs on state and local governments, preempts state law, or otherwise has federalism implications.

In compliance with the requirement of Executive Order 13132 that agencies examine closely any policies that may have federalism implications or limit the policy making discretion of the states, we have engaged in efforts to consult with and work cooperatively with affected states, including participating in conference calls with and attending conferences of the NAIC, and consulting with state insurance officials on an individual basis.

While developing this rule, we attempted to balance the states' interests in regulating health insurance issuers with the need to ensure market stability. By doing so, we complied with the requirements of Executive Order 13132.

Because states have flexibility in designing their Exchange and Exchange-related programs, state decisions will ultimately influence both administrative expenses and overall premiums. States are not required to establish an Exchange or risk adjustment program. For states that elected previously to operate an Exchange, those states had the opportunity to use funds under Exchange Planning and Establishment Grants to fund the development of data. Accordingly, some of the initial cost of creating programs was funded by Exchange Planning and Establishment Grants. After establishment, Exchanges must be financially self-sustaining, with revenue sources at the discretion of the state. Current State Exchanges charge user fees to issuers.

In our view, while this final rule will not impose substantial direct requirements or costs on state and local governments, this regulation has federalism implications due to potential direct effects on the distribution of power and responsibilities among the state and Federal governments relating to determining standards relating to health insurance that is offered in the individual and small group markets. We are also requiring non-Federal governmental plan sponsors to provide a notice when offering an excepted benefit HRA, but expect state and local governments to incur minimal costs to meet the requirements in this rule.

[181] *https://www.sba.gov/document/support--table-size-standards.*

[182] Available at *https://www.cms.gov/CCIIO/Resources/Data-Resources/mlr.html.*

We also believe this regulation has federalism implications for the PDM process provisions, specifically for QHP terminations resulting from Medicare, Medicaid/CHIP, BHP (if applicable) or deceased enrollee PDM. In these instances, HHS also believes that the federalism implications are substantially mitigated because the requirements merely clarify that the Exchange is following termination guidelines that differ from the processes when Exchanges are terminating only APTC/CSRs as part of the standard PDM processes. Furthermore, these clarifications will not impose new requirements on State Exchanges that operate their own eligibility and enrollment platform, but rather provide guidance that State Exchanges that operate their own eligibility and enrollment platform can choose to incorporate into their current operations for PDM.

We believe there may be federalism implications in connection with our provisions related to plan category limitations: (1) We added a new § 155.420(a)(4)(ii)(B) in order to allow enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP, to select a QHP one metal level higher or lower if they elect to change their QHP enrollment; and (2) we added a new § 155.420(a)(4)(iii)(C) to apply the same limitations to dependents who are currently enrolled in Exchange coverage that it applies to current, non-dependent Exchange enrollees. There may be operational costs to State Exchanges that have already implemented plan category limitations due to the need to update their application logic to reflect these changes. However, given the 2017 Market Stabilization Rule preamble language discussed above, it is possible that State Exchanges are already in compliance with our proposal to clarify the application of the same limitations to dependents who are currently enrolled in Exchange coverage that apply to current, non-dependent Exchange enrollees. We solicited comment on how many State Exchanges currently implement plan category limitations, as well as estimates related to how much time and expense would be required to update these systems to comply with the two proposals.

Comment: We did not receive comments describing State Exchanges' implementation of plan category limitations, or comments that included estimates of time and expense that this proposal would require. However, several commenters expressed support for providing State Exchanges with flexibility related to special enrollment period policy implementation in general, explaining that any special enrollment period changes require significant State Exchange effort and potentially unpredictable costs.

Response: Given most commenters' support for allowing enrollees and their dependents who become newly ineligible for CSRs and are enrolled in a silver-level QHP, to select a QHP one metal level higher or lower if they elect to change their QHP enrollment, we believe that the benefits of finalizing it as proposed outweigh general concerns about implementation. Additionally, we have delayed the effective date for this modification to January 2022, which we believe will allow Exchanges sufficient time to incorporate the change into their development priorities. We also believe that the benefit of simplifying plan category limitation rules and ensuring that these rules work as intended by applying the same limitations to enrolled dependents that apply to non-dependents will outweigh costs associated with implementation.

Additionally, we expect that amendment to § 155.420(d)(1)(ii) to codify the special enrollment period for qualified individuals and dependents who are provided a QSEHRA with a non-calendar year plan year will have some federalism implications, because it will require State Exchanges to update the wording of their applications, and to update instructions for verifying a special enrollment period due to a loss of MEC to include applicants with a non-calendar year plan year QSEHRA. Additionally, State Exchanges, as well as FFE Direct Enrollment and Enhanced Direct Enrollment partners, may see a nominal increase in the number of consumers obtaining coverage through the non-calendar year plan year special enrollment period at § 155.420(d)(1)(ii). However, we expect this number to be low.

We do not anticipate any federalism implications related to our revision providing that special enrollment periods currently following regular effective date rules would instead be effective on the first of the month following plan selection in the Exchanges using the Federal platform. We believe State Exchanges are best positioned to determine which effective date rules meet the needs of their issuers and consumers. As such, under our changes, State Exchanges may retain their current effective date rules or implement faster ones without needing to demonstrate issuer concurrence.

We do not expect there to be federalism implications related to removing the separate retroactive effective date rule for enrollments pended due to special enrollment period verification under § 155.420(b)(5). Neither the retroactive binder payment rule specific to enrollments pended due to special enrollment period eligibility verification at § 155.400(e)(1)(v), nor the original retroactive binder payment rule at § 155.400(e)(1)(iii), applies outside of Exchanges using the Federal platform. Although previous § 155.420(b)(5) did apply to State Exchanges, a State Exchange that has implemented special enrollment period verification will retain flexibility to apply the policy that if a consumer's enrollment is delayed until after the verification of the consumer's eligibility for a special enrollment period, and the assigned effective date would require the consumer to pay 2 or more months of retroactive premium to effectuate coverage or avoid cancellation, the consumer has the option to choose a coverage effective date that is no more than 1 month later than had previously been assigned.

We do not anticipate any federalism implications related to our requirement for QHP issuers to send to enrollees a termination notice for all termination events described in § 155.430(b).

We do not anticipate any federalism implications related to our provision described in § 155.430(d) to align the provision for termination after experiencing a technical error that did not allow the enrollee to terminate his or her coverage or enrollment through the Exchange with all other enrollee-initiated termination effective date rules under § 155.430 that, at the option of the Exchange, no longer require 14-days advance notice.

We continue to believe there may be federalism implications related to the requirement we are finalizing that states annually report to HHS, in a form and manner specified by HHS, any state-required benefits in addition to EHB in accordance with § 155.170 that are applicable to QHPs in the individual and/or small group market. States that do not report to HHS their required benefits considered to be in addition to EHB by the annual reporting submission deadline, or do not do so in the form and manner specified by HHS, will be relying on HHS to identify such benefits. We acknowledge that the state-required benefits HHS identifies as in addition to EHB and that therefore require defrayal, might conflict with the opinion of a state that does not annually report to HHS. However, such concerns are mitigated because states can avoid such a result by submitting the report. Further, as previously noted, HHS must ensure that APTC is paid in accordance

with federal law. If a state is not defraying the cost of a state-required benefit that is in addition to EHB, resulting in improper federal expenditures, we believe section 1313(a)(4) of the PPACA empowers HHS to take action consistent with its enforcement authorities to address a state's failure to comply with the PPACA's defrayal requirements. However, as also noted earlier in the preamble, we intend to continue the collaborative process we have cultivated with states up to this point, and to provide non-reporting states with an opportunity to review our identifications prior to releasing the annual reports on the CMS website for public viewing in an effort to mitigate the potential for disagreement between the state and HHS.

H. Congressional Review Act

This rule is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801, *et seq.*), which specifies that before a rule can take effect, the Federal agency promulgating the rule shall submit to each House of the Congress and to the Comptroller General a report containing a copy of the rule along with other specified information. Therefore, the rule has been transmitted to the Congress and the Comptroller. Pursuant to the Congressional Review Act, the Office of Information and Regulatory Affairs designated this final rule as a ''major rule'' as that term is defined in 5 U.S.C. 804(2), because it is likely to result in an annual effect on the economy of $100 million or more.

I. Reducing Regulation and Controlling Regulatory Costs

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017. Section 2(a) of Executive Order 13771 requires an agency, unless prohibited by law, to identify at least two existing regulations to be repealed when the agency publicly proposes for notice and comment, or otherwise issues, a new regulation. In furtherance of this requirement, section 2(c) of Executive Order 13771 requires that the incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations.

This final rule is an E.O. 13771 deregulatory action. We estimate cost savings of approximately $147.15 million in 2020 and $98.89 million in 2021 and annual costs of approximately $59,000 thereafter. Thus the annualized value of cost savings, as of 2016 and calculated over a perpetual time horizon with a 7 percent discount rate, is $11.40 million.

List of Subjects

45 CFR Part 146

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 149

Health care, Health insurance, Reporting and recordkeeping requirements.

45 CFR Part 155

Administrative practice and procedure, Advertising, Brokers, Conflict of interests, Consumer protection, Grants administration, Grant programs—health, Health care, Health insurance, Health maintenance organizations (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Intergovernmental relations, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, Technical assistance, Women and youth.

45 CFR Part 156

Administrative practice and procedure, Advertising, Advisory committees, Conflict of interests, Consumer protection, Grant programs—health, Grants administration, Health care, Health insurance, Health maintenance organization (HMO), Health records, Hospitals, Indians, Individuals with disabilities, Loan programs—health, Medicaid, Organization and functions (Government agencies), Public assistance programs, Reporting and recordkeeping requirements, State and local governments, Sunshine Act, Technical assistance, Women, Youth.

45 CFR Part 158

Administrative practice and procedure, Claims, Health care, Health insurance, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, under the authority at 5 U.S.C. 301, the Department of Health and Human Services amends 45 CFR subtitle A, subchapter B, as set forth below.

PART 146—REQUIREMENTS FOR THE GROUP HEALTH INSURANCE MARKET

■ 1. The authority citation for part 146 continues to read as follows:

Authority: 42 U.S.C. 300gg–1 through 300gg–5, 300gg–11 through 300gg–23, 300gg–91, and 300–gg–92.

■ 2. Section 146.145 is amended by adding paragraph (b)(3)(viii)(E) to read as follows:

§ 146.145 Special rules relating to group health plans.

* * * * *

(b) * * *

(3) * * *

(viii) * * *

(E) *Notice requirement.* For plan years beginning on or after January 11, 2021, the HRA or other account-based group health plan must provide a notice that describes conditions pertaining to eligibility to receive benefits, annual or lifetime caps, or other limits on benefits under the plan, and a description or summary of the benefits. This notice must be provided no later than 90 days after an employee becomes a participant and annually thereafter, in a manner reasonably calculated to ensure actual receipt by participants eligible for the HRA or other account-based group health plan.

* * * * *

PART 149—[REMOVED and RESERVED]

■ 3. Part 149 is removed and reserved.

PART 155—EXCHANGE ESTABLISHMENT STANDARDS AND OTHER RELATED STANDARDS UNDER THE AFFORDABLE CARE ACT

■ 4. 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.

■ 5. Section 155.330 is amended by revising paragraph (e)(2)(i)(D) to read as follows:

§ 155.330 Eligibility redetermination during a benefit year.

* * * * *

(e) * * *

(2) * * *

(i) * * *

(D) If the enrollee does not respond contesting the updated information within the 30-day period specified in paragraph (e)(2)(i)(B) of this section, proceed in accordance with paragraphs (e)(1)(i) and (ii) of this section, provided the enrollee has not directed the Exchange to terminate his or her coverage under such circumstances, in which case the Exchange will terminate the enrollee's coverage in accordance with § 155.430(b)(1)(ii), and provided the enrollee has not been determined to

be deceased, in which case the Exchange will terminate the enrollee's coverage in accordance with § 155.430(d)(7).

* * * * *

■ 6. Section 155.400 is amended by revising paragraphs (e)(1)(i) through (iii) and removing paragraph (e)(1)(iv) to read as follows:

§ 155.400 Enrollment of qualified individuals into QHPs.

* * * * *

(e) * * *

(1) * * *

(i) For prospective coverage to be effectuated under regular coverage effective dates, as provided for in § 155.410(f), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date, and no later than 30 calendar days from the coverage effective date.

(ii) For prospective coverage to be effectuated under special effective dates, as provided for in § 155.420(b)(2) and (3), the binder payment must consist of the first month's premium, and the deadline for making the binder payment must be no earlier than the coverage effective date and no later than 30 calendar days from the date the issuer receives the enrollment transaction or the coverage effective date, whichever is later.

(iii) For coverage to be effectuated under retroactive effective dates, as provided for in § 155.420(b)(2), including when retroactive effective dates are due to a delay until after special enrollment period verification, the binder payment must consist of the premium due for all months of retroactive coverage through the first prospective month of coverage, and the deadline for making the binder payment must be no earlier than 30 calendar days from the date the issuer receives the enrollment transaction. If only the premium for 1 month of coverage is paid, only prospective coverage should be effectuated, in accordance with § 155.420(b)(3).

* * * * *

■ 7. Section 155.420 is amended by—

■ a. Revising paragraphs (a)(4)(ii) and (iii), (b)(1) introductory text, and (b)(3);

■ b. Removing paragraph (b)(5); and

■ c. Revising paragraph (d)(1)(ii).

The revisions and addition read as follows:

§ 155.420 Special enrollment periods.

(a) * * *

(4) * * *

(ii)(A) If an enrollee and his or her dependents become newly eligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are not enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a silver-level QHP if they elect to change their QHP enrollment; or

(B) Beginning January 2022, if an enrollee and his or her dependents become newly ineligible for cost-sharing reductions in accordance with paragraph (d)(6)(i) or (ii) of this section and are enrolled in a silver-level QHP, the Exchange must allow the enrollee and his or her dependents to change to a QHP one metal level higher or lower, if they elect to change their QHP enrollment.

(iii) For the other triggering events specified in paragraph (d) of this section, except for paragraphs (d)(2)(i), (d)(4), and (d)(6)(i) and (ii) of this section for becoming newly eligible or ineligible for CSRs and paragraphs (d)(8), (9), (10), (12), and (14) of this section:

(A) If an enrollee qualifies for a special enrollment period, the Exchange must allow the enrollee and his or her dependents, if applicable, to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter;

(B) If a dependent qualifies for a special enrollment period, and an enrollee who does not also qualify for a special enrollment period is adding the dependent to his or her QHP, the Exchange must allow the enrollee to add the dependent to his or her current QHP; or, if the QHP's business rules do not allow the dependent to enroll, the Exchange must allow the enrollee and his or her dependents to change to another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter, or enroll the new qualified individual in a separate QHP; or

(C) If a qualified individual who is not an enrollee qualifies for a special enrollment period and has one or more dependents who are enrollees who do not also qualify for a special enrollment period, the Exchange must allow the newly enrolling qualified individual to add himself or herself to a dependent's current QHP; or, if the QHP's business rules do not allow the qualified individual to enroll in the dependent's current QHP, to enroll with his or her dependent(s) in another QHP within the same level of coverage (or one metal level higher or lower, if no such QHP is available), as outlined in § 156.140(b) of this subchapter, or enroll himself or herself in a separate QHP.

* * * * *

(b) * * *

(1) *Regular effective dates.* Except as specified in paragraphs (b)(2) and (3) of this section, for a QHP selection received by the Exchange from a qualified individual—

* * * * *

(3) *Option for earlier effective dates.* (i) For a QHP selection received by the Exchange under a special enrollment period for which regular effective dates specified in paragraph (b)(1) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph, and, beginning January 2022, a Federally-facilitated Exchange or a State Exchange on the Federal platform will ensure that coverage is effective on the first day of the month following plan selection.

(ii) For a QHP selection received by the Exchange under a special enrollment period for which special effective dates specified in paragraph (b)(2)(ii) of this section would apply, the Exchange may provide a coverage effective date that is earlier than specified in such paragraph.

* * * * *

(d) * * *

(1) * * *

(ii) Is enrolled in any non-calendar year group health plan, individual health insurance coverage, or qualified small employer health reimbursement arrangement (as defined in section 9831(d)(2) of the Internal Revenue Code); even if the qualified individual or his or her dependent has the option to renew or re-enroll in such coverage. The date of the loss of coverage is the last day of the plan year;

* * * * *

■ 8. Section 155.430 is amended by revising paragraphs (b)(1)(ii) and (d)(9) to read as follows:

§ 155.430 Termination of Exchange enrollment or coverage.

* * * * *

(b) * * *

(1) * * *

(ii) The Exchange must provide an opportunity at the time of plan selection for an enrollee to choose to remain enrolled in a QHP if he or she becomes eligible for other minimum essential coverage and the enrollee does not request termination in accordance with paragraph (b)(1)(i) of this section. If an enrollee does not choose to remain enrolled in a QHP in such situation, the Exchange must initiate termination of his or her enrollment in the QHP upon

completion of the process specified in § 155.330(e)(2).

* * * * *

(d) * * *

(9) In case of a retroactive termination in accordance with paragraph (b)(1)(iv)(A) of this section, the termination date will be no sooner than the date that would have applied under paragraph (d)(2) of this section, based on the date that the enrollee can demonstrate he or she contacted the Exchange to terminate his or her coverage or enrollment through the Exchange, had the technical error not occurred.

* * * * *

■ 9. Section 155.1400 is revised to read as follows:

§ 155.1400 Quality rating system.

The Exchange must prominently display quality rating information for each QHP on its website, in accordance with § 155.205(b)(1)(v), in a form and manner specified by HHS.

■ 10. Section 155.1405 is revised to read as follows:

§ 155.1405 Enrollee satisfaction survey system.

The Exchange must prominently display results from the Enrollee Satisfaction Survey for each QHP on its website, in accordance with § 155.205(b)(1)(iv), in a form and manner specified by HHS.

PART 156—HEALTH INSURANCE ISSUER STANDARDS UNDER THE AFFORDABLE CARE ACT, INCLUDING STANDARDS RELATED TO EXCHANGES

■ 11. The authority citation for part 156 is revised to read as follows:

Authority: 42 U.S.C. 18021–18024, 18031–18032, 18041–18042, 18044, 18054, 18061, 18063, 18071, 18082, and 26 U.S.C. 36B.

§ 156.20 [Amended]

■ 12. Section 156.20 is amended by removing the definition of ''Generic''.

■ 13. Section 156.111 is amended by—

■ a. Revising the section heading and paragraph (d) introductory text; and

■ b. Adding paragraphs (d)(2) and (f).

The revisions and additions read as follows:

§ 156.111 State selection of EHB-benchmark plan for plan years beginning on or after January 1, 2020, and annual reporting of state-required benefits.

* * * * *

(d) A State must notify HHS of the selection of a new EHB-benchmark plan by a date to be determined by HHS for each applicable plan year and, in accordance with paragraph (f) of this section, of any State-required benefits that are in addition to EHB identified under § 155.170(a)(3) of this subchapter.

* * * * *

(2) If the State does not notify HHS of its State-required benefits that are in addition to EHB identified under § 155.170(a)(3) of this subchapter in accordance with paragraph (f) of this section, HHS will identify which benefits are in addition to EHB for the applicable plan year in the State, consistent with § 155.170(a)(2) of this subchapter.

* * * * *

(f) A State must submit to HHS in a form and manner and by a date specified by HHS, a document that:

(1) Is accurate as of the day that is at least 60 days prior to the annual reporting submission deadline set by HHS and that lists all State benefit requirements applicable to QHPs in the individual and/or small group market under state mandates imposed on or before December 31, 2011, and that were not withdrawn or otherwise no longer effective before December 31, 2011, and any State benefit requirements that were imposed any time after December 31, 2011;

(2) Specifies which of those State-required benefits listed in accordance with paragraph (f)(1) of this section the State has identified as in addition to EHB and subject to defrayal in accordance with § 155.170 of this subchapter;

(3) Specifies which of those State-required benefits listed in accordance with paragraph (f)(1) of this section the State has identified as not in addition to EHB and not subject to defrayal in accordance with § 155.170 of this subchapter, and describes the basis for the state's determination;

(4) Provides other information about those State-required benefits listed in accordance with paragraph (f)(1) of this section that is necessary for HHS oversight, as specified by HHS;

(5) Is signed by a state official with authority to make the submission on behalf of the state certifying the accuracy of the submission; and

(6) Is updated annually, in a form and manner and by a date specified by HHS, to include any new State benefit requirements, and to indicate whether benefit requirements previously reported to HHS under this paragraph (f) have been amended, repealed, or otherwise affected by state regulatory or legislative action.

■ 14. Section 156.130 is amended by revising paragraph (h) to read as follows:

§ 156.130 Cost-sharing requirements.

* * * * *

(h) *Use of direct support offered by drug manufacturers.* Notwithstanding any other provision of this section, and to the extent consistent with State law, amounts paid toward reducing the cost sharing incurred by an enrollee using any form of direct support offered by drug manufacturers for specific prescription drugs may be, but are not required to be, counted toward the annual limitation on cost sharing, as defined in paragraph (a) of this section.

■ 15. Section 156.265 is amended by revising paragraphs (f) and (g) to read as follows:

§ 156.265 Enrollment process for qualified individuals.

* * * * *

(f) *Enrollment reconciliation.* A QHP issuer must reconcile enrollment files with the Exchange in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) and resolve assigned updates no less than once a month in accordance with § 155.400(d) of this subchapter, using the most recent enrollment information that is available and that has been verified to the best of the issuer's knowledge or belief.

(g) *Timely updates to enrollment records.* A QHP issuer offering plans through an Exchange must, in a format specified by the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), either:

(1) Verify to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) that the information in the enrollment reconciliation file received from the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) accurately reflects its enrollment data for the applicable benefit year in its next enrollment reconciliation file submission to the Exchange (or, for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform), and update its internal enrollment records accordingly; or

(2) Describe to the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform) within one reconciliation cycle any discrepancy it identifies in the enrollment reconciliation files it received from the Exchange (or for QHP issuers in State Exchanges on the Federal Platform, the Federal Platform).

■ 16. Section 156.270 is amended by revising paragraph (b) introductory text to read as follows:

§ 156.270 Termination of coverage or enrollment for qualified individuals.

* * * * *

(b) *Termination of coverage or enrollment notice requirement.* If a QHP issuer terminates an enrollee's coverage or enrollment in a QHP through the Exchange in accordance with § 155.430(b) of this subchapter, the QHP issuer must, promptly and without undue delay:

* * * * *

■ 17. Section 156.1210 is revised to read as follows:

§ 156.1210 Dispute Submission.

(a) *Responses to reports.* Within 90 calendar days of the date of a payment and collections report from HHS, the issuer must, in a form and manner specified by HHS describe to HHS any inaccuracies it identifies in the report.

(b) *Confirmation of HHS payment and collections reports.* At the end of each payment year, the issuer must, in a form and manner specified by HHS, confirm to HHS that the amounts identified in the most recent payment and collections report for the coverage year accurately reflect applicable payments owed by the issuer to the Federal Government and the payments owed to the issuer by the Federal Government, or that the issuer has disputed any identified inaccuracies.

PART 158—ISSUER USE OF PREMIUM REVENUE: REPORTING AND REBATE REQUIREMENTS

■ 18. The authority citation for part 158 is revised to read as follows:

Authority: 42 U.S.C. 300gg–18.

■ 19. Section 158.110 is amended by revising paragraph (a) to read as follows:

§ 158.110 Reporting requirements related to premiums and expenditures.

(a) *General requirements.* For each MLR reporting year, an issuer must submit to the Secretary a report which complies with the requirements of this part, concerning premium revenue and expenses related to the group and individual health insurance coverage that it issued. Reporting requirements of this part that apply to expenses incurred directly by the issuer also apply to expenses for functions outsourced to or services provided by other entities retained by the issuer.

* * * * *

■ 20. Section 158.140 is amended by revising paragraph (b)(1)(i) to read as follows:

§ 158.140 Reimbursement for clinical services provided to enrollees.

* * * * *

(b) * * *

(1) * * *

(i)(A) For MLR reporting years before 2022, prescription drug rebates received by the issuer;

(B) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions received and retained by the issuer, and prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

* * * * *

■ 21. Section 158.150 is amended by revising paragraph (b)(2)(iv)(A)(*5*) to read as follows:

§ 158.150 Activities that improve health care quality.

* * * * *

(b) * * *

(2) * * *

(iv) * * *

(A) * * *

(*5*)(*i*) For MLR reporting years before 2021, actual rewards, incentives, bonuses, and reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims should be allowed as a quality improvement activity for the group market to the extent permitted by section 2705 of the PHS Act;

(*ii*) Beginning with the 2021 MLR reporting year, actual rewards, incentives, bonuses, reductions in copayments (excluding administration of such programs) that are not already reflected in premiums or claims, to the extent permitted by section 2705 of the PHS Act;

* * * * *

■ 22. Section 158.160 is amended by adding paragraph (b)(2)(vii) to read as follows:

§ 158.160 Other non-claims costs.

* * * * *

(b) * * *

(2) * * *

(vii) Beginning with the 2022 MLR reporting year, prescription drug rebates and other price concessions that are received and retained by an entity providing pharmacy benefit management services to the issuer and are associated with administering the issuer's prescription drug benefits.

Dated: April 27, 2020.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

Dated: April 28, 2020.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

[FR Doc. 2020–10045 Filed 5–7–20; 4:15 pm]

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Part IV

Department of Homeland Security

8 CFR Parts 103, 208, 209, et al.

Implementation of the Northern Mariana Islands U.S. Workforce Act of 2018; Interim Final Rule

DEPARTMENT OF HOMELAND SECURITY

8 CFR Parts 103, 208, 209, 212, 214, 235, and 274a

[CIS No. 2630–18; DHS Docket No. USCIS–2019–0003]

RIN 1615–AC28

Implementation of the Northern Mariana Islands U.S. Workforce Act of 2018

AGENCY: U.S. Citizenship and Immigration Services, DHS.

ACTION: Interim final rule with request for comments.

SUMMARY: The Department of Homeland Security (DHS) is amending its regulations to implement provisions of the Northern Mariana Islands U.S. Workforce Act of 2018 (Workforce Act), which creates requirements to encourage the hiring of United States workers in the Commonwealth of the Northern Mariana Islands (CNMI) and to ensure that no U.S. worker is placed at a competitive disadvantage for employment compared to a non-U.S. worker or is displaced by a non-U.S. worker.

DATES:

Effective date: This rule is effective June 18, 2020.

Comment date: Written comments and related material must be submitted on or before July 13, 2020. Comments on the form, form instructions, and information collection revisions in this interim rule must be submitted on or before June 15, 2020.

ADDRESSES: You must submit comments, identified as DHS Docket No. USCIS–2019–0003, through *one* of the following methods:

· *Federal eRulemaking Portal* (preferred): *http://www.regulations.gov*. Follow the website instructions for submitting comments.

· *Mail:* Samantha Deshommes, Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW, Washington, DC 20529–2140. To ensure proper handling, please reference DHS Docket No. USCIS–2019–0003 in your correspondence. Mail must be postmarked by the comment submission deadline.

Comments submitted in a manner other than those listed above, including emails or letters sent to DHS or USCIS officials, will not be considered comments on the interim final rule. Please note that DHS and USCIS cannot accept any comments that are hand delivered or couriered. In addition, USCIS cannot accept mailed comments contained on any form of digital media storage devices, such as CDs/DVDs and USB drives.

FOR FURTHER INFORMATION CONTACT: Michael Graham, Adjudications (Policy) Officer, Office of Policy and Strategy, U.S. Citizenship and Immigration Services (USCIS), DHS, 20 Massachusetts Avenue NW, Washington, DC 20529–2140; telephone 202–272–8377 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: This supplementary information section is organized as follows:

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I. Public Participation

DHS invites all interested parties to participate in this rulemaking by submitting written data, views, comments, and arguments on all aspects of this interim final rule. DHS also invites comments that relate to the economic, environmental, or federalism effects that might result from this interim final rule. Comments must be submitted in English, or an English translation must be provided. Comments that will provide the most assistance to DHS in implementing these changes will reference a specific portion of the interim rule, explain the reason for any recommended change, and include data, information, or authority that support such recommended change.

Instructions: If you submit a comment, you must include the agency name (U.S. Citizenship and Immigration Services) and the DHS Docket No. USCIS–2019–0003 for this rulemaking. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary public comment submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy and Security Notice available at *http://www.regulations.gov*.

Docket: For access to the docket and to read background documents or comments received, go to *http://www.regulations.gov,* referencing DHS Docket No. USCIS–2019–0003. You may also sign up for email alerts on the online docket to be notified when comments are posted or a final rule is published.

II. Executive Summary

A. Purpose of the Regulatory Action

The Commonwealth of the Northern Mariana Islands (CNMI)-Only Transitional Worker (CW–1) program allows employers within the CNMI to apply for permission to employ nonimmigrant workers who are otherwise ineligible to work in the CNMI under other nonimmigrant

worker categories. *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification, 76 FR 55502 (Sept. 7, 2011). This transitional worker program was intended to provide for an orderly transition for those workers from the CNMI permit system to the U.S. federal immigration system under the Immigration and Nationality Act (INA), and to mitigate potential harm to the CNMI economy as employers adjust their hiring practices and as foreign workers obtain U.S. immigrant or nonimmigrant status.

On July 24, 2018, President Donald J. Trump signed the Northern Mariana Islands U.S. Workforce Act of 2018 (the Workforce Act), Public Law 115–218, 132 Stat. 1547. The stated purposes of the Workforce Act are to increase the percentage of United States workers in the total workforce of the CNMI, while maintaining the minimum number of non-U.S. workers to meet the demands of the CNMI's economy; to encourage the hiring of United States workers into the CNMI workforce; and to ensure that no U.S. worker is at a competitive disadvantage compared to a non-U.S. worker or is displaced by a non-U.S. worker. Workforce Act sec. 2. For a summary of the statutory history of CNMI immigration provisions, see section III below.

1. Need for the Regulatory Action and How the Action Will Meet That Need

The Workforce Act makes a number of changes to the transitional provisions of Title VII of the Consolidated Natural Resources Act of 2008 (CNRA), Public Law. 110–229, 122 Stat. 754, 853–854—which extended the U.S. immigration laws, with limited exceptions, to the CNMI—and requires the Secretaries of Homeland Security and Labor to each promulgate an Interim Final Rule (IFR) implementing the related statutory changes no later than January 20, 2019, which is 180 days from the date of enactment.[1] (Pub. L. 115–218, sec. 3(b)(1), (2)). The Department of Labor (DOL) IFR was published on April 1, 2019, and went into effect on April 4, 2019.[2] The DHS IFR was delayed by a number of months. The Workforce Act provides the Secretary with the discretionary authority to delay statutory provisions relating to the CW–1 program, except for provisions providing annual numerical caps for such workers, until the effective date of the IFR. (Pub. L. 115–218, sec. 3(e)(2)). On July 25, 2018, DHS announced that it would exercise its discretion, as provided in the Workforce Act, to delay implementation of other statutory changes to the CW–1 program affecting CW–1 filers until DHS issued an IFR.[3] In accordance with the Workforce Act, DHS is amending its regulations. The amendments would:

- Reflect the statutory extension of the transition period until December 31, 2029;
- Reflect the statutory CW–1 cap increase for fiscal year (FY) 2019 and codify the statutory CW–1 caps for subsequent fiscal years until the end of the transition period;
- Reflect the increase in the CNMI education funding fee to $200 per worker and the Secretary's discretionary authority to increase this fee in the future and the requirement to submit a new mandatory $50 fraud prevention and detection fee with each CW–1 petition filed;
- Specify the CW–1 numerical reservations for specific occupational categories;
- Require an approved temporary labor certification (TLC) from the DOL prior to filing a CW–1 petition;
- Reflect a minimum wage requirement;
- Impose a new CW–1 petition filing window;
- Require a CW–1 employer to file a semiannual reporting form to verify the CW–1 employment;
- Implement new revocation procedures;
- Revise the definitions of ''legitimate business'' (which includes participation in E-Verify as a condition of employing a CW–1 worker), ''direct Guam transit,'' ''lawfully present in the CNMI,'' and ''United States worker,'' as well as newly define ''participant in good standing in the E-Verify program'' and ''successor in interest'';
- Establish a new long-term worker subcategory of CW–1;
- Continue the bar on eligibility of certain construction worker occupations under the CW–1 program;
- Make conforming amendments to DHS regulations regarding inadmissibility, deportability, and asylum;
- Extend the asylum bar in the CNMI until December 31, 2029; and
- Impose temporary departure requirements for certain CW–1 workers.

Certain provisions of the Workforce Act took effect immediately upon enactment. Specifically, the Workforce Act extended the CW–1 program through 2029, increased the CW–1 cap for FY 2019, provided new CW–1 caps for subsequent fiscal years, and mandated a new fraud prevention and detection fee with each petition. In addition to extending the CW–1 program, it also immediately extended the following Consolidated Natural Resources Act of 2008[4] provisions until December 31, 2029:

- The exemption from national caps for H–1B and H–2B workers in the CNMI and on Guam;
- The bar on asylum applications in the CNMI; and
- The CNMI-Only Nonimmigrant Investor (E–2C) program.

B. Legal Authority

The Secretary of Homeland Security's authority for the regulatory amendments is found in various provisions of the Immigration and Nationality Act (INA), 8 U.S.C. 1101 *et seq.,* and the Homeland Security Act of 2002 (HSA), Public Law 107–296, 116 Stat. 2135, 6 U.S.C. 101 *et seq*. General authority for issuing the rule is found in section 103(a) of the INA, 8 U.S.C. 1103(a), which authorizes the Secretary to administer and enforce the immigration and nationality laws, and to establish such regulations as the Secretary deems necessary. In addition, section 214(a)(1) of the INA, 8 U.S.C. 1184(a)(1), provides the Secretary with authority to prescribe by regulation the terms and conditions of any alien's admission to the United States as a nonimmigrant. Further authority for the regulatory amendments in this interim final rule is found in:

- Title VII of the Consolidated Natural Resources Act of 2008 (CNRA), which extended U.S. immigration law, with limited exceptions, to the CNMI and provided CNMI-specific provisions affecting foreign workers. *See* Public Law 110–229, 122 Stat. 754, 853–854. The CNRA authorized the Secretary of Homeland Security to create a nonimmigrant classification that would ensure CNMI employers have access to adequate labor during the transition period. *See* section 702(a) of the CNRA; 48 U.S.C. 1806(d).
- The Workforce Act, Public Law 115–218, which, among other things, sets statutory caps, imposes a mandatory fraud fee, extends the transition period until December 31,

[1] The statutory deadline for rulemaking is 180 days after enactment, or January 20, 2019. However, under 1 CFR 18.17, when a date falls on a weekend or holiday, the next Federal business day is used for publication in the **Federal Register**. In this case, the next business day is January 22, 2019.

[2] 84 FR 12380 (Apr. 1, 2019).

[3] *See* USCIS, ''New Law Extends CNMI CW–1 Program, Mandates New Fraud Fee, and Will Require E-Verify Participation,'' available at *https://www.uscis.gov/news/alerts/new-law-extends-cnmi-cw-1-program-mandates-new-fraud-fee-and-will-require-e-verify-participation* (last visited May 28, 2019).

[4] *See* Public Law 110–229, 122 Stat. 754, 853–854.

2029, and requires DHS to issue an interim final rule.

C. Summary of the Major Provisions of This Regulatory Action

1. Statutory Changes

This IFR amends DHS regulations at 8 CFR 214.2(w) to include the following major changes:

First, DHS will revise 8 CFR 214.2(w)(1)(xvi) to reflect the statutory extension of the transition period and the CW program through December 31, 2029. While the CW program was previously extended via the DOL's discretionary authority [5] and later via statute,[6] the related regulation was not revised to reflect any of the CW program extensions. This change will reflect the new sunset date in existing regulations.

Second, the Workforce Act provided new CW–1 numerical limitations (caps) for subsequent fiscal years until the end of the transition period on December 31, 2029. To date, the CW–1 caps have been published via Notice in the **Federal Register** for each fiscal year, beginning with FY 2013, in accordance with 8 CFR 214.2 (w)(1)(x). The new CW–1 caps are now set by the Workforce Act for the remainder of the transition period. Consequently, a yearly **Federal Register** Notice is no longer necessary. The CW–1 caps are reflected in this IFR.

Third, this IFR updates the regulation, at 8 CFR 103.7(b)(1)(i)(J) and 8 CFR 214.2(w)(5), to reflect that in 2017 Congress raised the supplemental CNMI education funding fee from $150 to $200 [7] per each beneficiary issued CW–1 status, per year. Consistent with the Workforce Act, the IFR also provides the Secretary of Homeland Security the discretion to annually adjust this supplemental fee via notice in the **Federal Register**. This IFR also updates existing regulations, at 8 CFR 103.7(b)(1)(i)(J) and 8 CFR 214.2(w)(5), to include the Workforce Act's requirement that CW–1 employers must pay a mandatory $50 fraud prevention and detection fee with each petition, in addition to other current fees. This new fraud prevention and detection fee does not apply to CW petitions already filed and pending with USCIS as of July 24, 2018.

Fourth, this IFR updates regulations to include CW–1 cap reservations for certain occupational categories per fiscal year, as recommended by the Governor of the CNMI,[8] and indicates use of the DOL Standard Occupational Classification (SOC) system to specify which occupations are part of this cap reservation. *See* new 8 CFR 214.2(w)(1)(x)(D)(*1*) and (*2*). Accordingly, this IFR makes the following reservations of CW–1 numbers for specified occupational categories: (i) 200 for occupational categories 29–0000 (Healthcare Practitioners and Technical Occupations) and 31–0000 (Healthcare Support Occupations); and (ii) 60 for occupational categories related to the operations of the CNMI public utilities services, to include, but not limited to 17–2081 (Water/Waste Water Engineers), 17–2071 (Electrical Engineers), 17–2141(Mechanical Engineers), and Trades Technicians.[9] New 8 CFR 214.2(w)(1)(x)(D)(*1*). The reserved CW–1 numbers will be made available to eligible petitioners requesting such numbers for a fiscal year in order of filing until exhausted. Unused reserved numbers will not be available to other petitioners.

Fifth, this IFR revises petition procedures at 214.2(w)(6)(iv) to require that a CW–1 petition must be filed with an approved TLC [10] from DOL. The Workforce Act imposes this requirement for any CW–1 petition with an employment start date in FY 2020 and beyond. The Workforce Act requires a TLC approved by DOL to confirm that there are not sufficient United States workers in the CNMI who are able, willing, qualified, and available to fill the petitioning CW–1 employer's job opportunity. 48 U.S.C. 1806(d)(2)(A). The TLC also confirms that the foreign worker's employment in the job opportunity will not adversely affect the wages or working conditions of similarly employed United States workers. *Id.*

Sixth, this IFR revises 8 CFR 214.2(w)(6)(ii)(I) to include the statutory minimum wage requirements for a CW petitioner. It now specifies that the petitioner will pay the beneficiary a wage that is not less than the greater of (1) the CNMI minimum wage; (2) the Federal minimum wage; or (3) the prevailing wage in the CNMI for the occupation in which the beneficiary will be employed, as established by the DOL.

Seventh, this IFR establishes a new filing timeframe for CW–1 petitioners at 8 CFR 214.2(w)(12)(ii). The Workforce Act states that an employer seeking to extend the employment of a CW–1 worker may petition USCIS no earlier than 180 calendar days before the expiration of the CW–1 status. Employers filing an initial petition for CW–1 status may not petition earlier than 120 days before the date of actual need for the beneficiary's services.

Eighth, this IFR requires a CW–1 employer to file a semiannual reporting form to verify the continuing employment and payment of the CW–1 worker under the terms and conditions set forth in the CW–1 petition. *See* new 8 CFR 214.2(w)(26). DHS will implement this new statutory requirement via a new standalone form which will capture data to provide USCIS with the information necessary to help verify the continuing employment and payment of the CW–1 worker, and will contain an attestation confirming those elements. USCIS will not require submission of evidence at the time of filing, but employers must retain documents and records which support the attestation for three years after the ending date of the petition validity period. An employer must retain evidence that supports the semiannual report, including but not limited to: (a) Personnel records for each CW–1 worker including the name, address of current residence in the Commonwealth, age, domicile, citizenship, point of hire, and approved employment contract termination date; (b) payroll records for each CW–1 worker including the O*NET job classification, wage rate or salary,

[5] On June 3, 2014, the Secretary of Labor extended the CW program for an additional 5 years, through December 31, 2019. *See* Secretary of Labor Extends the Transition Period of the Commonwealth of the Northern Mariana Islands-Only Transitional Worker Program, 79 FR 31988 (June 3, 2014).

[6] On December 16, 2014, Congress amended the law to extend the transition period until December 31, 2019. *See* Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, sec. 10, 128 Stat. 2130, 2134. Congress also eliminated the Secretary of Labor's authority to provide for future extensions of the CW–1 program, requiring the CW–1 program to sunset on December 31, 2019.

[7] In 2017, Congress enacted the Northern Mariana Islands Economic Expansion Act, Public Law 115–53, 131 Stat. 1091, which increased the supplemental fee paid for each CW permit to $200 and banned issuing new CW–1 permits to construction workers.

[8] *See* Letter from Rafael DLG Torres, Governor of the CNMI, to Kirstjen Nielsen, Secretary, DHS (Aug. 8, 2018), available at *http://www.regulations.gov* under DHS Docket No. USCIS–2019–0003. References in this IFR to ''the Governor'' are to the Governor of the CNMI.

[9] A corresponding SOC code does not exist that would include all Trades Technicians occupations.

[10] To obtain a TLC, employers must submit a complete *Application for Prevailing Wage Determination* (Form ETA–9141C) with the OFLC National Prevailing Wage Center (NPWC) containing information about the job opportunity in which the nonimmigrant workers will be employed, as required by 20 CFR 655.410. Once the NPWC issues a prevailing wage determination, the employer may submit the *CW–1 Application for Temporary Employment Certification* and supporting documentation, as required by 20 CFR 655.420–423. Once all CW–1 regulatory requirements are met, the TLC is issued. Under the provisions at 20 CFR 655.452, if DOL issues a TLC, it will transmit a Final Determination notice and a copy of the certified *CW–1 Application for Temporary Employment Certification* (Form ETA–9142C) to the employer, with a copy to the employer's representative if it has one.

number of hours worked each week, gross compensation, itemized deductions, and evidence of net payments made and received biweekly; and (c) direct evidence of payment of wages and overtime, such as receipts for cash payments, cancelled checks, or deposit records of payment of wages and overtime.

Ninth, this IFR establishes revocation procedures, at new 8 CFR 214.2(w)(27), for an employer's CW–1 petition using existing revocation grounds in place for other nonimmigrants programs (such as the H classification revocation procedures at 8 CFR 214.2(h)(11)), which include automatic revocation grounds if the petitioner either ceases operations or files a written withdrawal of the petition, or DOL revokes the TLC upon which the petition is based. This IFR also includes discretionary grounds for revocation on a notice of intent to revoke (NOIR) to incorporate the good cause grounds listed in the Workforce Act. In accordance with the Workforce Act, for each beneficiary of a petition revoked in a fiscal year, USCIS will add a CW–1 cap number to the next fiscal year.

Tenth, this IFR incorporates the definition of legitimate business as set forth in the Workforce Act. The new definition, at 8 CFR 214.2 (w)(1)(vii), mirrors current section 214.2(w)(1)(vi), but adds a provision to address human trafficking in general (the previous definition specified human trafficking in minors). It also requires E-Verify participation as a condition of filing CW–1 petitions. Additionally, it updates the definition with the statutory requirement for substantial current and past compliance with wage and hour laws, occupational safety and health requirements, nondiscrimination, and all other Federal, CNMI, and local requirements relating to employment during the five-year period immediately preceding the date of filing the petition. Finally, also consistent with the Workforce Act, it precludes participation by businesses (including successors in interest to businesses) with an owner, investor, manager, operator, or person meaningfully involved with the undertaking, if such individual has been an owner, investor, manager, operator, or person otherwise meaningfully involved with an undertaking that was not in compliance with certain employment-related legal requirements at any time during which such individual was involved with the undertaking, or is an agent of such individual.

Eleventh, this IFR creates a subcategory of CW–1 workers known as ''long-term workers'' at 8 CFR 214.2(w)(1)(viii). Under the Workforce Act, these are workers who were admitted or otherwise granted status as a CW–1 during FY 2015, and during every subsequent fiscal year through July 24, 2018.[11] This subcategory of CW–1 workers is eligible for a longer period of stay, in increments of up to 3-year periods, during the transition period. These periods are renewable and will be counted against the cap on a yearly basis.

Twelfth, at 8 CFR 214.2(w)(2)(vii), this IFR amends the bar on certain construction worker occupations, which was enacted in 2017,[12] and prohibits the CW–1 classification from being available to workers who will be performing jobs classified as ''construction and extraction occupations'' as defined in the DOL's SOC system; this prohibition does not apply to ''long-term workers'' as defined by the Workforce Act.

Thirteenth, this IFR imposes temporary departure requirements for certain CW–1 workers at 8 CFR 214.2 (w)(18)(v). Specifically, it requires CW–1 workers who have received a second extension to depart the CNMI for at least 30 continuous days prior to filing for CW–1 status again. However, consistent with the Workforce Act, it exempts the ''long-term workers'' from this departure requirement.

2. Technical Changes

This IFR also makes a number of conforming amendments to DHS regulations regarding the asylum provisions to extend the asylum bar in the CNMI until December 31, 2029.[13]

D. Summary of Costs and Benefits

The costs associated with the revisions to the DHS regulations in this interim final rule (IFR) include costs of preparing and filing the Petition for a CNMI-Only Nonimmigrant Transitional Worker (Form I–129CW), filing applications for extension of stay, participating in the E-Verify program, submitting semiannual reports and document retention, submitting notifications to USCIS, and filing revoked petitions. These costs are discussed in detail in the Executive Order 12866 and 13563 sections of this rule. Overall, the lower bound net total estimated cost of the rule is $73,578,345 undiscounted, $62,851,776 discounted at 3 percent, and $51,858,612 discounted at 7 percent from FY 2019 to 2030. Likewise, the upper bound net total estimated cost of the rule is $61,741,219 undiscounted, $52,693,918 discounted at 3 percent, and $43,433,060 discounted at 7 percent from FY 2019 to 2030. The total estimated lower bound transfers are $25,712 at 7 percent and $32,361 at 3%, while the total estimated upper bound transfers are $13,845,180 discounted at 7% and $16,806,753 discounted at 3%. The annualized cost of the rule discounted at 7 percent is $5,468,222 for the lower bound and $6,528,999 for the upper bound estimates.

A petitioner is required to file Form I–129CW to employ nonimmigrant workers who are otherwise ineligible to work in the CNMI under other nonimmigrant worker categories. DHS estimates the total petitioners' cost to file Form I–129CW petitions to be $57,047,877 undiscounted, $48,668,535 discounted at 3 percent, and $40,092,491 discounted at 7 percent from FY 2019 to 2030, which includes the opportunity cost of time to complete Form I–129CW, the postage cost to mail the completed form, and the costs associated with Form I–129CW filing fee, education funding fee, and fraud prevention and detection fee. Petitioners are also required to file a new petition to request an extension of stay for their currently approved CW–1 nonimmigrant employees. However, the cost of filing a petition for an extension of stay is already captured by the cost of filing Form I–129CW petitions.

The IFR requires that any employer petitioning for a CW–1 nonimmigrant worker must be an E-Verify program participant in good standing. Participating in the E-Verify program requires employers to enter information from their newly hired employee's Form I–9, Employment Eligibility Verification, to be electronically matched against records available to DHS and the Social Security Administration (SSA) to confirm the employee's identity and employment eligibility. This results in a cost burden to employers. Employers also incur additional cost burden for annual training in E-Verify as they continue to comply with E-Verify requirements. DHS estimates the total cost of participating in the E-Verify program to be $1,224,618 undiscounted, $1,061,385 discounted at 3 percent, and $894,425 discounted at 7 percent from FY 2019 to 2030.

An employer whose petition has been approved will be required to submit a

[11] *See* 48 U.S.C. 1806(d)(7)(B). President Trump signed the Workforce Act on July 24, 2018.

[12] *See* Northern Mariana Islands Economic Expansion Act, Public Law 115–53 (amending Section 6 of Public Law 94–241, 48 U.S.C. 1806).

[13] The Department of Justice will be publishing a separate rule to make technical amendments to 8 CFR Chapter V to reflect that Congress has extended the statutory bar for asylum in the CNMI until December 31, 2029. *See* Workforce Act at sec. 3(a). 48 U.S.C. 1806(a)(2),(7).

semiannual report every six months to DHS, using Form I–129CWR, after the petition validity start date to verify the continuing employment and payment of the beneficiary under the terms and conditions of the approved petition. Petitioners are also required to retain all documents and records in support of the petition, and the semiannual report, for 3 years after the petition validity period end date. DHS estimates the total cost of semiannual reporting and document retention will be $15,996,725 undiscounted, $13,647,084 discounted at 3 percent, and $11,242,286 discounted at 7 percent from FY 2019 to 2030.

DHS requires a petitioner to immediately notify USCIS of any changes in the terms and conditions of employment of a nonimmigrant worker which may affect eligibility under section 214.2(w) either by (1) filing an amended petition if the petitioner continues to employ the nonimmigrant worker, or (2) sending a letter to the USCIS office at which the CW–1 petition was filed explaining the basis on which the specific CW–1 nonimmigrant is no longer employed. DHS estimates the total cost of filing an amended petition to be $215,296 undiscounted, $183,673 discounted at 3 percent, and $151,307 discounted at 7 percent from FY 2019 to 2030. In the absence of data to estimate the total cost of submitting a notification letter, DHS estimates a unit cost of mailing a notification letter to USCIS. An affected petitioner on average will incur a unit cost of $43.65 to send a letter notifying USCIS that a CW–1 nonimmigrant is no longer working for him or her.

USCIS reserves the authority to fully or partially revoke petitions at any time under specified conditions. The conditions for immediate and automatic revocations and the discretionary grounds for revocation on notice are discussed in the preamble of this IFR. For each beneficiary of a petition revoked in a fiscal year, USCIS will add it to a CW–1 numerical cap of the next fiscal year. DHS estimates employers' total cost to file Form I–129CW petitions for such additions to the numerical cap to be $108,957 undiscounted, $90,410 discounted at 3 percent, and $71,834 discounted at 7 percent from FY 2019 to 2030. The IFR also provides the conditions for appealing revoked petitions. DHS is unable to estimate the cost employers will incur appealing petitions that have been revoked on notice in the implementation period (FY 2019 to 2030); however, DHS estimates a unit cost to show the minimum cost petitioners are likely to incur appealing petitions revoked on notice. DHS estimates that an affected employer on average incurs a cost of $782.95 appealing a petition revoked on notice.

Qualifying dependents (*i.e.,* an eligible spouse or child) of nonimmigrant workers with a CW–1 status may file applications requesting a grant of a CW–2 status using Form I–539, Application to Extend/Change Nonimmigrant Status. DHS estimates the total cost of filing applications for CW–2 status to be $7,826,181 undiscounted, $6,676,651 discounted at 3 percent, and $5,500,136 discounted at 7 percent for nonimmigrant in FYs 2019 to 2030.

The IFR states that an extension of stay may be granted for a period of up to three years if the CW–1 worker is a long-term worker. DHS estimates the cost savings for petitioners who will request a three-year extension of stay for their long-term workers using the lower and upper bound estimates for the net number of beneficiaries for whom a three-year extension of stay will be requested. Accordingly, the total cost savings to petitioners resulting from filing a three-year extension of stay for long-term nonimmigrant workers range from $978,034 to $8,802,309 undiscounted ($827,067 to $7,443,600 discounted at 3 percent, and $674,239 to $6,068,155 discounted at 7 percent) from FY 2019 to 2030.

III. Background

A. Legal Framework

Under the INA, as amended by the Homeland Security Act of 2002, Public Law 107–296, 116 Stat. 2135 (codified at 6 U.S.C. 101 *et seq.*), the Secretary of Homeland Security is charged with the administration and enforcement of the INA, and all other laws relating to the immigration and naturalization of aliens, except as such laws relate to the powers, functions, or duties conferred upon the President, the Attorney General, the Secretary of State, or consular officers. *See* INA 103(a)(1), 8 U.S.C. 1103(a)(1). The Homeland Security Act, however, preserved the functions of the Executive Office for Immigration Review (EOIR) (including the immigration judges, the Board of Immigration Appeals (BIA), and the Office of the Chief Administrative Hearing Officer (OCAHO)) within the Department of Justice (DOJ) under the authority of the Attorney General. *See* 6 U.S.C. 521; INA 103(g), 8 U.S.C. 1103(g). In addition, DOJ's Civil Rights Division, Immigrant and Employee Rights Section (IER) continues to have authority to enforce the INA's employment anti-discrimination provisions. *See* INA 274B, 8 U.S.C. 1324b.

The changes implemented under the Workforce Act affect existing regulations governing DHS immigration policy and procedures, and these revisions to the DHS regulations are described in Part IV below.

However, given the authority of the immigration judges and the BIA to adjudicate asylum claims for aliens who are placed in proceedings before the immigration judges and the BIA, the Attorney General is publishing a separate rule to make technical amendments to the EOIR regulations (*i.e.,* a change of date) to reflect that Congress has provided that the statutory bar to applying for asylum in the CNMI will continue prior to January 1, 2030.

B. Legislative Authority

1. Legislation Prior to the Workforce Act

The CNMI, located in the Western Pacific, is a self-governing commonwealth in political union with, and under the sovereignty of, the United States. In 1976, Congress approved the Covenant to Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America (the 1976 Covenant), which defined the political relationship between the CNMI and the United States, provided U.S. citizenship to certain CNMI residents, and exempted the CNMI from certain federal minimum wage provisions and immigration laws but reserved the right of the federal government to apply federal law in these exempted areas without the consent of the CNMI government.[14] As a result, the CNMI administered its own immigration system under the terms of the 1976 Covenant with the United States for many years.

In 2008, Title VII of the Consolidated Natural Resources Act (CNRA) amended the 1976 Covenant, by extending U.S. immigration law, with limited exceptions, to the CNMI and providing CNMI-specific provisions affecting foreign workers. *See* Public Law 110–229, 122 Stat. 754, 853–854; 48 U.S.C. 1806(d). Since 1978, the CNMI had admitted a substantial number of foreign workers who constituted a majority of the CNMI labor force. The CNRA provided for a transition period to phase out the CNMI's nonresident contract worker program and phase in the U.S. federal immigration system in a manner that minimized adverse economic and fiscal effects and maximized the CNMI's potential for future economic and

[14] *See* A Joint Resolution to Approve the Covenant To Establish a Commonwealth of the Northern Mariana Islands in Political Union with the United States of America, Public Law 94–241, 90 Stat. 263 (1976), 48 U.S.C.1801 note.

business growth. *See* sections 701 and 702(a) of the CNRA.

The CNRA authorized the Secretary of Homeland Security to create a nonimmigrant classification that would ensure adequate employment in the CNMI during the transition period. *See* section 702(a) of the CNRA; 48 U.S.C. 1806(d). DHS published a final rule on September 7, 2011, amending the regulations at 8 CFR 214.2(w) to implement a temporary, CNMI-only transitional worker nonimmigrant classification (CW classification, which includes CW–1 for principal workers and CW–2 for spouses and minor children). *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification, 76 FR 55502 (Sept. 7, 2011).

The CNRA mandated an annual reduction in the number of permits issued per year and the total elimination of the CW nonimmigrant classification by the end of the transition period. *See* section 702(a) of the CNRA. At the outset of the transitional worker program, DHS set the CW–1 numerical limitation (also known as the CW–1 cap) for FY 2011 at 22,417 and for FY 2012 at 22,416. DHS announced these annual caps in DHS regulations at 8 CFR 214.2(w)(1)(viii)(A) and (B). DHS published subsequent annual caps by **Federal Register** notice. *See* 8 CFR 214.2(w)(1)(viii)(C).

The CNRA directed the U.S. Secretary of Labor to determine whether an extension of the CW program for an additional period of up to five years beyond the expiration of the initial transition period on December 31, 2014, was necessary to ensure that an adequate number of workers would be available for legitimate businesses in the CNMI. *See* section 702(a) of the CNRA. The CNRA further provided the Secretary of Labor with the authority to provide for such an extension through notice in the **Federal Register**. *See id.*

On June 3, 2014, the Secretary of Labor extended the CW program for an additional five years, through December 31, 2019. *See* Secretary of Labor Extends the Transition Period of the Commonwealth of the Northern Mariana Islands-Only Transitional Worker Program, 79 FR 31988 (June 3, 2014). Since the Secretary of Labor extended the CW program at least until December 31, 2019, DHS decided to generally preserve the then current conditions relating to CW–1 workers, rather than aggressively reduce CW–1 permit numbers for FY 2015. DHS therefore reduced the CW–1 cap nominally by one, resulting in an FY 2015 limit of 13,999.[15] *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2015, 79 FR 58241 (Sept. 29, 2014).

On December 16, 2014, Congress amended the law to extend the transition period until December 31, 2019. *See* Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, sec. 10, 128 Stat. 2130, 2134. Congress also eliminated the Secretary of Labor's authority to provide for future extensions of the CW–1 program, requiring the CW–1 program to end (or sunset) on December 31, 2019. *See id.*

The Northern Mariana Islands Economic Expansion Act (NMIEEA), Public Law 115–53, 131 Stat. 1091 (2017), which was enacted into law on August 22, 2017, revised the CW–1 visa classification to, among other things, (1) add 350 CW–1 visas to the FY 2017 CW–1 cap for purposes of extending certain existing CW–1 permits, raising the total number of visas that may be issued in that fiscal year from 12,998 to 13,348; and (2) prohibit the CW–1 classification from being available to workers who will be performing jobs classified as ''construction and extraction occupations'' as defined in the DOL's SOC system, other than to extend CW–1 permits of such workers first issued before October 1, 2015. This latter provision effectively barred employers of new construction and extraction occupation workers from using the CW–1 classification. As described by the NMIEEA's sponsor in the Congressional Record, the bar on construction and extraction workers is intended to require construction companies to fill new positions (including those filled by CW–1 workers after October 1, 2015) with non-CW–1 workers.[16]

2. The Workforce Act

On July 24, 2018, President Trump signed the Workforce Act, Public Law 115–218, 132 Stat. 1547. The stated purposes of the Workforce Act are to increase the percentage of United States workers in the total workforce of the CNMI while maintaining the minimum number of non-U.S. workers to meet the demands of the CNMI's economy; encourage the hiring of United States workers into the CNMI workforce; and ensure that no U.S. worker is at a competitive disadvantage compared to a non-U.S. worker or is displaced by a non-U.S. worker.

In discussing the background and need for the Workforce Act, the accompanying Senate Report notes the CNMI's continuing dependence on foreign labor.[17] The Senate Report cites the May 2017 report by the Government Accountability Office (GAO), entitled *Commonwealth of the Northern Mariana Islands; Implementation of Federal Minimum Wage and Immigration Laws,* noting that since FY 2013, demand for CW–1 permits had doubled, and in FY 2016, demand exceeded the numerical cap for the first time.[18] In 2016, USCIS received enough petitions to approve 12,999 CW–1 permits by May 5, 2016, reaching the cap five months prior to the end of the fiscal year.[19] For the 2017 fiscal year cap, USCIS received a sufficient number of petitions to reach the CW–1 cap of 12,998 by October 14, 2016.[20] On April 11, 2017, USCIS received a sufficient number of petitions to reach the FY 2018 cap of 9,998.[21] The GAO report

[15] This section only discusses legislation prior to the enactment of the Workforce Act. It is important to note that after establishing the transitional worker program, DHS published **Federal Register** Notices to reduce the CW–1 cap. DHS set the CW–1 numerical limitation at 15,000 and 14,000 respectively for FY 2013 and FY 2014. *See* CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2013, 77 FR 71287 (Nov. 30, 2012); CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2014, 78 FR 58867 (Sept. 25, 2013). DHS reduced the CW–1 cap for FY 2015 nominally in response to the Secretary of Labor's extension of the transition period (explained above). For FY 2016, DHS reduced the cap by 1,000 to a limit of 12,999. *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2016, 80 FR 63911 (Oct. 22, 2015). DHS reduced the cap for FY 2017 by only one to 12,998. *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2017, 81 FR 60581 (Sept. 2, 2016). In 2017, DHS published a reduction plan to inform the public of the number of CW–1 workers available during each of the fiscal years for the remainder of the transition period. *See* Commonwealth of the Northern Mariana Islands (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Years 2018 Through 2020, 82 FR 55493 (Nov. 22, 2017).

[16] *See* 163 Cong. Rec. E1132 (daily ed. Aug. 15, 2017) (statement of Delegate Sablan).

[17] *See* S. Rep. No. 115–214, at 7 (2018), available at *https://www.congress.gov/115/crpt/srpt214/CRPT-115srpt214.pdf* (last visited May 28, 2019).

[18] *See* U.S. Govt. Accountability Office, Commonwealth of the Northern Mariana Islands: Implementation of Federal Minimum Wage and Immigration Laws, GAO–17–437 (May 2017), *https://www.gao.gov/products/GAO-17-437* (last visited May 28, 2019).

[19] *See* ''USCIS Reaches CW–1 Cap for Fiscal Year 2016,'' available at *https://www.uscis.gov/archive/archive-news/uscis-reaches-cw-1-cap-fiscal-year-2016* (last visited May 28, 2019).

[20] *See* ''USCIS Reaches CW–1 Cap for Fiscal Year 2017,'' available at *https://www.uscis.gov/news/alerts/uscis-reaches-cw-1-cap-fiscal-year-2017* (last visited May 28, 2019).

[21] *See* ''As CNMI Transitional Worker Program Draws Down, USCIS Announces Cap for Final Three Fiscal Years,'' available at *https://*

Continued

attributes the increased demand for CW–1 permits to the CNMI's recent economic expansion, specifically, the construction of casinos and hotels.

The CNMI business community expressed concern that the reduced levels of available CW–1 permits would have a negative impact on the CNMI's economy. The GAO report found that in 2015, foreign workers (totaling 12,784) made up more than half of the CNMI's workforce and filled 80 percent of all hospitality and construction jobs. The GAO also found that in 2015, if all CW–1 workers were removed from the CNMI's labor market, the CNMI's gross domestic product would be reduced by between 26 and 62 percent. The GAO report noted that the unemployed domestic workforce, estimated at 2,386 in 2016, would be well below the CNMI's demand for labor.

The Senate Report notes that, in response to labor abuses by certain employers in the CNMI, there is a call for additional labor protections, including higher minimum wage requirements, the potential for revocation, legitimate business requirements, and the prohibition on the use of CW–1 permits for construction workers.[22]

Certain provisions of the Workforce Act took effect immediately. Specifically, it extended the CNMI-Only Transitional Worker program (the CW–1 program) through 2029, increased the CW–1 cap for FY 2019, provided new CW–1 caps for subsequent fiscal years, and mandated a new fraud prevention and detection fee with each petition. In addition to extending the CW–1 program, it also extended the following CNRA provisions until December 31, 2029:

- The exemption from national caps for H–1B and H–2B workers in the CNMI and on Guam;
- The bar on asylum applications in the CNMI; and
- The CNMI-Only Nonimmigrant Investor (E–2C) program.

The Workforce Act's section 3(a) also amends the 1976 Covenant to make a number of changes to the transitional provisions and, as noted above, requires the Secretaries of Homeland Security and Labor to each promulgate an IFR implementing the related statutory changes no later than January 20, 2019, which is 180 days from the date of enactment.[23] (Pub. L. 115–218, sec. 3(b)(1), (2)). The Department of Labor (DOL) IFR was published on April 1, 2019, and went into effect on April 4, 2019.[24] The DHS IFR was delayed by a number of months.

The Workforce Act provides the Secretary with the discretionary authority to delay statutory provisions relating to the CW–1 program, except for provisions providing annual numerical caps for such workers, until the effective date of the IFR. (Pub. L. 115–218, sec. 3(e)(2)). On July 25, 2018, DHS announced that it would exercise its discretion, as provided in the Workforce Act, to delay implementation of other statutory changes to the CW–1 program affecting CW–1 filers until DHS issued an IFR.[25]

IV. Changes to DHS Regulations

A. Codifying the Provisions Effective Immediately Pursuant to the Workforce Act

1. Extension of the Transition Period

DHS is revising 8 CFR 214.2(w)(1)(xvi) to update the extension of the transition period, and thus the CW–1 program, through December 31, 2029. While the transition period has been previously extended, the related regulation was not revised to reflect any of the CW–1 program extensions. This change will reflect the new sunset date within existing regulations.

This IFR also revises 8 CFR 214.2(e)(23) to extend the E–2C program until December 31, 2029. The E–2C visa classification allows foreign, long-term investors to remain lawfully present in the CNMI through the transition period and is extendable in 2 year increments.[26] *See* 8 CFR 214.2(e)(23)(xii), (xiv). The E–2 CNMI Investor program was intended to provide a smooth transition for existing CNMI investors and to mitigate potential adverse consequences to the CNMI economy if the current investments could not otherwise be maintained as a basis for immigration status during the transition period. As with the CW–1 classification, the E–2C classification also ceases to exist at the end of the transition period. *See* 8 CFR 214.2(e)(23)(xiv).

This IFR also updates DHS regulations to make a number of conforming amendments to extend the asylum bar in the CNMI, *see* INA sec. 208(e), 8 U.S.C. 1158(e), until December 31, 2029.

2. CW–1 Numerical Limitation

As previously noted, the CNRA mandated an annual reduction (not a specific numerical reduction) in the number of permits issued per year and the total elimination of the CW nonimmigrant classification by the end of the transition period. *See* 48 U.S.C. 1806(d)(2). DHS regulations provided that the CW–1 cap for any fiscal year would be less than the number established for the previous fiscal year, and that the adjusted number would be reasonably calculated in DHS's discretion to reduce the number of CW–1 nonimmigrant workers to zero by the end of the program. 8 CFR 214.2(w)(1)(viii)(C). DHS could adjust the cap for a fiscal year or any other period, at any time by publishing a Notice in the **Federal Register**, as long as the number was less than the cap for the previous fiscal year. *See* 8 CFR 214.2(w)(1)(viii)(D).

At the outset of the transitional worker program, DHS set the CW–1 numerical limitation (also known as the CW–1 cap) for FY 2011 at 22,417 and for FY 2012 at 22,416. DHS announced these annual caps in DHS regulations at 8 CFR 214.2(w)(1)(viii)(A) and (B). DHS subsequently published annual caps by **Federal Register** notice. *See* 8 CFR 214.2(w)(1)(viii)(C). DHS set the CW–1 numerical limitation at 15,000 and 14,000 respectively for FY 2013 and FY 2014. *See* CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2013, 77 FR 71287 (Nov. 30, 2012); CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2014, 78 FR 58867 (Sept. 25, 2013). For FY 2015, DHS reduced the numerical limitation nominally by one, resulting in an FY 2015 limit of 13,999. *See* CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2015, 79 FR 58241 (Sept. 29, 2014). For FY 2016, DHS reduced the cap by 1,000 to a limit of 12,999. *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2016, 80 FR 63911 (Oct. 22, 2015). DHS

www.uscis.gov/news/news-releases/cnmi-transitional-worker-program-draws-down-uscis-announces-cap-final-three-fiscal-years (last visited May 28, 2019).

[22] *See* S. Rep. No. 115–214, at 8 (2018), available at *https://www.congress.gov/115/crpt/srpt214/CRPT-115srpt214.pdf* (last visited May 28, 2019).

[23] The statutory deadline for rulemaking is 180 days after enactment, or January 20, 2019. However, under 1 CFR 18.17, when a date falls on a weekend or holiday, the next Federal business day is used for publication in the **Federal Register**. In this case, as January 20 was a Sunday and January 21 was a Federal holiday, the next business day is January 22, 2019.

[24] 84 FR 12380 (Apr. 1, 2019).

[25] *See* USCIS, ''New Law Extends CNMI CW–1 Program, Mandates New Fraud Fee, and Will Require E-Verify Participation,'' available at *https://www.uscis.gov/news/alerts/new-law-extends-cnmi-cw-1-program-mandates-new-fraud-fee-and-will-require-e-verify-participation* (last visited May 28, 2019).

[26] While E–2C status can be extended, the filing period for initial requests for the E–2C classification ended on January 18, 2013. *See* 8 CFR 214.2(e)(23)(i).

reduced the cap for FY 2017 by only one to 12,998. *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2017, 81 FR 60581 (Sept. 2, 2016). Finally, in 2017, DHS published a reduction plan to inform the public of the number of CW–1 workers available during each of the fiscal years for the remainder of the then-existing transition period. *See* Commonwealth of the Northern Mariana Islands (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Years 2018 through 2020, 82 FR 55493 (Nov. 22, 2017). DHS set the CW–1 cap for FY 2018 at 9,998. For FY 2019, the cap was set at 4,999. For FY 2020, the cap was set at 2,499 and was to be in effect until the previous end of the transition period on December 31, 2019. *See id.* DHS believed that this approach would further encourage the recruitment of United States workers and the transition into the U.S. immigration system, consistent with the goals of the CNRA and the general policy direction provided by Executive Order 13,788, Buy American and Hire American, 82 FR 18837, 18838 (Apr. 21, 2017) ''to protect the interests of United States workers in the administration of our immigration system.''

The Workforce Act did not make any changes to the CW–1 cap for FY 2018. However, it immediately raises the CW–1 cap for FY 2019 and then provides gradually diminishing CW–1 caps for subsequent fiscal years until the end of the transition period on December 31, 2029. It starts with a cap of 13,000 for FY 2019, then reduces each fiscal year by 500 through FY 2023; that number then declines by 1,000 for each fiscal year through 2029. By FY 2029 it drops to 5,000 and then to 1,000 for FY 2030 (until December 31, 2029).

The new caps took effect immediately and are reflected in this interim final rule as follows:

(1) 9,998 for fiscal year 2018;
(2) 13,000 for fiscal year 2019;
(3) 12,500 for fiscal year 2020;
(4) 12,000 for fiscal year 2021;
(5) 11,500 for fiscal year 2022;
(6) 11,000 for fiscal year 2023;
(7) 10,000 for fiscal year 2024;
(8) 9,000 for fiscal year 2025;
(9) 8,000 for fiscal year 2026;
(10) 7,000 for fiscal year 2027;
(11) 6,000 for fiscal year 2028;
(12) 5,000 for fiscal year 2029; and
(13) 1,000 for the first quarter of fiscal year 2030.

3. CNMI Education Fee

The Workforce Act implements the raise in the supplemental CNMI education funding fee from $150 to $200 (per each beneficiary issued CW–1 status, per year). *See* 48 U.S.C. 1806(a)(6)(A)(i). It also provides the Secretary of Homeland Security the discretion to annually adjust this supplemental fee. *See* 48 U.S.C. 1806(a)(6)(A)(ii). Beginning in FY 2020, the Secretary, through notice in the **Federal Register**, may annually adjust the supplemental fee by a percentage equal to the annual change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics. *See* 48 U.S.C. 1806(a)(6)(A)(ii). This IFR updates the regulation at 8 CFR 103.7(b)(1)(i)(J) and 8 CFR 214.2(w)(5) to include the new fee and the Secretary's discretionary authority for inflation adjustment.

4. Fraud Prevention and Detection Fee

The Workforce Act requires DHS to impose a $50 fee for fraud prevention and detection purposes on each CW–1 petitioner. *See* 48 U.S.C. 1806(a)(6)(A)(iv)(I). This fee is for the sole purpose of preventing and detecting immigration benefit fraud in the Northern Mariana Islands. *See* 48 U.S.C. 1806(a)(6)(A)(iv)(II). USCIS implemented the antifraud fee as soon as it began accepting new petitions under the revised FY 2019 CW–1 cap.[27] This new fraud prevention and detection fee did not apply to CW–1 petitions already filed and pending with USCIS as of July 24, 2018, but was imposed on any petitions received after July 24, 2018. USCIS rejects petitions with incorrect or insufficient fees. This IFR updates the regulation at 8 CFR 103.7(b)(1)(i)(J) and 8 CFR 214.2(w)(5) to include the new fraud prevention and detection fee.

B. CW–1 Numerical Reservation for Specific Occupational Categories

Section 3(b)(3) of the Workforce Act requires the Secretary of Homeland Security to consider the Governor's recommendations in developing the interim final rule implementing the law. The Workforce Act specifically states that DHS shall consider in good faith any written public recommendations regarding Workforce Act implementation that are submitted by the Governor of the Commonwealth not later than 60 days after the date of the Workforce Act's enactment. The Workforce Act further provides that DHS may include provisions in its IFR that are responsive to any recommendation of the Governor and not inconsistent with the Workforce Act, including a recommendation to reserve a number of permits each year for occupational categories necessary to maintain public health or safety in the Commonwealth.

In an August 8, 2018 letter,[28] Governor Torres requested that DHS reserve 200 CW–1 permits in FY 2019 for ''occupational categories'' 29–0000 (Healthcare Practitioners and Technical Occupations) and 31–0000 (Healthcare Support Occupations). For FY 2019, Governor Torres also requested that DHS reserve 60 CW–1 permits for occupational categories related to the operations of the CNMI public utilities services, to include Water/Waste Water Engineers, Electrical Engineers, Mechanical Engineers, and Trades Technicians. Governor Torres stressed the importance of reserving these cap numbers in order to maintain labor access and, therefore, adequate staffing of the CNMI's healthcare system and public utilities services. Additionally, Governor Torres recommended that the CW–1 cap reservations should be changed based on labor demands within these sectors. Finally, Governor Torres requested the ability to recommend changes to these CW–1 cap reservations throughout the duration of the transition period as this would help the CNMI's goals of truly transitioning occupations toward U.S. citizens, or alternative visa classifications when United States workers are not available.

As directed by the Workforce Act, DHS considered the Governor's recommendations in developing this IFR. As mentioned above, the Governor requested that DHS reserve 200 CW–1 permits for health occupations and 60 CW–1 permits for public utilities occupations for FY 2019. In an October 29, 2018 response to Governor Torres,[29] DHS explained that it did not have the authority to reserve permits for occupational categories prior to the IFR taking effect and that the ability to make any such reservations for FY 2019, as opposed to future fiscal years, would depend upon when the IFR takes effect and whether FY 2019 CW–1 permits are still available at that time.

[27] *See* USCIS, ''New Law Extends CNMI CW–1 Program, Mandates New Fraud Fee, and Will Require E-Verify Participation,'' available at *https://www.uscis.gov/news/alerts/new-law-extends-cnmi-cw-1-program-mandates-new-fraud-fee-and-will-require-e-verify-participation* (last visited May 28, 2019).

[28] *See* Letter from Rafael DLG Torres, Governor of the CNMI, to Kirstjen Nielsen, Secretary, DHS (Aug. 8, 2018), available at *http://www.regulations.gov* under DHS Docket No. USCIS–-2019–0003.

[29] *See* Letter from L. Francis Cissna, Director, USCIS to Rafael DLG Torres, Governor of CNMI (October 29, 2018), available at *http://www.regulations.gov* under DHS Docket No. USCIS–-2019–0003.

DHS understands the Governor's concerns regarding the availability of CW–1 cap numbers for these critical occupations. After careful consideration, DHS will include a CW–1 cap reservation for all critical occupations, as recommended by the Governor.

With respect to the occupational categories identified by the Governor regarding the operations of the CNMI public utilities services, DHS is concerned that the Governor's recommendation refers to these occupations in general terms rather than providing a specific definition or offering a more precise way to identify them. DHS can better implement and operationally manage a CW–1 cap reservation by defining the occupational categories that will be considered as part of that cap reservation.

After careful consideration, DHS has determined that, consistent with the Governor's use of the occupational categories to refer to health occupations, DHS will generally use the DOL SOC [30] system to specify which occupations are part of this cap reservation. The SOC system is a federal statistical standard used by federal agencies to classify workers into occupational categories for the purpose of collecting, calculating, or disseminating data.[31] DOL uses the SOC system to group and classify jobs and occupations. The purpose of the SOC system is to organize occupational data and classify workers into distinct occupational categories. It covers all occupations where work is performed for pay or for profit. Occupations are generally categorized based on the type of work performed. Additionally, certain occupations are also classified based on the skills, education and training required to perform the job. The SOC system is organized using codes, which generally consist of six numerical digits. In sum, the SOC code provides an objective approach to define affected groups.

Currently, USCIS uses these SOC codes as one basis for determining whether the beneficiary's proposed employment qualifies for CW–1 classification.[32] For purposes of adjudicating the Form I–129CW, USCIS reviews the totality of the record, including the listed SOC code and any additional evidence submitted by the CW–1 petitioner. If all information found in the Form I–129CW is consistent with the TLC, and provided all other eligibility requirements are met, then USCIS may approve the Form I–129CW and use the SOC code listed on the petition to identify the petitions set aside for the cap reservation. If the SOC code is blank or if the evidence submitted with the Form I–129CW does not establish that the proposed employment matches the SOC code listed on the petition, USCIS may request additional information. In determining whether the proposed employment matches the listed SOC code, USCIS considers factors including but not limited to the job duties and responsibilities of the proposed employment, and any educational, experience, and/or training requirements. If USCIS finds a mismatch between the SOC code on the Form I–129CW and the TLC, or finds conflicting information in the Form I–129CW and TLC, then USCIS may consider such information to deny or revoke the Form I–129CW.[33]

USCIS already collects the SOC code on the Form I–129CW to help administer the statutory prohibition of construction occupations.[34] This IFR adopts this same approach of using the SOC code to help USCIS properly identify the occupations for which a portion of the CW–1 numerical limitation is reserved. However, it is noted that the occupational categories related to the operations of the CNMI public utilities may not be able to be properly limited or defined to specific corresponding SOC codes. For example, there is not a specific SOC code for ''Trades Technicians.'' Rather, there are a large number of SOC codes which could potentially be used to describe a number of different technicians. For this occupation, it is not practical to include every possible code that would be eligible for the CW–1 cap reservation. As a result, this IFR includes a single SOC code for the specific occupational category related to the operations of the CNMI public utilities services, if known, but does not limit this CW–1 cap reservation only to the included SOC codes.

Accordingly, this IFR makes the following reservations of CW–1 numbers for specified occupational categories: (i) 200 total for occupational categories 29–0000 (Healthcare Practitioners and Technical Occupations) and 31–0000 (Healthcare Support Occupations); and (ii) 60 for occupational categories related to the operations of the CNMI public utilities services, to include, but not limited to, 17–2081 (Water/Waste Water Engineers), 17–2071 (Electrical Engineers), 17–2141 (Mechanical Engineers), and Trades Technicians.[35] New 8 CFR 214.2(w)(1)(x)(D)(*1*). The reserved CW–1 numbers will be made available to eligible petitioners requesting such numbers for a fiscal year in order of filing until exhausted. New 8 CFR 214.2(w)(1)(x)(D)(*2*). DHS will not impose an arbitrary deadline for petitioners to exhaust this cap reservation as it would be contrary to the CNMI government's request to preserve access to labor in these critical occupations. As a result, unused reserved numbers for these occupational categories will not be available to other petitioners. *Id.* Accordingly, DHS is also updating the Form I–129CW to include a new data field on the Form I–129CW requesting whether the petitioner would like to be considered under one of the occupational category reservations. This approach is consistent with the Governor's request to reserve CW–1 numbers for specified occupations.

This new CW–1 cap reservation will not apply to any fiscal year cap that has been reached prior to the effective date of this IFR. For any fiscal year cap that has not been reached as of the date this IFR takes effect, the CW–1 cap reservation will be considered completely unsubscribed at that time and will only be filled by petitions received on or after such date that specifically request consideration under the Governor's recommendations in the corresponding data field on the Form I–129CW.

As noted above, the Governor also recommended that any CW–1 cap reservation should be subject to change based on labor demand and requested the ability to recommend changes to

[30] *See* U.S. Department Labor, Bureau of Labor Statistics, Standard Occupational Classification, available at *https://www.bls.gov/soc/* (last visited May 28, 2019).

[31] The Office of Management and Budget is charged by statute with coordinating the U.S. Federal statistical system. All workers are classified into one of 867 detailed occupations according to their occupational definition. To facilitate classification, detailed occupations are combined to form 459 broad occupations, 98 minor groups, and 23 major groups. Detailed occupations in the SOC with similar job duties, and in some cases skills, education, and/or training, are grouped together. For an overview, *see* ''Office of Management and Budget, Statistical Programs & Standards,'' available at *https://www.whitehouse.gov/omb/information-regulatory-affairs/statistical-programs-standards/* (last visited May 28, 2019).

[32] *See* Instructions for Form I–129CW, Petition for a CNMI-Only Nonimmigrant Transitional Worker, available at *https://www.uscis.gov/i-129cw* (last visited May 28, 2019).

[33] USCIS generally defers to DOL to determine the correct SOC code for purposes of the TLC. Nevertheless, USCIS maintains the authority to consider the SOC code as one basis for purposes of adjudicating the Form I–129CW.

[34] In fiscal year 2017, DHS also used the SOC codes to identify CW–1 health care workers to manage the statutory sub-cap for healthcare workers.

[35] A corresponding SOC code does not exist that would include all Trades Technicians occupations.

these CW–1 cap reservations throughout the duration of the transition period. DHS agrees with the Governor's recommendation that any CW–1 cap reservation should be adjustable to future labor market needs, in light of the declining number of CW–1 visas available in future years. As such, this IFR, per new 8 CFR 214.2(w)(1)(x)(D)(*3*), provides that DHS may adjust the reservation of numbers for specified occupational categories for a fiscal year or other period via notice in the **Federal Register**, as long as such adjustment is consistent with the numerical limitations set forth by statute and as updated in new 8 CFR 214.2(w)(1)(x)(A) for FY 2018 through the first quarter of FY 2030. DHS may adjust this CW–1 cap reservation in future years following consideration of a range of factors, including, but not limited to, demand for the reservation of numbers and if any reservation resulted in unused permits, the overall numerical decreases in permits in future years, and any recommendation received from the Governor of the CNMI relating to CNMI labor market needs, consistent with the Workforce Act and this IFR. This will provide DHS with the flexibility to make future adjustments to the CW–1 cap reservation in response to the CNMI's labor workforce needs and to the decreasing yearly caps.

C. U.S. Department of Labor, Temporary Labor Certification Requirement

The current DHS CW–1 regulations do not require that an employer obtain any documentation from DOL as a prerequisite to filing a CW–1 petition with USCIS. The Workforce Act changed petition procedures by imposing a temporary labor certification requirement beginning with CW–1 petitions filed with USCIS with employment start dates in FY 2020.[36] *See* 48 U.S.C. 1806(d)(2)(A)(i). Now, as a prerequisite to filing a CW–1 petition with USCIS, an employer must first obtain an approved TLC from DOL confirming that: (1) There are not sufficient United States workers in the CNMI who are able, willing, qualified, and available at the time and place needed to perform the services or labor involved in the petition; and (2) the employment of a nonimmigrant worker who is the subject of a petition will not adversely affect the wages and working conditions of similarly employed United States workers. *See* 48 U.S.C. 1806(d)(2)(A).

To ensure that the CW–1 employment will not adversely affect similarly employed United States workers' wages and working conditions, the Workforce Act also mandates minimum wage requirements. Specifically, it requires the employer to pay a CW–1 worker the greater of the CNMI minimum wage, the federal minimum wage, or the prevailing wage as determined by DOL. 48 U.S.C. 1806(d)(2)(C). It requires DOL to make a prevailing wage determination, by allowing DOL to meet this requirement in a number of ways. 48 U.S.C. 1806(d)(2)(B). DOL will use or make available to employers annual occupational wage surveys conducted by the Governor meeting the statistical standards established by DOL for determining prevailing wages in the CNMI. 48 U.S.C. 1806(d)(2)(B)(i). In the absence of a DOL-approved Governor's survey, the Workforce Act sets forth that the prevailing wage for an occupation in the CNMI is the arithmetic mean of the wages of workers similarly employed in the territory of Guam according to the Occupational Employment Statistics Survey conducted by DOL's Bureau of Labor Statistics. 48 U.S.C. 1806(d)(2)(B)(ii).

Consistent with the Workforce Act, DOL administers these additional labor protections and has issued a separate regulation[37] governing the TLC process, but this IFR updates DHS regulations to include the new TLC requirement at 8 CFR 214.2(w)(6)(iv) as a prerequisite to filing a CW–1 petition with USCIS. Any CW–1 petition requesting an employment start date on or after October 1, 2019 must be filed with a DOL approved TLC. The certified TLC confirms that there are not sufficient United States workers in the CNMI who are able, willing, qualified, and available at the time and place needed to perform the services or labor involved in the petition, and that the employment of the CW–1 nonimmigrant will not adversely affect the wages and working conditions of similarly employed United States workers. Any petition filed without the approved DOL TLC will be rejected. If the TLC approves certain education, training, experience, or special requirements, USCIS will further require sufficient evidence to determine whether the CW–1 worker qualifies for the job offer. The IFR also updates 8 CFR 214.2(w)(6)(ii)(I) to include the related minimum wage statutory requirements.

D. CW–1 Petition Filing Window

The Workforce Act sets forth new CW–1 petition filing windows for employers renewing the permits of their CW–1 workers and for those requesting new CW–1 workers. It provides that employers renewing the permits of their CW–1 employees can file 180 days before the expiration of current CW–1 status. Employers filing for new CW–1 employment authorization may file no more than 120 days prior to the need for such employment. 48 U.S.C. 1806(d)(3)(D)(i).

To adhere to this filing window, it is important to note again that, a CW–1 petition for temporary employment filed with USCIS must be accompanied by an approved TLC from DOL. 48 U.S.C. 1806(d)(2). This prerequisite does not change the statutory filing window. Under DOL regulations at 20 CFR 655.420 (b)(1), an employer seeking to hire a CW–1 worker must first apply for a TLC with DOL, no more than 120 calendar days before the employer's date of need. However, where the employer is seeking a TLC to support a petition to renew a visa (extending the employment of a CW–1 worker), 20 CFR 655.420(b)(2) requires that the employer file the TLC application no more than 180 calendar days before the date on which the CW–1 status expires. Once DOL approves the TLC, the employer can file the CW–1 petition with USCIS.

E. Semiannual Report for CW–1 Employers

The Workforce Act prescribes that DHS shall establish a system for each CW–1 employer to submit a semiannual report to the Secretary of Homeland Security and the Secretary of Labor that provides evidence to verify the continuing employment and payment of such worker under the terms and

[36] On September 24, 2019, USCIS announced it was providing a one-time, limited accommodation to facilitate the initial implementation of the new requirement that CW–1 petitions with employment start dates on or after October 1, 2019 include a TLC approved by DOL. USCIS would consider certain FY 2020 CW–1 petitions seeking an extension of status for temporary workers present in the CNMI to be filed on time, even if USCIS received them after the worker's current period of CW–1 petition validity expires, under the following limited circumstances: (1) The petition was otherwise properly filed, and included an approved TLC with a start date on or after October 1, 2019; (2) USCIS received the petition no later than 30 days after the date of TLC approval, or by November 1, 2019, whichever was earliest; and (3) the expiration date of the currently approved petition was on or after September 1, 2019. If an employer filed an extension petition meeting these requirements, the CW–1 worker could continue employment with the same employer for up to 240 days beginning on the expiration of the authorized period of stay, pending adjudication of the petition (or, in the case of a non-frivolous petition for extension of stay with change of employer, until USCIS adjudicates the petition). *See* USCIS, Filing Guidance for CW–1 Petitions Seeking to Extend Status for Fiscal Year 2020, *https://www.uscis.gov/news/alerts/filing-guidance-cw-1-petitions-seeking-extend-status-fiscal-year-2020* (Last Reviewed/Updated Sept. 24, 2019).

[37] The DOL IFR was published on April 1, 2019, and went into effect on April 4, *See* Labor Certification Process for Temporary Employment in the Commonwealth of the Northern Mariana Islands (CW–1 Workers), 84 FR 12380 (Apr. 1, 2019).

conditions set forth in the CW–1 petition that the employer filed on behalf of such worker. 48 U.S.C. 1806(d)(3)(D)(ii). In order to implement the semiannual reporting requirement, USCIS created a standalone form, the Form I–129CWR, Semiannual Report for CW–1 Employers (semiannual report). USCIS is requiring petitioners to file the semiannual report, with a required attestation, in order to capture data to verify the continued employment and payments to their CW–1 workers. *See* new 8 CFR 214.2(w)(26)(i) and (ii).

In accordance with the Workforce Act's reporting requirement, all approved CW–1 petitioners must file a semiannual report. USCIS interprets this as a filing requirement for all approved CW–1 petitioners, whose petitions have been approved for a validity period of six months or more, to be submitted during the petition's validity period. An approved CW–1 petition may be approved for a period of up to one year, unless the beneficiary is a long-term worker, in which case an approved petition will be valid for a period of up to three years. As a result, CW–1 petitions have varying validity periods, as petitioners can request the entire validity period available or any shortened period of time necessary for the employment opportunity. USCIS will use the semiannual report to verify the continuing employment and payment of such workers, on a semiannual basis, whether the CW–1 petitioner is requesting a validity period of up to 1 year or up to 3 years. Under 8 CFR 214.2(w)(26)(i)(A), an employer whose CW–1 petition has been approved for an employment start date on or after October 1, 2019 and for a validity period of six months or more, must file a semiannual report every six months after the petition validity start date up to and including the sixth month preceding the petition's validity end date. As such, a CW–1 petition approved for a validity period of 1 year requires the filing of a single semiannual report while a CW–1 petition approved for a validity period of 3 years requires the filing of 5 semiannual reports. The semiannual report must be filed within a 60 day window surrounding each six-month anniversary of the petition validity start date, with the filing window opening 30 days before and closing 30 days after the six-month anniversary of the petition validity start date.

This form creates a streamlined approach for easy USCIS intake while creating targeted data requests to ensure that USCIS captures the information necessary for verification of the CW–1 employment. Data fields include information to verify what was approved on the petition versus the actual terms under which the CW–1 is employed. For example, the form requests information on how many CW–1 beneficiaries were approved on the original petition; how many of the approved beneficiaries remain in CW–1 status and are still working for the petitioner; the wage offered, per week or year, on the approved Form I–129CW versus the actual wage, per week or per year, currently paid to the CW–1 workers; and the hours per week, offered on the approved Form I–129CW versus the actual hours worked per week. Petitioners can file one form to report the information on multiple beneficiaries as long as they were approved on the same petition.

Although this IFR does not require submission of evidence at the time of filing the semiannual report, it does contain an attestation of compliance for the petitioner to affirm, under penalty of perjury, the continuing employment and payment of the CW–1 worker under the terms and conditions set forth in the petition. The attestation serves as initial evidence to USCIS regarding the petitioner's continued eligibility as a CW–1 petitioner.

In addition, although there is no requirement to submit evidence, the regulations are revised to add a new document retention requirement at 8 CFR 214.2(w)(26)(iii). In accordance with these requirements, the petitioner must retain documents and records meeting their burden to demonstrate compliance with this rule, and must provide the documents and records upon the request of DHS or DOL, such as in the event of an audit or investigation. An employer must retain evidence that supports the approved petition and semiannual report including, but not limited to: (a) Personnel records for each CW–1 worker including the name, current residence address in the Commonwealth, age, domicile, citizenship, point of hire, and approved employment contract termination date; (b) Payroll records for each CW–1 worker, including the O*NET job classification wage rate or salary, number of hours worked each week, gross compensation, itemized deductions, and evidence of net payments made and received biweekly; and (c) Direct evidence of payment of wages and overtime, such as receipts for cash payments, cancelled checks or deposit records of payment of wages and overtime. Petitioners must retain all documents and records in support of an approved petition and any semiannual report(s) for a period of three years after the ending date of the petition validity period. If requested, petitioners must provide the documents and records supporting the information in the approved petition and the semiannual report to DHS and DOL at any time during the aforementioned retention period. The document retention is necessary from an investigative perspective as the information collected may be used in conjunction with any site visits conducted by DHS or requests for additional evidence to verify compliance. Per 8 CFR 214.2(w)(26)(ii), DHS may provide such semiannual reports to other federal partners, including DOL for investigative or other use as DOL may deem appropriate. Failure to comply with the semiannual report requirement may be a basis for revocation of an approved petition as provided below or for denial of subsequent petitions filed by the employer.

To ensure fairness and equal footing among CW–1 petitioners in the application of this statutory requirement, this IFR establishes that the semiannual report shall be required beginning with all CW–1 petitions approved by USCIS with employment start dates in FY 2020 for a validity period of six months or more. The semiannual reporting requirement will apply to CW–1 petitions with such employment start dates approved by USCIS before the effective date of this IFR and before the requirement was stated in the instructions for the CW–1 petition. Completion of the report will rely on readily attainable facts by the petitioner that are based on the terms and conditions previously set forth in the CW–1 petition. Requiring the semiannual report for all CW–1 petitions approved by USCIS with employment start dates in FY 2020 for a validity period of six months or more ensures uniform compliance with the statutory requirement by requiring the submission of the same information across the same period of time, and will avoid data gaps and incomplete information collections for the initial FY 2020 reporting period.

F. Revocations

The Workforce Act provides the Secretary discretionary authority to revoke a petition approval for good cause and provides a non-exhaustive list of examples that may serve as a basis for revocation, such as: The employer failing to maintain the continuous employment of the CW–1 worker, failing to pay the CW–1 worker, or failing to timely file a semiannual report; if the employer commits any other violation of the terms and

conditions of employment, or otherwise ceases to operate as a legitimate business; if the beneficiary of such petition does not apply for admission to the CNMI by the date that is 10 days after the period of petition validity begins, if the employer has requested consular processing; or if the employer fails to provide a former, current, or prospective CW–1 worker with the original (or a certified copy of the original) of all petitions, notices, and other written communication related to the worker (other than sensitive financial or proprietary information of the employer, which may be redacted) that has been exchanged between the employer and the DOL, DHS, or any other Federal agency or department. *See* 48 U.S.C. 1806(d)(3)(D)(iii)(I).

The Workforce Act also authorizes the Secretary to reallocate a revoked permit to the following fiscal year. *See* 48 U.S.C. 1806(d)(3)(D)(iii)(II). Pursuant to section 3(b)(3) of the Workforce Act,[38] Governor Torres submitted comments and recommendations to DHS on the implementation of this revocation provision.[39] On the statutory revocation provision, the Governor expressed concern with a specific statutory provision, allowing for revocation of a permit if the petition was approved for consular processing and the beneficiary does not apply for admission to the CNMI during the ten day period after the start date of petition validity. He requested that DHS delay the implementation of the statutory revocation provision until the U.S. Department of State's role in this process is established or alternatively, that the provision be interpreted and implemented so that it does not immediately disqualify admission into the CNMI if all other petition criteria are met. The Governor stated that consular processing delays, which are outside the control of employers, may lead to petition revocations and this would be detrimental to the CNMI business community.[40]

In accordance with the Workforce Act, DHS has considered the Governor's recommendations in the development of this regulation. The Workforce Act is clear that petition revocation is within the Secretary's discretionary authority and therefore does not mandate automatic revocation pursuant to any of the listed grounds. However, in considering how to implement the revocation authority based on ''good cause,'' including for any of the examples specified in the Workforce Act, DHS examined the revocation procedures already in place for other nonimmigrant classifications. For example, the H classification revocation procedures at 8 CFR 214.2(h)(11)(ii) include immediate and automatic revocation if the petitioner goes out of business or files a written withdrawal of the petition, or DOL revokes the temporary labor certification upon which the petition is based. Similarly, the provisions relating to the H classification at 8 CFR 214.2(h)(11)(iii) provide for revocation on notice and issuance of a NOIR on certain grounds, which are tied to elements specified in the petition. These procedures provide for a NOIR if the beneficiary is no longer employed by the petitioner in the capacity specified in the petition, or the beneficiary is no longer receiving training as specified in the petition; the statement of facts contained in the petition or on the application for a temporary labor certification was not true and correct, inaccurate, fraudulent, or misrepresented a material fact; the petitioner violated terms and conditions of the approved petition; the petitioner violated requirements of section 101(a)(15)(H) of the INA or 8 CFR 214.2(h); or the approval of the petition violated related regulations or involved gross error. *Id.*

The Workforce Act does not provide specific procedural requirements for implementation but DHS is closely mirroring existing revocation procedures already in place for other nonimmigrant classifications.[41] Under new 8 CFR 214.2(w)(27)(i), the petitioner must immediately notify USCIS of any changes in the terms and conditions of employment of a beneficiary which may affect eligibility. If the petitioner continues to employ the beneficiary, it must notify USCIS of these changes on an amended Form I–129CW petition. If the petitioner no longer employs the beneficiary, the petitioner shall send a letter to the office at which the CW–1 petition was filed explaining the basis on which the specific CW–1 nonimmigrant is no longer employed.

Under 8 CFR 214.2(w)(27)(ii), a petition will be immediately and automatically revoked if the petitioner ceases operations or files a written withdrawal of the petition, or if DOL revokes the temporary labor certification upon which the petition is based. Under 8 CFR 214.2(w)(27)(iii), USCIS will also pursue discretionary NOIRs in a manner that mirrors the existing H classification grounds for revocation on notice and for additional elements listed in the Workforce Act. Specifically, under 8 CFR 214.2(w)(27)(iii)(A), USCIS may, in its discretion, send the petitioner a NOIR for good cause, including if it finds that:

(1) The beneficiary is no longer employed by the petitioner in the capacity specified in the petition;

(2) The petition or the application for a temporary labor certification was not true and correct, inaccurate, fraudulent, or misrepresented a material fact;

(3) The petitioner violated terms and conditions of the approved petition;

(4) The petitioner violated a requirement of 8 CFR 214.2(w);

(5) The approval of the petition violated 8 CFR 214.2(w) or involved gross error;

(6) The petitioner failed to maintain the continuous employment of the CW–1 nonimmigrant, failed to pay the nonimmigrant, failed to timely file a semiannual report, committed any other violation of the terms and conditions of employment, or otherwise ceased to operate as a legitimate business;

(7) The beneficiary did not apply for admission to the CNMI within 10 days after the beginning of the petition validity period if the petition has been approved for consular processing; or

(8) The employer failed to provide a former, current, or prospective CW–1 nonimmigrant, not later than 21 business days after a written request from such individual, with the original (or a certified copy of the original) of all petitions, notices, and other written communication related to the worker (other than sensitive financial or proprietary information of the employer

[38] As stated in sec. 3(b)(3), the Secretary shall consider, in good faith, any written public recommendations regarding the implementation of this Act that are submitted by the CNMI Governor and may include provisions in the IFR that are responsive to any recommendation of the Governor that is not inconsistent with the Workforce Act.

[39] *See* Letter from Rafael DLG Torres, Governor of the CNMI, to Kirstjen Nielsen, Secretary, DHS (Sept. 18, 2018), available at *http://www.regulations.gov* under DHS Docket No. USCIS–2019–0003.

[40] While the Governor's letter does not mention concerns regarding admission, it is important to note that the statutory basis for revocation is tied to admission, and therefore to U.S. Customs and Border Protection's (CBP) role, rather than to visa issuance. That said, delays in consular processing of visas with DOS would inherently delay any admission by CBP.

[41] For example, provisions related to the O and P classifications also provide for immediate and automatic revocation if the petitioner or employer goes out of business, or files a written withdrawal of the petition, or notifies USCIS that the beneficiary is no longer employed by the petitioner. *See* 8 CFR 214.2(o)(8)(ii) and 8 CFR 214.2(p)(10)(ii). The R classification regulations include immediate and automatic revocation if the petitioner ceases to exist or files a written withdrawal of the petition. *See* 8 CFR 214.2(r)(18)(ii). As with the H classifications, the O, P, and R regulations also provide for revocation on notice and issuance of a NOIR on certain elements specified in the petition. *See* 8 CFR 214.2(o)(8)(iii), 8 CFR 214.2(p)(10)(iii), and 8 CFR 214.2(r)(18)(iii). However, these classifications do not require an approved TLC as a prerequisite to filing the petition with USCIS.

which may be redacted) that has been exchanged between the employer and DOL, DHS, or any other Federal agency or department.

Under 8 CFR 214.2(w)(27)(iii)(B), the NOIR will state the grounds for the revocation. The petitioner may submit evidence in rebuttal within 30 days of receipt of the notice. USCIS may revoke the petition in whole or in part. There is no appeal of an automatic revocation. Under 8 CFR 214.2(w)(28), revocations on notice may be appealed under existing appeal procedures in 8 CFR 103.

The grounds listed in 8 CFR 214.2(w)(27)(iii) provide clear guidelines for the program consistent with the Workforce Act. The new 8 CFR 214.2(w)(27) creates automatic revocation grounds for clear-cut scenarios, consistent with other nonimmigrant classifications, allows for revocation for good cause, and specifies the statutory grounds for instituting revocation-on-notice proceedings while providing petitioners with notice and an opportunity to cure any deficiencies. For each beneficiary of a petition revoked, entirely or in part in a fiscal year, USCIS will add a CW–1 cap number to the next fiscal year and inform the public as appropriate. *See* new 8 CFR 214.2(w)(1)(x)(C). These new revocation provisions shall apply to all CW–1 petitions approved by USCIS or that otherwise remain valid as of the effective date of this IFR.

G. Definition of Legitimate Business

The Workforce Act retains the regulatory definition of a ''legitimate business'' [42] as set forth in 8 CFR 214.2(w)(1)(vi), and adds an E-Verify requirement. 48 U.S.C. 1806(d)(3)(D)(iv). Further, it states that a CW–1 petition may not be approved for a CW–1 employer that is not a legitimate business. *Id.* While The Workforce Act authorizes the Secretary to determine what constitutes a legitimate business, it also specifically defines the term ''legitimate business'' as a real, active, and operating commercial or entrepreneurial undertaking that the Secretary determines, in the Secretary's sole discretion: Produces services or goods for profit, or is a governmental, charitable, or other validly recognized nonprofit entity; meets applicable legal requirements for doing business in the CNMI; has substantially complied with wage and hour laws, occupational safety and health requirements, and all other Federal, CNMI, and local requirements related to employment during the preceding 5 years; does not directly or indirectly engage in, or knowingly benefit from, prostitution, human trafficking, or any other activity that is illegal under Federal, CNMI, or local law; and is a participant in good standing in the E-Verify program. *Id.* Further pursuant to The Workforce Act, a ''legitimate business'' must not have, as a current or former owner, investor, manager, operator, or person meaningfully involved with the undertaking, who has not substantially complied with wage and hour laws, occupational safety and health requirements, and all other Federal, Commonwealth, and local requirements related to employment during the preceding 5 years; or who directly or indirectly engages in, or knowingly benefits from, prostitution, human trafficking, or any other activity that is illegal under Federal, Commonwealth, or local law. *Id.* Also under the Workforce Act, a ''legitimate business'' must not be the agent of such an individual, or a successor in interest to an undertaking that does not comply with such requirements. *Id.*

This IFR incorporates the revised definition of legitimate business into 8 CFR 214.2(w)(1)(vii) to include the new E-Verify requirement and successor in interest prohibitions. Pursuant to 48 U.S.C. 1806(d)(3)(D)(iv), only legitimate businesses may petition for a CW–1 employer. The statutory definition of a legitimate business, among other things, requires CW–1 employers to be a participant in good standing in the E-Verify program as a prerequisite for filing for a CW–1 worker. This IFR implements the Workforce Act's E-Verify requirement for CW–1 employers at 8 CFR 214.2(w)(1)(vii)(E) and provides a definition of a participant in good standing for E-Verify purposes at 8 CFR 214.2(w)(1)(xii).

The E-Verify program is a web-based system that allows enrolled employers to confirm the eligibility of their employees to work in the United States.[43] E-Verify employers verify the identity and employment eligibility of newly hired employees by electronically matching information provided by employees on the Form I–9, Employment Eligibility Verification, against records available to DHS and SSA. While E-Verify is a voluntary program, some employers are required to enroll in it as a condition of federal contracting, or a result of state legislation or other applicable law.

Before an employer can participate in the E-Verify program, the employer must enter into a Memorandum of Understanding (MOU) with DHS. By executing the MOU, employers agree to abide by lawful hiring requirements and to follow the E-Verify process to prevent unauthorized disclosure of personal information and unlawful discriminatory practices based on national origin or citizenship status. Specifically, in the MOU, the employer agrees not to use E-Verify for pre-employment screening of job applicants or in support of any unlawful employment practice. The employer further agrees to comply with Title VII of the Civil Rights Act of 1964 and section 274B of the INA, 8 U.S.C. 1324b, by not discriminating unlawfully against any individual in hiring, firing, employment eligibility verification, or recruitment or referral practices because of his or her national origin or citizenship status, or by committing discriminatory documentary practices. Illegal practices can include selective verification, improper use of E-Verify, or discharging or refusing to hire employees because they appear or sound ''foreign'' or have received tentative non-confirmations. The MOU also makes clear that USCIS may suspend or terminate an employer's access to E-Verify if the employer violates Title VII or section 274B of the INA, 8 U.S.C. 1324b, fails to follow required verification procedures, or otherwise fails to comply with E-Verify requirements. Any employer who violates the immigration-related unfair employment practices provisions in section 274B of the INA could face civil penalties, including back pay awards. Employers who violate Title VII face potential back pay awards, as well as compensatory and punitive damages. Under the MOU, employers who violate either section 274B of the INA or Title VII may have their participation in E-Verify terminated. DHS may also immediately suspend or terminate the MOU, and thereby the employer's participation in E-Verify, if DHS or the SSA determines that the employer failed to comply with established E-Verify procedures or requirements. In sum, violation of the terms of this agreement

[42] The ''legitimate business'' definition set forth in the CNRA was incorporated into DHS CW transitional worker regulations via the final rule, published on September 7, 2011. 76 FR 55502 (Sept. 7, 2011). On December 16, 2014, Congress amended the law to extend the transition period until December 31, 2019. *See* Consolidated and Further Continuing Appropriations Act, 2015.

Public Law 113–235, sec. 10, 128 Stat. 2130, 2134 (codified at 48 U.S.C. 1806(d)). Congress also eliminated the Secretary of Labor's authority to provide for future extensions of the CW–1 program, requiring the CW–1 program to end (or sunset) on December 31, 2019. Public Law 113–235 removed section (d)(5), the DOL extension provision, which is where the definition of legitimate business was contained in the original Act.

[43] *See* E-Verify, available at *https://www.e-verify.gov/* (last visited May 28, 2019).

by the employer is grounds for immediate termination of its participation in the program.[44]

Employers participating in E-Verify must still complete a Form I–9 for each newly hired employee, as required under current law.[45] Following completion of Form I–9, the employer must enter the newly hired worker's information into E-Verify, which then checks that information against information contained in government databases.[46] It is important to note that once an employer enrolls in E-Verify, that employer is responsible for verifying all new hires in E-Verify, at the hiring site(s) identified in the MOU executed between the employer and DHS.[47] The earliest an employer may use E-Verify with respect to an individual is after the individual accepts an offer of employment and the employee and employer complete the Form I–9.[48] Verification of the employee's identity and employment eligibility and creating the E-Verify case must be done no later than the end of three business days after the new hire's first day of employment. E-Verify applies to new hires only and cannot be used to verify expiring work authorization of a current employee (including CW–1 employees).

While participation in E-Verify is a new requirement for CW–1 employers, it is not a new requirement for certain employers that are required to enroll in it as a condition of federal contracting, or a result of state legislation or other applicable law. It is also a requirement for employers of certain nonimmigrants. For example, employers of certain F–1 students with science, technology, engineering, or mathematics (STEM)[49] degrees are subject to E-Verify requirements. Employers of these nonimmigrants must remain participants in good standing in the E-Verify program, as determined by USCIS in its discretion.[50] While the requirements of the program are clearly defined in the MOU and related guidance, DHS has not expressly defined ''participant in good standing'' in the regulations applicable to that program.[51]

An explicit definition of this term, applicable exclusively to the context of CW–1 adjudication, will provide greater transparency for CW–1 employers as to their responsibilities as E-Verify participants. Defining ''participant in good standing'' will also help USCIS more closely monitor employer compliance with E-Verify requirements for CW–1 employers throughout the period of participation with E-Verify. Under new 8 CFR 214.2(w)(1)(xii), which is limited to CW–1 petitioners, a participant in good standing in the E-Verify program means an employer that has enrolled in E-Verify with respect to all hiring sites in the United States as of the time of filing a petition; is in compliance with all requirements of the E-Verify program as identified in the MOU and program guidance, including but not limited to verifying the employment eligibility of newly hired employees in the United States; and continues to be a participant in good standing in E-Verify at any time during which the employer employs any CW–1 nonimmigrant. Accordingly, the Form I–129CW is updated to include a new data field on the Form I–129CW to capture the employer's E-Verify information (employer's name as listed in E-Verify, along with the E-Verify Company Identification Number).

This rule requires participating employers to have enrolled in E-Verify with respect to all hiring sites in the United States. DHS had other options for implementing the E-Verify requirement. DHS could require enrollment only for work at the specific worksite, could require E-Verify across hiring sites in the CNMI only, or could require that the employer enroll in E-Verify for all its worksites. Under current procedures, applicable to voluntary E-Verify participation, an employer can choose which hiring sites will participate in E-Verify, and each employer has the ability to organize or incorporate itself as it chooses and enroll as that chosen entity in E-Verify.[52] While the Workforce Act was silent on this issue, and while any of the above interpretations are reasonable, Congress could have specified the reach of the E-Verify requirement or could have simply limited such participation in statute, but it did not provide any limits on the requirement.

The Workforce Act's definition of ''legitimate business'' states that determinations regarding whether an employer is a ''legitimate business'' are ''in the Secretary's sole discretion,'' thus demonstrating Congressional intent that this authority would be exercised flexibly, as deemed appropriate by DHS. The definition of ''legitimate business,'' which contains the E-Verify participation requirement, also contains multiple elements that relate to an employer's operations in the CNMI, as well as activities in the United States outside of the CNMI. In particular, the business must have substantially complied with all Federal laws relating to employment, and not to have engaged in or benefited from activities such as human trafficking or any other activity that is illegal under Federal law. If, for example, a business complied with laws related to its CNMI operations, but was engaged in human trafficking in Guam or elsewhere in the United States, the employer would not be a legitimate business under this definition.

With respect to the E-Verify requirement, if it were limited to new hires at hiring sites in the CNMI only, the rule would be impractical for DHS to manage and too easy for an employer to undermine because an employer could avoid enrolling a non-CNMI work site in E-Verify. Not all hires of an employer are hired through the location where they work. It is very common for an employer to hire through a central site that has no connection to various work sites. In addition, there are few employers who have segregated their workforces to have no interaction with other worksites. Modern technology, most notably electronic messaging, has

[44] *See* E-Verify, Employers, Enrolling in E-Verify: The E-Verify Memorandum of Understanding for Employers, available at *https://www.e-verify.gov/sites/default/files/everify/memos/MOUforEVerifyEmployer.pdf* (last visited May 28, 2019).

[45] *See* E-Verify, Employers, Monitoring and Compliance available at *https://www.e-verify.gov/employers/monitoring-and-compliance* (last visited May 28, 2019).

[46] *See id.* For example, E-Verify compares employee information against records in the SSA database and those available to DHS. Most employees are automatically confirmed as work authorized. In Fiscal Year Q3 2018 (Oct. 2017–June 2018), the E-Verify program processed a total of 27,357,051 cases. During this same time period, 98.88 percent of employees were automatically confirmed as authorized to work (''work authorized'') either instantly or within 24 hours, requiring no employee or employer action. *See* E-Verify, About E-Verify, E-Verify Data, E-Verify Performance available at *https://www.e-verify.gov/about-e-verify/e-verify-data/e-verify-performance* (last visited May 28, 2019).

[47] *Id.*

[48] *Id.*

[49] *See* 8 CFR 214.2(f)(10)(ii)(C)(5).

[50] *See* 8 CFR 214.2(f)(10)(ii)(C)(5) and 8 CFR 274a.12(b)(21).

[51] *But see* 81 FR 13039, 13082 (Mar. 11, 2016) (interpreting the participant in good standing requirement to apply to a specific hiring site or work site).

[52] See the Benefit Analysis Issues discussion in the E-Verify FAR Case 2007–013 at 73 FR 67651, 67689 (Nov. 14, 2008). The ''E-Verify User Manual for Corporate Administrators'' defines hiring sites as follows: ''2.1.1 HIRING SITES A hiring site is the location where the employer hires employees and they complete Form I–9. If your company creates cases in E-Verify at the same location, it is a verification location and a hiring site. Employers select which sites participate in E-Verify on a hiring site by hiring site basis. This means that if you decide to have a hiring site participate in E-Verify, you must verify all newly hired employees for that hiring site. If you decide not to have a hiring site participate, you are not permitted to verify any employees at that location.'' Available at *https://www.e-verify.gov/e-verify-user-manual-for-corporate-administrators-20-company-location-administration-21* (last visited June 26, 2019).

broadened and facilitated doing work in multiple dispersed locations through a national and even international network of collaborators. For example, an employer could hire an employee through a hiring site in Guam and then station that person in the CNMI, thereby circumventing the E-Verify requirement. Thus, narrowly defining the verification requirement would be too unwieldy for an effective rule, making enforcement of this aspect of the rule too difficult and making the rule too easy to misinterpret or undermine, such as in situations as the above example illustrated, the employer can merely hire an employee at one hiring site and then transfer him/her to a worksite in the CNMI. Consequently, DHS believes it is reasonable to take a more expansive interpretation to fully support increased participation.

DHS's more expansive interpretation is also consistent with Executive Order (E.O.) 13788, ''Buy American Hire American'',[53] which among other elements, directs the Secretary of Homeland Security, ''to protect the interests of U.S. workers in the administration of our immigration system, including through the prevention of fraud or abuse.'' See E.O. 13788 Section 5(a). A main purpose of E-Verify is to ensure that U.S. employers hire only people who are legally permitted to work. This interpretation directly supports the E.O. by requiring that CW–1 employers use E-Verify to confirm the employment eligibility of their new employees at all hiring sites in the United States to ensure the integrity of the immigration system and preserve jobs for U.S. workers.

Under this IFR, a CW–1 employer will need to enroll and participate in E-Verify with respect to all of its hiring sites, to include the CNMI and other locations in the rest of the United States, as of the time of filing a petition. A hiring site is the location where the employer hires employees and they complete Form I–9.[54] This means that the CW–1 employer must select all hiring sites to participate in E-Verify so that the employer can verify all newly hired employees for all hiring sites. The Workforce Act further bars petitioners that have not substantially complied with wage and hour laws, occupational safety and health requirements, and all other Federal, Commonwealth, and local requirements related to employment during the preceding 5 years and that have directly or indirectly engaged in, or knowingly benefitted from, prostitution, human trafficking, or any other activity that is illegal under Federal, Commonwealth, or local law. Notably, the current regulatory definition mentioning trafficking in minors will be amended to the more expansive term, human trafficking. These statutory changes to the legitimate business definition also cast a wider net by expanding the population it covers by extending these prohibitions to any ''successor in interest.'' This IFR, consistent with DOL's implementing interim regulation for the Workforce Act,[55] defines successor in interest at 8 CFR 214.2(w)(1)(xiv) as an employer that is controlling and carrying on the business of a previous employer. The following factors may be considered in determining whether an employer is a successor in interest; no one factor is dispositive, but all of the circumstances will be considered as a whole to have:

- Substantial continuity of the same business operations;
- Use of the same facilities;
- Continuity of the work force;
- Similarity of jobs and working conditions;
- Similarity of supervisory personnel;
- Whether the former management or owner retains a direct or indirect interest in the new enterprise;
- Similarity in machinery, equipment, and production methods;
- Similarity of products and services; and
- The ability of the predecessor to provide relief.

H. Long-Term Workers

The Workforce Act creates a new subcategory of CW–1 workers. Per statute, a long-term worker is one who was admitted to the CNMI as a CW–1 nonimmigrant during FY 2015, and who was granted CW–1 nonimmigrant status, as defined by DHS, during each of FYs 2016 through 2018. 48 U.S.C. 1806(d)(7)(B). As provided by the Workforce Act, long-term workers are exempt from the prohibition on Construction and Extraction Occupations (under DOL's SOC Group 47–0000). 48 U.S.C. 1806(d)(3)(D)(v). Extensions for long-term workers may be granted for a period of up to three years until the end of the transition period, subject to the numerical limitation. 48 U.S.C. 1806(d)(7)(B) and new 8 CFR 214.2(w)(13). Long-term workers are not subject to the temporary departure requirement. 48 U.S.C. 1806(d)(7)(A) and new 8 CFR 214.2(w)(18)(v).

Current regulations do not differentiate between a beneficiary with initial CW–1 status and a beneficiary that has been in status for a number of years. CW–1 status currently may be granted for a period of up to one year only. An employer may request an extension of status by filing a new I–129CW petition. Extensions are also granted in periods that are not to exceed one year. However, the Workforce Act now distinguishes between certain CW–1 beneficiaries, based on their previous status as a CW–1, and provides this new subcategory of CW–1 beneficiaries, the long-term workers, with up to a three year validity period. This IFR incorporates the statutory definition of ''long-term workers'' at 8 CFR 214.2(w)(1)(viii); the exemption from the construction prohibition at 8 CFR 214.2(w)(2)(vii); the exemption from the temporary departure requirement at 8 CFR 214.2(w)(18)(v) and the longer extension period at 8 CFR 214.2(w)(18)(iii).

USCIS will begin accepting CW–1 petitions requesting long-term workers as of the effective date of this IFR. Accordingly, the Form I–129CW is updated to specifically identify a request for such long-term workers.

I. Bar on Certain Construction Worker Occupations

The Workforce Act amends the ban on certain construction worker occupations first enacted in 2017 [56] and prohibits the CW–1 classification from being available to workers who will be performing jobs classified as ''construction and extraction occupations,'' as defined in DOL's SOC system, other than long-term workers (CW–1 workers first issued such status before October 1, 2015). 48 U.S.C. 1806(d)(3)(D)(v). It bans employers of new construction and extraction occupation workers from using the CW–1 classification.

[53] On April 18, 2017, the President issued Executive Order (E.O.) 13788, ''Buy American and Hire American'' available at *https://www.whitehouse.gov/presidential-actions/presidential-executive-order-buy-american-hire-american/,* (last visited June 26, 2019).

[54] *See* ''The E-Verify User Manual for Corporate Administrators'', available at *https://www.e-verify.gov/e-verify-user-manual-for-corporate-administrators-20-company-location-administration-21* (last visited June 26, 2019).

[55] *See* 20 CFR 655.402(rr). DHS has not previously defined this concept by regulation and finds the DOL definition relating to TLCs for CW–1 petitions applicable here.

[56] The Northern Mariana Islands Economic Expansion Act (the NMIEEA), Public Law 115–53, which was enacted into law on August 22, 2017, revised the CW–1 visa classification to, among other things, prohibit the CW–1 classification from being available to workers who will be performing jobs classified as ''construction and extraction occupations'' as defined in the U.S. Department of Labor's SOC system other than to extend CW–1 permits of such workers first issued before October 1, 2015.

As noted above, the original construction ban was imposed in 2017, but DHS did not update its regulations at that time. USCIS interpreted the 2017 exemption to the ban as applying to extensions from the same petitioner and same qualifying beneficiary. This new exemption broadly allows any CW–1 petitioner to request a CW–1 beneficiary for ''construction and extraction occupations'' as long as that beneficiary qualifies as a long-term worker. Accordingly, this IFR updates DHS regulations to include this amended bar on construction workers (and an exemption for long-term workers) at 8 CFR 214.2(w)(2)(vii), but does not change any other petitioning procedures.

Petitioners are required to comply with all U.S. Federal and CNMI labor laws including the requirements to submit a DOL-approved TLC. While USCIS will consider the job classification identified on these documents, USCIS is not bound by this determination and may make a separate and independent judgment on the CW–1 petition based on a preponderance of the evidence in each case. USCIS will deny CW–1 petitions for construction and extraction occupations if it is not established that the beneficiary is eligible for the long-term worker subcategory.

J. Temporary Departure Requirement

The Workforce Act contains a requirement for CW–1 transitional workers (other than ''long-term workers'' who have had CW–1 status continuously since FY 2015) to remain outside the United States after a second renewal period (*i.e.,* extending up to a total of three years of CW–1 status) before another petition for CW–1 classification may be filed. 48 U.S.C. 1806(d)(7). Specifically, the language states, ''at the expiration of the second renewal period, an alien may not again be eligible for such a permit until after the alien has remained outside of the United States for a continuous period of at least 30 days prior to the submission of a renewal petition on their behalf.'' 48 U.S.C. 1806(d)(7)(A)(ii).

In a September 18, 2018 letter to Secretary Nielsen, Governor Torres requested that DHS interpret the requirement for a CW–1 permit holder to remain outside of the United States for 30 continuous days prior to the submission of a [third] renewal petition by their employer such that the first relevant renewal petition would be filed for employment in FY 2020.[57] Governor Torres stated that this approach would provide clarity to employers on the mandates of the Workforce Act and allow them to make the necessary adjustments to their internal processes to plan for the departure of their CW–1 employees following the end of the second renewal.

In accordance with the Workforce Act, DHS has considered the Governor's recommendations in the development of this regulation. The Governor's request is inconsistent with the best reading of the statute. The Workforce Act exempts long-term workers from the departure requirement. Eligibility for the long-term worker subcategory is specifically based on their CW–1 status before the date of enactment (*i.e.,* in CW–1 status since FY 2015). DHS therefore believes the Workforce Act is best read as indicating that pre-enactment renewals will be taken into consideration in applying the departure bar to other workers. Otherwise, DHS is arguably (at least for the first two years) creating an exception for all workers that Congress did not intend. The Workforce Act specifically exempts long-term workers from the departure requirement and ensures that they receive preferential consideration under the cap. As a result, this provision limits the stay of CW–1 workers, other than long-term workers, by imposing a new 30-day departure before the third petition to renew CW–1 classification.

USCIS will count renewals issued before the interim final rule effective date, so that the 30-day departure requirement is implemented immediately. As such, it shall apply to all CW–1 petitions filed with USCIS on or after the effective date of this IFR. This reading of the Workforce Act is more in line with Congressional intent (given the express carve-out for the long-term workers from the 30-day departure requirement). New 8 CFR 214.2(w)(18)(v).

K. Transit Through Guam

The Workforce Act also authorizes CW–1 and CW–2 status holders to transit through Guam. Existing regulations allow direct Guam transit under limited conditions only. This IFR updates regulations at 8 CFR 214.2(w)(1)(ii) and (w)(23)(iii) to incorporate the statutory language.

Under the current 8 CFR 214.2(w)(22), CW–1 and CW–2 status is only applicable in the CNMI. It does not authorize entry to Guam or to any other part of the United States. Entry, employment, and residence in the rest of the United States (including Guam) require the appropriate visa or visa waiver eligibility. An alien with CW–1 or CW–2 status who enters or attempts to enter, who travels or attempts to travel to any other part of the United States without the appropriate visa or visa waiver eligibility, or who violates conditions of nonimmigrant stay applicable to any such authorized status in any other part of the United States is deemed to have violated CW–1 or CW–2 status. However, the regulations provide an exception to this limitation on travel to Guam. Currently, under 8 CFR 214.2(w)(22)(iii), USCIS allows a CW–1 or CW–2 who is a national of the Philippines, to travel from the CNMI to the Philippines (and back) via a direct Guam transit without being deemed to violate that status. Under 8 CFR 214.2(w)(1)(ii), such direct transit can only be on a direct itinerary involving a flight stopover or connection in Guam (and no other place) within 8 hours of arrival in Guam, without the alien leaving the Guam airport. Under this limited travel exception, if an immigration officer determines that the individual warrants a discretionary exercise of parole authority, the CW may be paroled into Guam via direct Guam transit to undergo pre-inspection outbound from Guam for admission to the CNMI pursuant to 8 CFR 235.5(a) or to proceed for inspection upon arrival in the CNMI. During any such pre-inspection, the individual may be admitted in CW–1 or CW–2 status if the immigration officer in Guam determines that the he or she is admissible to the CNMI. A condition of the admission is that the individual must complete the direct Guam transit.

DHS included this regulatory exception to alleviate the travel problems arising from the general limitation of CW status to the CNMI. While this provision helped reduce the travel restrictions placed on certain CW workers, the 8-hour limitation often proved challenging for travelers as they are subject to limited flight schedules which exceeded these regulatory time limits. In these cases, CBP could waive the 8-hour limit and extend up to 24 hours on a case-by-case basis.[58]

As this limited travel exception is applicable only to Philippine nationals, other CW status holders cannot easily transit through Guam, which continues

[57] As previously stated, the Workforce Act states that DHS should consider in good faith the implementation recommendations of the Governor submitted within 60 days after enactment.

[58] *See* USCIS, Legal Resources, Immigration From the Commonwealth of the Northern Mariana Islands (CNMI), ''CNMI Transitional Worker Classification Questions and Answers,'' available at *https://www.uscis.gov/legal-resources/immigration-commonwealth-northern-mariana-islands-cnmi/cnmi-transitional-worker-classification-questions-and-answers* (last visited May 28, 2019).

to pose travel problems for other CW nonimmigrants. The latter cannot travel without advance approval of travel by USCIS.[59] Such CW status holders must first obtain an approved advance parole from USCIS in order to transit via Guam when arriving from a foreign place.

The statutory provision reduces the existing travel issues by removing the travel restrictions and allowing transit of all CW status holders through Guam. New 8 CFR 214.2 (w)(1)(ii) and (w)(23)(iii) allow all CW status holders to travel to and from a foreign place via a direct Guam transit without being deemed to violate that status.

L. Other Technical Amendments

This IFR revises DHS regulations to reflect that Congress has extended the statutory bar for asylum in the CNMI, *see* INA sec. 208(e), 8 U.S.C. 1158(e), until December 31, 2029. *See* Workforce Act at sec. 3(a); 48 U.S.C. 1806(a)(2). *See* Part IV.A.1 above.

V. Statutory and Regulatory Requirements

A. Administrative Procedure Act

The Administrative Procedure Act (APA) generally requires agencies to issue a proposed rule before revising legislative regulations, subject to certain exceptions. *See* 5 U.S.C. 553(b). The Workforce Act specifically exempts this rulemaking from the notice-and-comment requirement, and instead directs the Secretary of Homeland Security to publish in the **Federal Register** an IFR that specifies how the Secretary intends to implement the Workforce Act's amendments. Pursuant to section 3(e)(2) of the Workforce Act, this authority persists even in the event that the IFR is published after the 180-day deadline established in the Act. DHS is proceeding by IFR as a consequence of these statutory provisions. DHS nevertheless invites written comments on this interim rule and will consider those comments in the development of a final rule in this action.

B. Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Executive Order 13771 (Reducing Regulation and Controlling Regulatory Costs)

Executive Order (E.O.) 12866 directs agencies to assess the 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. E.O. 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. E.O. 13771 directs agencies to reduce regulation and control regulatory costs. This interim final rule (IFR) is considered a regulatory action for the purposes of E.O. 13771.

The Office of Information and Regulatory Affairs, of the Office of Management and Budget, has designated this rule a ''significant regulatory action'' that is not economically significant because it is not estimated to have an annual effect on the economy of $100 million or more, under section 3(f)(1) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has reviewed this regulation.

1. Summary

The Northern Mariana Islands U.S. Workforce Act of 2018 (Workforce Act) creates requirements to encourage the hiring of United States workers in the Commonwealth of the Northern Mariana Islands (CNMI). The Workforce Act extends the transition period through December 31, 2029 and provides new CW–1 numerical limitations for each fiscal year until the end of the transition period. This IFR amends the relevant sections of USCIS regulations to reflect these changes. The provisions of the IFR are discussed in detail in the sections that follow.

The costs associated with the IFR include costs of preparing and filing Form I–129CW petitions, filing applications for extension of stay, participating in the E-Verify program, submitting semiannual reports and document retention, submitting notifications to USCIS, and filing revoked petitions. Accordingly, the lower bound net total estimated cost of the regulatory changes to employers and nonimmigrant CW–2 applicants is $73,578,345 undiscounted, $62,851,776 discounted at 3 percent, and $51,858,612 discounted at 7 percent from FY 2019 to 2030. Likewise, the upper bound net total estimated cost of the regulatory changes to employers and nonimmigrant CW–2 applicants is $61,741,219 undiscounted, $52,693,918 discounted at 3 percent, and $43,433,060 discounted at 7 percent from FY 2019 to 2030. These costs are summarized in Table 1. The total estimated lower bound transfers are $25,712 at 7 percent and $32,361 at 3% while the total estimated upper bound transfers are $13,845,180 discounted at 7% and $16,806,753 discounted at 3%. The annualized cost of the regulatory changes to employers and nonimmigrant CW–2 applicants discounted at 7 percent is $5,468,222 for the lower bound and $6,528,999 for the upper bound estimates.

A petitioner is required to file Form I–129CW to employ nonimmigrant workers who are otherwise ineligible to work in the CNMI under other nonimmigrant worker categories. DHS estimates the total petitioners' cost to file Form I–129CW petitions to be $57,047,877 undiscounted, $48,668,535 discounted at 3 percent, and $40,092,491 discounted at 7 percent from FY 2019 to 2029, which includes the opportunity cost of time to complete Form I–129CW, the postage cost to mail the completed form, and the costs associated with Form I–129CW filing fee, education funding fee and fraud prevention and detection cost. Petitioners are also required to file a new petition to request an extension of stay for their currently approved CW–1 nonimmigrants employees. Because the cost of filing a petition for an extension of stay is already captured by the cost of filing Form I–129CW petitions, DHS does not separately present the cost of filing an extension of stay.

The IFR requires that any employer petitioning for a CW–1 nonimmigrant worker must be an E-Verify program participant in good standing. Participating in the E-Verify program requires entering newly hired employees' information from Form I–9 to electronically match against records available to DHS and the SSA to confirm the employees' identity and employment eligibility. This results in a cost burden to employers that petition for CW–1 nonimmigrant workers and operate in the CNMI and other locations in the U.S. Employers also incur additional cost burden for annual training in E-Verify as they continue to comply with E-Verify requirements. DHS estimates the total cost of participating in the E-Verify program to be $1,224,618 undiscounted, $1,061,385 discounted at 3 percent, and $894,425 discounted at 7 percent from FYs 2019 to 2030.

An employer whose petition has been approved will be required to submit a semiannual report to USCIS every six months, using Form I–129CWR, after the petition validity start date to verify the continuing employment and payment of the beneficiary under the terms and conditions of the approved petition. Petitioners are also required to retain all documents and records in support of the petition, including

[59] These individuals file a Form I–131 Application for Travel Document with the fee at the USCIS Guam Office to obtain an advance parole document.

information submitted to USCIS in the semiannual report, for three years from the petition validity start date. DHS estimates the total cost of semiannual reporting and document retention will be $15,996,725 undiscounted, $13,647,084 discounted at 3 percent, and $11,242,286 discounted at 7 percent from FY 2019 to 2030.

The IFR requires a petitioner to immediately notify USCIS of any changes in the terms and conditions of employment of a nonimmigrant worker which may affect eligibility for CW–1 status either by (1) filing an amended petition if the petitioner continues to employ the nonimmigrant worker, or (2) sending a letter to the USCIS office at which the CW–1 petition was filed explaining the basis on which the CW–1 nonimmigrant worker no longer works for the petitioner. DHS estimates the total cost of filing an amended petition to be $215,296 undiscounted, $183,673 discounted at 3 percent, and $151,307 discounted at 7 percent from FY 2019 to 2030. Although DHS is not able to estimate the total cost of submitting a notification letter due to lack of data, DHS provides a unit cost of mailing a notification letter. Hence, an affected petitioner on average will incur a unit cost of $43.65 to send a letter notifying USCIS that a CW–1 nonimmigrant is no longer working for him or her. This unit cost estimate consists of the opportunity cost of time to prepare a notification letter and the postage cost to mail the notification letter to USCIS.

USCIS reserves the authority to fully or partially revoke petitions at any time under specified conditions. The conditions for immediate and automatic revocations and the discretionary grounds for revocation on notice are discussed in the preamble of this IFR. For each beneficiary of a petition revoked in a fiscal year, USCIS will add it to a CW–1 numerical cap of the next fiscal year. DHS estimates employers' total cost to file Form I–129CW petitions for such additions to the numerical cap to be $108,957 undiscounted, $90,410 discounted at 3 percent, and $71,834 discounted at 7 percent from FY 2019 to 2030. The IFR also provides the conditions for appealing revoked petitions. For revocation on notice, a petitioner may file an appeal with the USCIS Administrative Appeals Office or a motion with the USCIS office that revoked the petition by submitting Form I–1290B, Notice of an Appeal or Motion, in accordance with 8 CFR 103. There is no appeal of an automatic revocation. DHS is unable to estimate the total cost employers will incur appealing petitions that have been revoked on notice in the implementation period, however, DHS estimates a unit cost to show the minimum cost petitioners are likely to incur appealing petitions revoked on notice. DHS estimates that an affected employer on average incurs a cost of $782.95 appealing a petition revoked on notice. This unit cost estimate consists of the filing fee for Form I–290B, the opportunity cost of time to complete the form, and the postage cost to mail the form to USCIS.

Qualifying dependents (*i.e.,* an eligible spouse or child) of nonimmigrant workers with a CW–1 status may file applications requesting an extension of CW–2 status using Form I–539, Application to Extend/Change Nonimmigrant Status. DHS estimates the total cost of filing applications for CW–2 status to be $7,826,181 undiscounted, $6,676,651 discounted at 3 percent, and $5,500,136 discounted at 7 percent for nonimmigrant CW–2 applicants from FY 2019 to 2030.

The IFR states that an extension of stay may be granted for a period of up to three years if the employee is a long-term worker. DHS estimates the cost savings for petitioners who will request a three-year extension of stay for their long-term workers using the lower and upper bound estimates for the net number of beneficiaries for whom a three-year extension of stay will be requested. Accordingly, the total cost savings to petitioners resulting from filing a three-year extension of stay for long-term nonimmigrant workers range from $978,034 to $8,802,309 undiscounted ($827,067 to $7,443,600 discounted at 3 percent, and $674,239 to $6,068,155 discounted at 7 percent) from FY 2019 to 2030.

Table 1 provides a detailed summary of the regulatory changes and their impacts.

TABLE 1—SUMMARY OF MAJOR PROVISIONS AND ECONOMIC IMPACTS OF THE RULE

Provisions	Regulatory changes	Expected impact of regulatory changes
Amending 8 CFR 103.7 by revising paragraph (b)(1)(i)(J) and CFR 214.2(w)(5).	This is not a new fee as in 2017 Congress enacted the Northern Mariana Islands Economic Expansion Act, Public Law 115–53, 131 Stat. 109, which raised the supplemental CNMI education funding fee from $150 to $200 per each beneficiary issued CW–1 permit status. The Act also banned issuing new CW–1 permits to construction workers. This IFR also updates existing regulations, to include the Workforce Act's requirement that CW–1 employers must pay a mandatory $50 fraud prevention and detection fee per petition The additional $50 fee is intended for a new and permanent site visit program. The fee is for the sole purpose of fraud deterrence and detecting immigration benefit fraud in the Northern Mariana Islands. DHS characterizes this fee as a cost because in general, fee revenues will support new activities that were not previously conducted.	*Quantified Costs* • Total cost of $40.1 million discounted at 7 percent *Transfers* • The $50 increase in the education funding fee would be a transfer of $13.8 million discounted at 7 percent.
Amending 8 CFR 214.2(w)(18)(iii).	DHS provides that an extension of CW–1 status may be granted for a period of up to 1 year (or up to 3 years of the beneficiary is a long-term worker).	*Quantified Cost Savings* • Because approved extension of stay requests are counted towards each year's numerical cap, the cost of filing a one-year extension of stay is already captured by the above CW–1 petition filing cost • Using sensitivity analysis, the total cost savings to petitioners arising from three-year extension of stay requests range from $0.07 million to $6.1 million discounted at 7 percent.

TABLE 1—SUMMARY OF MAJOR PROVISIONS AND ECONOMIC IMPACTS OF THE RULE—Continued

Provisions	Regulatory changes	Expected impact of regulatory changes
Amending 8 CFR 214.2(w)(1)(vii)(E).	DHS imposes the requirement that petitioners who file Form I–129CW petitions must be an E-Verify program participant in good standing.	*Quantified Costs* • Total cost of $0.89 million discounted at 7 percent.
Amending 8 CFR 214.2(w)(26)(i)&(iii).	DHS requires petitioners to submit semiannual reports every six months and retain all documents and records in support of the petition for 3 years.	*Quantified Costs* • Total cost of $11.2 million discounted at 7 percent.
Amending 8 CFR 214.2(w)(27)(i)(A).	DHS requires petitioners to immediately notify USCIS when changes that affect the employment of CW–1 nonimmigrant workers occur.	*Quantified Costs* • Total cost of $ $0.15 million discounted at 7 percent.
Adding 8 CFR 214.2(w)(27)(ii) & (iii).	DHS adds the number of petitions revoked in a fiscal year to the next year's numerical cap so that petitioners may file Form I–129CW petitions for each revoked petition.	*Quantified Costs* • Total cost of $0.07 million discounted at 7 percent, to file revoked petitions *Transfer Payments* • A transfer of $0.03 million education funding discounted at 7 percent.
Adding 8 CFR 214.2(w)(28)	DHS adds a provision that a petition revoked on notice may now be appealed.	*Quantified Costs* • Total cost not estimated due to lack of data; a unit cost of $783 to appeal a petition revoked on notice.
8 CFR 214.2(w)(16)	Current DHS requirement for nonimmigrant workers with approved CW–1 status to file Form I–539 requesting an extension of CW–2 status for their qualifying dependents.	*Quantified Costs* • Total cost of $5.5 million discounted at 7 percent to nonimmigrant CW–2 applicants *Note:* This cost is estimated because the current rule was set to expire on FY 2020 before the Workforce Act extends it to FY 2030. Hence, the CW–2 extension of stay requirement will be applied to the affected population during the IFR implementation period. To account for the overlapping period (FYs 2019 & 2020) the difference between the proposed and current numerical caps is taken as shown in Table 8.

2. Background and Purpose of the Rule

The Consolidated Natural Resources Act of 2008 (CNRA) amended the 1976 Covenant by extending the U.S. immigration laws, with limited exceptions, to the CNMI and providing CNMI-specific provisions affecting foreign workers. The CNMI had been admitting a substantial number of foreign workers since 1978 who constituted a majority of the CNMI labor force. The CNRA provided for a transition period to phase out the CNMI's nonresident contract worker program and phase in the U.S. federal immigration system in a manner that minimized adverse economic and fiscal effects and maximized the CNMI's potential for future economic and business growth.

The CNRA authorized the Secretary of DHS to create a nonimmigrant classification that would ensure adequate employment in the CNMI during the transition period, also known as CW nonimmigrant classification. The CNRA also mandated an annual reduction in the number of permits issued per year and the total elimination of the CW nonimmigrant classification by the end of the transition period. As a result, DHS published a final rule on September 7, 2011, amending the regulations at 8 CFR 214.2(w) to implement a temporary, CNMI-only transitional worker nonimmigrant classification (CW classification, which includes CW–1 for principal workers and CW–2 for spouses and minor children).[60] DHS also set the CW–1 numerical limitations (or caps) starting from FY 2011. DHS initially announced annual caps for the first two fiscal years in the DHS regulations at 8 CFR 214.2(w)(1)(viii)(A) and (B), and thereafter published subsequent annual caps in **Federal Register** notices.[61]

The Northern Mariana Islands U.S. Workforce Act of 2018 (the Workforce Act) creates requirements to encourage the hiring of United States workers in the CNMI in order to (a) increase the percentage of U.S. workers in the CNMI while maintaining the minimum number of workers who are not U.S. workers to meet the changing demands of the CNMI economy, and (b) ensure that no U.S. worker is placed at a competitive disadvantage for employment compared to a non-U.S. worker or is displaced by a non-U.S. worker. The Workforce Act amends the statute by which employers within the CNMI may apply for permission to employ nonimmigrant workers who are otherwise ineligible to work in the CNMI under other nonimmigrant worker categories. The Workforce Act makes a number of changes to the transitional provisions (which extended U.S. immigration law, with limited exceptions, to the CNMI) and requires the Secretary of DHS to promulgate an Interim Final Rule (IFR) implementing the related statutory changes. These changes are discussed in detail in the next section.

3. Changes in the IFR

This section provides a brief description of the major regulatory changes in this IFR. The regulatory changes in the IFR arise from the statutory requirements of the Workforce Act.

In accordance with the statutory requirements in the Workforce Act, DHS amends its regulations in this IFR. DHS extends the transition period and the CW–1 program through December 31, 2029, reflecting the new sunset date in existing regulations. As the Workforce Act provides new CW–1 numerical limitations for each fiscal year until the end of the transition period, this IFR amends the relevant sections of USCIS regulations to reflect these changes.

This IFR updates existing regulations to reflect that the supplemental CNMI education funding fee is raised from

[60] *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification, 76 FR 55502 (Sept. 7, 2011)

[61] *See* 8 CFR 214.2(w)(1)(viii)(C).

$150 to $200[62] per each nonimmigrant worker with a CW–1 status per year. This education fee is paid by petitioners on behalf of the CW–1 worker. Consistent with the Workforce Act, this IFR also provides DHS the discretion to annually adjust this supplemental fee via notice in the **Federal Register**. However, in providing DHS with the discretion to adjust the fee, the Workforce Act also sets forth that DHS can only adjust the fee by a percentage equal to the annual change in the Consumer Price Index for All Urban Consumers. Furthermore, this IFR updates existing regulations to include the statutory requirement that CW–1 petitioners must pay a mandatory $50 fraud prevention and detection fee with each petition, in addition to other current fees. This new fraud prevention and detection fee does not apply to CW–1 petitions already filed and pending with USCIS as of July 24, 2018.

This IFR revises existing procedures to require that a CW–1 petition be filed with an approved TLC from DOL.[63] The Workforce Act imposes this requirement for any CW–1 petition with an employment start date in FY 2020 and beyond. Per the Workforce Act, a TLC approved by DOL confirms that there are not sufficient United States workers in the CNMI who are able, willing, qualified, and available to fill the petitioning CW–1 employer's job opportunity. The TLC also confirms that the foreign worker's employment in the job opportunity will not adversely affect the wages or working conditions of similarly employed United States workers.

DHS is revising existing regulations to include the statutory minimum wage requirements for a CW–1 petitioner. It now specifies, in alignment with the Workforce Act, that the petitioner will pay the nonimmigrant worker a wage that is not less than the greater of (1) the CNMI minimum wage; (2) the Federal minimum wage; or (3) the prevailing wage in the CNMI for the occupation in which the nonimmigrant worker will be employed as established by the DOL.

Additionally, DHS will now require a CW–1 employer to file a semiannual reporting form to verify the continuing employment and payment of the CW–1 nonimmigrant worker under the terms and conditions set forth in the CW–1 petition. DHS implements this new statutory requirement via a new standalone form that captures data to provide USCIS with information necessary to help verify the continuing employment and payment of the CW–1 nonimmigrant worker. The standalone form also contains employers' attestations confirming the validity of the data provided. USCIS will not require submission of evidence at the time of filing, but employers must retain documents and records which support the attestation for three years after the ending date of petition validity period.

DHS will now require employers filing CW–1 petitions to be E-Verify program participants in good standing. The E-Verify program is a USCIS web-based system that allows enrolled employers to confirm the eligibility of their employees to work in the United States.[64] Employers participating in the E-Verify program are required to verify the identity and employment eligibility of newly hired workers by electronically matching information provided by workers on the Form I–9, Employment Eligibility Verification, against records available to DHS and the SSA. A participant in good standing in the E-Verify program means an employer that has enrolled in E-Verify with respect to all hiring sites in the United States, not just the CNMI locations, as of the time of filing a petition, and is in compliance with all requirements of the E-Verify program, including but not limited to verifying the employment eligibility of newly hired employees in the United States, and not just in the CNMI. This is a new requirement with respect to all CW–1 employers and affects how they handle new hires at all hiring sites, not just in the CNMI.

This IFR establishes notification and revocation procedures for approved CW–1 petitions. Specifically, DHS will now require a petitioner to immediately notify USCIS of any changes in the terms and conditions of employment of a nonimmigrant worker that may affect eligibility either by (1) filing an amended petition if the petitioner continues to employ the nonimmigrant worker, or (2) sending a letter to the USCIS office at which the CW–1 petition was filed explaining the basis on which the specific CW–1 nonimmigrant no longer works for the petitioner. Further, this IFR establishes conditions for immediate and automatic revocations and the discretionary grounds for revocation on notice. A petition that has been revoked on notice, in whole or in part, may be appealed under 8 CFR 103; however, automatic revocations may not be appealed. Further, under this IFR, for each beneficiary of a petition revoked in a fiscal year, USCIS will add an equivalent number of CW–1 visas to a CW–1 numerical cap of the next fiscal year. This recapture of CW–1 visas does not exist under the current regulations.

4. Population

The population affected by this IFR consists of petitioners (or employers) within the CNMI who file Form I–129CW requesting a CW–1 visa for nonimmigrant workers and the nonimmigrant workers who are beneficiaries of the program. DHS estimates the number of the affected population based on the CNMI transitional worker program historical data for FYs 2012 to 2018 and the numerical caps set by this IFR limiting the total number of visas to be issued each year during the implementation period (FY 2019 to 2030).

i. CNMI Only Transitional Worker Program Historical Data

Table 2 shows historical data on the number of Form I–129CW petitions received, beneficiaries approved, and petitions denied by USCIS in FYs 2012 to 2018.[65] DHS estimates the number of petitions approved by subtracting the number of petitions denied from the number of petitions received for each year. Since a petitioner can request more than one beneficiary on a Form I–129CW, DHS also estimates the number of beneficiaries approved per petitioner by dividing the number of beneficiaries approved by the number of petitions approved for each year. Over the 7-year period, USCIS received an average of 6,880 petitions from 1,471 petitioners (or employers) and approved an average of 6,391 petitions and 10,276 beneficiaries annually. Based on this, DHS concludes that USCIS approves 93 percent of the CW–1 petitions annually and that a petitioner files a petition on average for approximately 2

[62] In 2017, Congress enacted Public Law 115–53, which increased the supplemental fee paid for each CW permit to $200 and banned issuing new CW–1 permits to construction workers.

[63] To obtain a TLC, employers must submit a complete *Application for Prevailing Wage Determination* (Form ETA–9141C) with the OFLC National Prevailing Wage Center (NPWC) containing information about the job opportunity in which the nonimmigrant workers will be employed, as required by 20 CFR 655.410. Once the NPWC issues a prevailing wage determination, the employer may submit the *CW–1 Application for Temporary Employment Certification* as required by 20 CFR 655.410 and supporting documentation, as required by 20 CFR 655.420–423. Once all CW–1 regulatory requirements are met, the TLC is issued. Under the provisions at 20 CFR 655.452, the TLC is considered both, the Final Determination notice and a copy of the certified *CW–1 Application for Temporary Employment Certification* (Form ETA–9142C).

[64] *See* E-Verify, available at *https://www.e-verify.gov/* (last visited May 28, 2019).

[65] The number of beneficiaries approved is based on the validity start date. If validity start date is unavailable, approval is based on approval date. The number of petitions denied is based on the date the application was denied irrespective of the initial date of submission.

beneficiaries (or CW–1 nonimmigrant workers).

TABLE 2—TOTAL NUMBER OF FORM I–129CW PETITIONS RECEIVED AND APPROVED

[FY 2012 to 2018]

Fiscal year	Number of petitioners who filed Form I–129CW	Form I–129CW petitions received	Form I–129CW beneficiaries approved	Form I–129CW petitions denied	Form I–129CW petitions approved	Number of beneficiaries approved per petition	Percent of Form I–129CW petitions approved (%)
	A	B	C	D	E = B − D	F = C ÷ E	G = E ÷ B
2012	1,789	5,899	10,548	244	5,655	1.87	95.9
2013	1,393	7,057	6,325	540	6,517	0.97	92.3
2014	1,698	7,196	9,188	564	6,632	1.39	92.2
2015	1,668	6,388	9,715	442	5,946	1.63	93.1
2016	1,503	7,805	13,299	668	7,137	1.86	91.4
2017	1,189	6,537	13,563	259	6,278	2.16	96.0
2018	1,054	7,278	9,294	708	6,570	1.41	90.3
Total		48,160	71,932	3,425	44,735		
7-year average	1,471	6,880	10,276	489	6,391	2.00	93.0

Source: Office of Policy and Strategy, Research and Evaluation Division (OP&S RED) and USCIS analysis.

Table 3 shows the number of Form I–129CW petitions amended by petitioners and CW–1 visas revoked by USCIS out of the total number of petitions and beneficiaries (or visas) approved, respectively, in FYs 2012 to 2018. Based on these historical data, DHS estimates the percentage of petitions amended and visas revoked in each year. Over the 7-year period, from an average of 6,391 approved petitions, an average of 141 (or 2.20 percent) petitions were amended annually, and from an average of 10,276 approved beneficiaries, an average of 20 (or 0.20 percent) petitions were revoked annually.

TABLE 3—TOTAL NUMBER OF FORM I–129CW PETITIONS AMENDED AND CW–1 VISAS REVOKED

[FY 2012 to 2018]

Fiscal year	Form I–129CW petitions approved	Form I–129CW beneficiaries approved	Form I–129CW petitions amended	Form I–129CW petitions revoked	Percent of Form I–129CW petitions amended (%)	Percent of Form I–129CW revoked (%)
	A	B	C	D	E = C ÷ A	F = D ÷ B
2012	5,655	10,548	72	38	1.27	0.36
2013	6,517	6,325	124	25	1.90	0.40
2014	6,632	9,188	124	21	1.87	0.23
2015	5,946	9,715	175	14	2.94	0.14
2016	7,137	13,299	127	22	1.78	0.17
2017	6,278	13,563	171	11	2.72	0.08
2018	6,570	9,294	194	7	2.95	0.08
Total	44,735	71,932	987	138		
7-year average	6,391	10,276	141	20	2.20	0.20

Source: Office of Policy and Strategy, Research and Evaluation Division (OP&S RED) and USCIS analysis.

The historical data also show the number of petitioners who filed applications requesting extension of stay for their CW–1 workers in FYs 2013 to 2018.[66] Petitioners are required to file a new petition using Form I–129CW to request an extension of stay for their currently approved CW–1 nonimmigrants employees. As shown in Table 4, DHS estimates the number of applications approved by subtracting the number of applications denied from the total number of applications received for each year. DHS also estimates the number of beneficiaries approved per application by dividing the number of beneficiaries approved by the number of applications approved for each year. Over the 6-year period, USCIS received an average of 5,271 extension of stay applications and approved 5,056 applications and 7,545 beneficiaries (or CW–1 nonimmigrant workers) annually. DHS then concludes

[66] The data on extension of stay for FY 2012 are incomplete and therefore, dropped from this analysis.

that USCIS approves 96 percent of extension of stay applications annually and that a petitioner files an extension of stay application on average for approximately 2 beneficiaries per petition.

TABLE 4—TOTAL NUMBER OF EXTENSION OF STAY APPLICATIONS RECEIVED AND APPROVED

[FY 2013 to 2018]

Fiscal year	Extension of stay applications received A	Beneficiaries approved B	Applications denied C	Applications approved D = A − C	Beneficiaries approved per application E = B ÷ D	Percent of applications approved (%) F = D ÷ A
2013	4,743	6,003	464	4,279	1.40	90.2
2014	6,293	8,327	245	6,048	1.38	96.1
2015	4,899	7,230	174	4,725	1.53	96.4
2016	7,672	11,151	202	7,470	1.49	97.4
2017	3,767	6,280	102	3,665	1.71	97.3
2018	4,253	6,280	102	4,151	1.51	97.6
Total	31,627	45,271	1,289	30,338		
6-year average	5,271	7,545	215	5,056	2.00	96.0

Source: Office of Policy and Strategy, Research and Evaluation Division (OP&S RED) and USCIS analysis.

To estimate the proportion of extension of stay applications filed on behalf of CW–1 nonimmigrant workers out of the total petitions approved, DHS divides the total number of extension of stay applications received by the total number of Form I–129CW petitions approved in FYs 2013 to 2018 as shown in Table 5. Overall, of the total number of CW–1 nonimmigrant workers that have been approved in FYs 2013 to 2018, an average of 80 percent of applications request an extension of stay.

TABLE 5—PERCENT OF EXTENSION OF STAY APPLICATIONS

[FY 2013 to 2018]

Fiscal year	Form I–129CW petitions approved A	Extension of stay applications received [a] B	Percent of extension of stay applications (%) C = B ÷ A
2013	6,517	4,743	72.8
2014	6,632	6,293	94.9
2015	5,946	4,899	82.4
2016	7,137	7,672	107.5
2017	6,278	3,767	60.0
2018	6,570	4,253	64.7
Total	39,080	31,627	
6-year average	6,513	5,271	80.0

Source: Office of Policy and Strategy, Research and Evaluation Division (OP&S RED) and USCIS analysis.
[a] Data for extension of stay applications are not available for FY 2012.

DHS uses the data from Form I–539, Application to Extend/Change Nonimmigrant Status, on applicants for an initial grant or extension of a CW–2 status, shown in Table 6, to determine the total number of qualifying dependents (*i.e.,* eligible spouse or child) of nonimmigrant workers with a CW–1 visa in FYs 2012 to 2018. DHS estimates the number of applications approved by subtracting the number of applications denied from the number of applications received for each year. DHS also estimates the number of dependents approved per application by dividing the number of dependents approved by the number of applications approved for each year. Over the 7-year period, USCIS received on average 933 applications and approved 898 applications and 782 qualified dependents annually. Table 6 also shows that USCIS approves 96 percent of applications for CW–2 status annually and that an applicant uses Form I–539 to apply for a CW–2 status on average for approximately 1 dependent.

TABLE 6—TOTAL NUMBER OF APPLICATIONS FOR CW–2 STATUS (FORM I–539) RECEIVED AND APPROVED

[FY 2012 to 2018]

Fiscal year	CW–2 applications received A	CW–2 dependents approved B	CW–2 applications denied C	CW–2 applications approved D = A − C	CW–2 dependents approved per application E = B ÷ D	Percent of CW–2 applications approved (%) F = D ÷ A
2012	889	426	28	861	0.495	96.9
2013	687	622	85	602	1.033	87.6
2014	1,081	799	33	1,048	0.762	96.9
2015	906	785	13	893	0.879	98.6
2016	1,406	1,034	21	1,385	0.747	98.5
2017	867	934	27	840	1.112	96.9
2018	695	873	35	660	1.323	95.0
Total	6,531	5,473	242	6,289		
6-year average	933	782	35	898	1.00	96.0

Source: Office of Policy and Strategy, Research and Evaluation Division (OP&S RED) and USCIS analysis.

To estimate the proportion of applications who filed for CW–2 status, DHS assumes that qualifying dependents of nonimmigrant workers file Form I–539 for CW–2 status after the CW–1 status of the nonimmigrants workers have been approved by USCIS. Hence, DHS divides the total number of applications received for CW–2 status by the total number of CW–1 petitions approved in FYs 2013 to 2018 as shown in Table 7. The result shows that applications requesting a CW–2 status are filed by qualifying dependents of on average 15 percent of the total number of nonimmigrant workers with approved CW–1 status in FYs 2013 to 2018.

TABLE 7—PERCENT OF CW–2 APPLICATIONS

[FY 2013 to 2018]

Fiscal year	Form I–129 CW CW–1 petitions approved A	Form I–539 CW–2 initial or extension of stay applications received B	Percent of initial or extension of stay applications (%) C = B ÷ A
2013	5,655	889	15.7
2013	6,517	687	10.5
2014	6,632	1,081	16.3
2015	5,946	906	15.2
2016	7,137	1,406	19.7
2017	6,278	867	13.8
2018	6,570	695	10.6
Total	39,080	6,531	
6-year average	6,513	933	15.0

Source: Office of Policy and Strategy, Research and Evaluation Division (OP&S RED) and USCIS analysis.

ii. CNMI-Only Transitional Worker Program Numerical Limitations

The Consolidated Natural Resources Act of 2008 (CNRA), which extended U.S. immigration and naturalization laws to the CNMI, authorized DHS to create a temporary nonimmigrant worker permit program and to gradually reduce the annual number of visas issued to zero at the end of the five-year transition period. However, in December 16, 2014, Congress extended the transition period until the first quarter of FY 2020 (or December 31, 2019),[67] DHS had to readjust the CW–1 numerical limitations in such a way that the annual number of visas issued would become zero at the sunset date of December 31, 2019. DHS published these annual numerical caps in a series of **Federal Register** notices. Table 8 shows the numerical caps set by DHS for each year prior to this IFR (see column A).

The Workforce Act extended the CW–1 program through FY 2030, increased the CW–1 numerical cap for FY 2019, and provided new CW–1 numerical caps for subsequent fiscal years as shown in column B of Table 8. For FYs 2018 through 2020, DHS estimates the net numerical caps resulting from the Workforce Act by subtracting the numerical caps prior to the Workforce Act from those in the Workforce Act (see column C, Table 8). For FYs 2021 through 2030, the net numerical caps

[67] *See* Public Law 113–235, section 10 (Dec. 16, 2014).

are the same as those set by the Workforce Act.

TABLE 8—NUMERICAL CAPS FOR CW–1 VISAS PRIOR TO THIS IFR AND SET BY THE WORKFORCE ACT

Fiscal year	CW–1 visa numerical caps prior to this IFR A	CW–1 visa numerical caps set by the Workforce Act B	Net CW–1 visas numerical caps as a result of the Workforce Act C = B − A
2011	[68] 22,417		
2012	22,416		
2013	[69] 15,000		
2014	[70] 14,000		
2015	[71] 13,999		
2016	[72] 12,999		
2017	[73] 13,348		
2018	[74] 9,998	9,998	0
2019	4,999	13,000	8,001
2020	[75] 2,499	12,500	10,001
2021		12,000	12,000
2022		11,500	11,500
2023		11,000	11,000
2024		10,000	10,000
2025		9,000	9,000
2026		8,000	8,000
2027		7,000	7,000
2028		6,000	6,000
2029		5,000	5,000
2030		[76] 1,000	1,000

iii. Population Affected by This IFR

DHS uses the estimates derived from the historical data in Tables 1 through 7 and the numerical limitations set by the Workforce Act in Table 8 to estimate the total population affected by this IFR. The net numerical caps in this IFR show the maximum number of persons who may be granted CW–1 visas during each of the FYs 2019 through 2030.[77] DHS assumes that employers petition for, and DHS approves, the maximum number of available visas for each fiscal year. As the historical data in Table 2 show, the number of petitions received and beneficiaries approved exceeded the CW–1 numerical cap, in certain fiscal years.[78] Receiving more petitions than would potentially be approved helps minimize the number of CW–1 visas that may remain unused in each fiscal year due to beneficiaries who may not ultimately be granted a CW–1 visa or whose petition may ultimately be denied. Similarly, to ensure that there are no unused visas in any fiscal year during the IFR's implementation period, DHS assumes that USCIS receives more petitions than may potentially be approved each year to account for the number of petitions that may be denied each year. As shown in Table 2, because USCIS may on average approve 93 percent of the petitions, on average 7 percent of the petitions may be denied each year. This means USCIS may receive on average 7 percent more petitions each year to ensure the net numerical caps are met as shown in Table 8.

As shown in Table 2, on average one petition is for approximately two beneficiaries. USCIS estimates the number of petitions that may be approved each year by dividing the number of visas available for each year by the average number of beneficiaries per petition (two). Overall, a total of 98,502 CW–1 visas are available for the implementation period. These 98,502 CW–1 visas would be filed by 49,251

[68] DHS announced the 2011 and 2012 numerical caps in its current regulation at 8 CFR 214.2(w)(1)(viii)(A) and (B).

[69] See CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2013, 77 FR 71287 (Nov. 30, 2012).

[70] *See* CNMI-Only Transitional Worker Numerical Limitation for Fiscal Year 2014, 78 FR 58867 (Sept. 25, 2013).

[71] DHS decided to preserve the status quo at 13,999 for 2015, nominally reducing the 2014 cap by one, rather than aggressively reducing the 2015 CW–1 numbers since DOL and later Congress extended the CW program until Dec. 31, 2019. *See* Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2015, 79 FR 58241 (Sept. 29, 2014).

[72] For FY 2016, DHS reduced the cap by 1,000 to a limit of 12,999. See Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2016, 80 FR 63911 (Oct. 22, 2015).

[73] DHS reduced the cap for FY 2017 by only one to 12,998. See Commonwealth of the Northern Mariana Islands Transitional Worker Classification (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Year 2017, 81 FR 60581 (Sept. 2, 2016). But Congress enacted Public Law 115–53, 2 to add 350 CW–1 permits to the 2017 cap (*i.e.,* 13,348 = 12,998 + 350).

[74] In 2017, DHS published a reduction plan on the number of CW–1 workers available during fiscal years 2018 through 2020. See Commonwealth of the Northern Mariana Islands (CNMI)-Only Transitional Worker Numerical Limitation for Fiscal Years 2018 Through 2020, 82 FR 55493 (Nov. 22, 2017).

[75] Prior to the Workforce Act, the sunset date for CNMI-Only Transitional Worker Program was quarter one of FY 2020 (or Dec. 31, 2019).

[76] The Workforce Act now extends the sunset date for the CNMI-Only Transitional Worker Program to quarter one of FY 2030 (or Dec. 31, 2029).

[77] For this analysis the statutory changes start from fiscal year 2019 because the Workforce Act did not change the numerical caps for 2018 set by DHS on Nov. 22, 2017.

[78] Generally, CW–1 petitions are adjudicated on a first-come, first-serve basis. As the number of CW–1 workers approaches the numerical limit, USCIS will monitor the number of petitions received (including the number of beneficiaries requested) until a determination is made on the final receipt date. Petitions will be accepted in the order in which the petitions are filed until such time as USCIS has accepted the number of petitions necessary to achieve the numerical limit (the ''cap''). Once this happens, USCIS will announce the final receipt date, which is the date after which USCIS will not accept any petitions subsequently filed. Any petitions that were received after the final receipt date will be rejected.

petitioners [79] and be approved by USCIS. To account for the number of beneficiaries who may not ultimately be granted a CW–1 visa or whose petition may ultimately be denied, DHS uses the average denial rate (7 percent) as described above. Hence to approve 49,251 petitions and use all available visas, USCIS will accept a total of 52,699 petitions during the implementation period.[80] Table 9 shows the estimated number of petitions that would be approved and filed in FYs 2019 to 2030.

TABLE 9—ESTIMATED NUMBER OF FORM I–129CW PETITIONS APPROVED AND FILED

[FY 2019 to 2030]

Fiscal year	Net CW–1 visa numerical cap limitation [81] (from Table 8) A	Estimated number of Form I–129CW petitions approved B = A ÷ 2	Estimated number of Form I–129CW petitions filed with USCIS C = B × (1+7%)
2019	8,001	4,001	4,281
2020	10,001	5,001	5,351
2021	12,000	6,000	6,420
2022	11,500	5,750	6,153
2023	11,000	5,500	5,885
2024	10,000	5,000	5,350
2025	9,000	4,500	4,815
2026	8,000	4,000	4,280
2027	7,000	3,500	3,745
2028	6,000	3,000	3,210
2029	5,000	2,500	2,675
2030	1,000	500	535
Total	98,502	49,251	52,699

Source: USCIS analysis.

The IFR allows petitioners to request an extension of stay for their CW–1 nonimmigrant workers by filing a new Form I–129CW petition. The extension of stay may be granted for a period of up to one year (or a period of up to three years if the employee is a long-term worker). However, as the three year extension period for long-term nonimmigrant workers is a new provision in the IFR, DHS does not have historical data showing the total number of CW–1 long-term workers in the CNMI. As a result, DHS is not able to estimate the number of long-term workers for FYs 2019 to 2030. In the absence of historical data, DHS assumes that the extension of stay request will be granted for a period of one year for non-long-term workers, and for a period of three years for long-term workers. DHS conducts a sensitivity analysis to estimate the potential range of 0 to 90 percent of petitioners who may request an extension of stay for a period of three years (which conversely means 10 to 100 percent of petitioners will be requesting an extension of stay for a period of one year). In this analysis, DHS reports the case where 100 percent of petitioners are requesting an extension of stay for a period of one year as well as the 10 percent lower bound and 90 percent upper bound estimates for the number of petitioners requesting an extension of stay for a period of three years.

Table 10 shows the number petitioners requesting a one-year extension of stay. DHS multiplies the estimated number of petitions that will be approved in FYs 2019 to 2030 by 80 percent (see Table 5) to obtain the estimated number of extension of stay applications that may be filed in the same period. Similarly, DHS multiplies the estimated number of extension of stay applications that may be filed in FYs 2019 to 2030 by 96 percent (see Table 4) to obtain the estimated number of extension of stay applications that will be approved in the same period. DHS also calculates the estimated number of nonimmigrant workers whose extension of stay requests will be granted each year by multiplying the estimated number of extension of stay applications that will be approved each year by the average number of nonimmigrant workers approved per application. Overall, a total of 39,401 petitioners in the CNMI may file a one-year extension of stay applications, of which 37,825 petitions requesting a one-year extension of stay for a total of 75,650 beneficiaries may be approved by USCIS in FYs 2019 to 2030.

[79] 49,251 petitions to be approved = 98,502 available visas ÷ 2 employees per petition.

[80] 52,699 petitions would need to be filed with USCIS to fill the cap limitations = 49,251 petitions to be approved × (1 + 7 percent).

[81] These numerical caps represent the maximum number of visas (CW–1 nonimmigrant workers) that will be approved during the implementation period.

TABLE 10—TOTAL NUMBER OF EXTENSION OF STAY APPLICATIONS AND CW–1 NONIMMIGRANT WORKERS APPROVED

[FY 2019 to 2030]

Fiscal year	Estimated number of petitions approved A	Estimated number of extension of stay applications B = A × 80%	Estimated number of workers requesting extension of stay C = B × 2	Estimated number of petitions approved D = B × 96.0%	Estimated number of workers whose extension of stay approved E = D × 2
2019	4,001	3,200.4	6,400.8	3,072.4	6,144.8
2020	5,001	4,000.4	8,000.8	3,840.4	7,680.8
2021	6,000	4,800.0	9,600.0	4,608.0	9,216.0
2022	5,750	4,600.0	9,200.0	4,416.0	8,832.0
2023	5,500	4,400.0	8,800.0	4,224.0	8,448.0
2024	5,000	4,000.0	8,000.0	3,840.0	7,680.0
2025	4,500	3,600.0	7,200.0	3,456.0	6,912.0
2026	4,000	3,200.0	6,400.0	3,072.0	6,144.0
2027	3,500	2,800.0	5,600.0	2,688.0	5,376.0
2028	3,000	2,400.0	4,800.0	2,304.0	4,608.0
2029	2,500	2,000.0	4,000.0	1,920.0	3,840.0
2030	500	400.0	800.0	384.0	768.0
Total	49,251	39,401.0	78,802.0	37,825.0	75,650.0

Source: USCIS analysis.

As shown in Tables 11 and 12, the three-year extension of stays requested in FY 2019 will be valid, if ultimately granted, for three consecutive years (FYs 2020 to 2022), and hence will be counted towards these years' numerical caps. The same applies for extension of stay requests in the rest of the implementation years. To illustrate using numbers from Table 11, a three-year extension of stay is requested for 640 beneficiaries in FY 2019, which if granted will be valid for three consecutive years (FYs 2020 to 2022) and counted towards the numerical caps of 800, 960 and 920 in the corresponding years. As a result, the number of valid three-year extension of stays will be 640 in FY 2020,[82] 160 in FY 2021,[83] and 160 in FY 2022.[84] The footnotes to Tables 11 and 12 show similar calculations for the net number of beneficiaries for whom three-year extension of stay will be requested in the rest of the implementation years.

TABLE 11—ESTIMATED NUMBER OF APPLICATIONS FOR THREE-YEAR EXTENSION OF STAY (LOWER BOUND)

[FY 2019 to 2030]

Fiscal year	Number of beneficiaries for whom extension of stay requested (from Table 10) [a] A	Number of beneficiaries for whom three-year extension of stay can be requested B = A × 10 percent	Net number of beneficiaries for whom three-year extension of stay requested C = B adjusted for three-year validity period	Estimated number of applications for three-year extension of stay D = C ÷ 2
2019	6,401	640	.....	.....
2020	8,001	800	640	320
2021	9,600	960	160	80
2022	9,200	920	160	80
2023	8,800	880	[b] 600	300
2024	8,000	800	[c] 120	60
2025	7,200	720	[d] 80	40
2026	6,400	640	[e] 520	260
2027	5,600	560	[f] 40	20
2028	4,800	480	[g] 0	0
2029	4,000	400	[h] 440	220
2030	800	80	0	0
Total	78,802	7,880	2,760	1,380

Source: USCIS analysis.

[a] This assumes that all the requests are only for one-year extension of stay.

[82] There will be 640 valid three-year extension of stays in FY 2020 because the validity period of the 640 extension of stay requests made in FY 2019 will start in FY 2020.

[83] 160 net three-year extension of stays in FY 2021 = (800 requests for extension of stay beneficiaries in FY 2020 whose validity period starts in FY 2021) – (640 beneficiaries from FY 2020 counted towards FY 2021 numerical cap).

[84] 160 net three-year extension of stays in FY 2022 = (960 requests for extension of stay beneficiaries in FY 2021 whose validity period starts in FY 2022) – (640 beneficiaries from FY 2020 counted towards FY 2022 numerical cap) – (160 beneficiaries from FY 2021 counted towards FY 2022 numerical cap).

[b] 600 net three-year extension of stay requests in FY 2023 = (920 requests for extension of stay beneficiaries in FY 2022 whose validity period starts in FY 2023) − (160 beneficiaries from FY 2021 counted towards FY 2022 numerical cap) − (160 beneficiaries from FY 2022 counted towards FY 2023 numerical cap).

[c] 120 net three-year extension of stay requests in FY 2024 = (880 requests for extension of stay beneficiaries in FY 2023 whose validity period starts in FY 2024) − (160 beneficiaries from FY 2022 counted towards FY 2024 numerical cap) − (600 beneficiaries from FY 2023 counted towards FY 2024 numerical cap).

[d] 80 net three-year extension of stay requests in FY 2025 = (800 requests for extension of stay beneficiaries in FY 2024 whose validity period starts in FY 2025) − (600 beneficiaries from FY 2023 counted towards FY 2025 numerical cap) − (120 beneficiaries from FY 2024 counted towards FY 2025 numerical cap).

[e] 520 net three-year extension of stay requests in FY 2026 = (720 requests for extension of stay beneficiaries in FY 2025 whose validity period starts in FY 2026) − (120 beneficiaries from FY 2024 counted towards FY 2026 numerical cap) − (80 beneficiaries from FY 2025 counted towards FY 2026 numerical cap).

[f] 0 net three-year extension of stay requests in FY 2027 = (640 requests for extension of stay beneficiaries in FY 2026 whose validity period starts in FY 2027) − (80 beneficiaries from FY 2025 counted towards FY 2027 numerical cap) − (520 beneficiaries from FY 2026 counted towards FY 2027 numerical cap).

[g] 0 net three-year extension of stay requests in FY 2028 = (560 requests for extension of stay beneficiaries in FY 2027 whose validity period starts in FY 2028) − (520 beneficiaries from FY 2026 counted towards FY 2028 numerical cap) − (40 beneficiaries from FY 2027 counted towards FY 2028 numerical cap).

[g] 440 net three-year extension of stay requests in FY 2029 = (480 requests for extension of stay beneficiaries in FY 2028 whose validity period starts in FY 2029) − (40 beneficiaries from FY 2027 counted towards FY 2029 numerical cap) − (0 beneficiaries from FY 2028 counted towards FY 2029 numerical cap).

[h] There is no new three-year extension of stay request in FY 2030 because the 400 and 80 requests for extension of stay beneficiaries in FYs 2029 and 2030, respectively, will not be requested for three-year validity period. Instead, all will be a one-year extension of stay requests.

TABLE 12—ESTIMATED NUMBER OF APPLICATIONS FOR THREE-YEAR EXTENSION OF STAY (UPPER BOUND)

[FY 2019 to 2030]

Fiscal year	Number of beneficiaries for whom extension of stay requested (from Table 10) [a] A	Number of beneficiaries for whom three-year extension of stay can be requested B = A × 90 percent	Net number of beneficiaries for whom three-year extension of stay requested C = B adjusted for three-year validity period	Estimated number of applications for three-year extension of stay D = C ÷ 2
2019	6,401	5,761	.....	.....
2020	8,001	7,201	[b] 5,761	2,880
2021	9,600	8,640	[c] 1,440	720
2022	9,200	8,280	[d] 1,439	720
2023	8,800	7,920	[e] 5,401	2,700
2024	8,000	7,200	[f] 1,080	540
2025	7,200	6,480	[g] 719	360
2026	6,400	5,760	[h] 4,681	2,340
2027	5,600	5,040	[i] 360	180
2028	4,800	4,320	[j] 0	0
2029	4,000	3,600	[k] 3,960	1,980
2030	800	720	[l] 0	0
Total	78,802	70,921	24,841	12,420

Source: USCIS analysis.

[a] This assumes that all the requests are only for one-year extension of stay.

[b] 5,761 extension of stays will be requested in FY 2020 because the validity period of the 5,761 extension of stay requests made in FY 2019 will start in FY 2020.

[c] 1,400 net three-year extension of stay requests in FY 2021 = (7,201 requests for extension of stay beneficiaries in FY 2020 whose validity period starts in FY 2021) − (5,761 beneficiaries from FY 2020 counted towards FY 2021 numerical cap).

[d] 1,439 net three-year extension of stay requests in FY 2022 = (8,640 requests for extension of stay beneficiaries in FY 2021 whose validity period starts in FY 2022) − (5,761 beneficiaries from FY 2020 counted towards FY 2022 numerical cap) − (1,440 beneficiaries from FY 2021 counted towards FY 2022 numerical cap).

[e] 5,401 net three-year extension of stay requests in FY 2023 = (8,280 requests for extension of stay beneficiaries in FY 2022 whose validity period starts in FY 2023) − (1,440 beneficiaries from FY 2021 counted towards FY 2022 numerical cap) − (1,439 beneficiaries from FY 2022 counted towards FY 2023 numerical cap).

[f] 1,080 net three-year extension of stay requests in FY 2024 = (7,920 requests for extension of stay beneficiaries in FY 2023 whose validity period starts in FY 2024) − (1,439 beneficiaries from FY 2022 counted towards FY 2024 numerical cap) − (5,401 beneficiaries from FY 2023 counted towards FY 2024 numerical cap).

[g] 719 net three-year extension of stay requests in FY 2025 = (7,200 requests for extension of stay beneficiaries in FY 2024 whose validity period starts in FY 2025) − (5,401 beneficiaries from FY 2023 counted towards FY 2025 numerical cap) − (1,080 beneficiaries from FY 2024 counted towards FY 2025 numerical cap).

[h] 4,681 net three-year extension of stay requests in FY 2026 = (6,480 requests for extension of stay beneficiaries in FY 2025 whose validity period starts in FY 2026) − (1,080 beneficiaries from FY 2024 counted towards FY 2026 numerical cap) − (719 beneficiaries from FY 2025 counted towards FY 2026 numerical cap).

[i] 360 net three-year extension of stay requests in FY 2027 = (5,760 requests for extension of stay beneficiaries in FY 2026 whose validity period starts in FY 2027) − (719 beneficiaries from FY 2025 counted towards FY 2027 numerical cap) − (4,681 beneficiaries from FY 2026 counted towards FY 2027 numerical cap).

[j] 0 net three-year extension of stay requests in FY 2028 = (5,040 requests for extension of stay beneficiaries in FY 2027 whose validity period starts in FY 2028) − (4,681 beneficiaries from FY 2026 counted towards FY 2028 numerical cap) − (360 beneficiaries from FY 2027 counted towards FY 2028 numerical cap). The result is rounded from −1 that shows an extra three-year extension of stay request above the FY 2027 cap limit (5,040) whose validity period starts in 2028.

[k] 3,960 net three-year extension of stay requests in FY 2029 = (4,320 requests for extension of stay beneficiaries in FY 2028 whose validity period starts in FY 2029) − (360 beneficiaries from FY 2027 counted towards FY 2029 numerical cap) − (0 beneficiaries from FY 2028 counted towards FY 2029 numerical cap).

[1] There is no new three-year extension of stay request in FY 2030 because the 3,600 and 720 requests for extension of stay beneficiaries in FYs 2029 and 2030, respectively, will not be requested for three-year validity period. Instead, all will be a one-year extension of stay requests.

The IFR provides that, of the total number of approved petitions, petitioners may amend a certain number of petitions when there are material changes in the terms and conditions of employment. USCIS may revoke some of the approved petitions, in whole or in part, immediately and automatically if the petitioner ceases operations, files a written withdrawal of the petition, or DOL revokes the temporary labor certification. USCIS also has the discretion to revoke on notice when petitioners violate the grounds for revocation as listed in the preamble of this IFR. From the historical data presented in Table 3, on average 2.20 percent of approved petitions were amended annually while 0.20 percent of approved visas were revoked annually. DHS uses these rates to estimate the number of petitions to be amended and visas to be revoked, respectively, during the implementation period.

Accordingly, DHS multiplies the number of petitions to be approved in the implementation period by 2.20 percent to obtain the estimated number of petitions that may be amended in the same period. Similarly, DHS multiplies the number of visas available for the implementation period by 0.20 percent to obtain the estimated number of visas that may be revoked in the same period. DHS also estimates the number of petitions to be revoked each year by dividing the number of visas to be revoked each year by the average number of beneficiaries per petition. Table 13 shows these calculations in detail. In general, a total of 1,084 petitions will be amended by petitioners [85] and 197 visas may be revoked by USCIS [86] from FYs 2019 to 2030.

As discussed in the preamble, for each beneficiary of a petition revoked in a fiscal year, DHS will add an equivalent number of CW–1 visas to the numerical caps of the next fiscal year. This means that visas revoked in FY 2019 will be added to the numerical cap of FY 2020, visas revoked in FY 2020 will be added to the numerical cap of FY 2021, and so on. As a result, all the revoked visas will be available for filing in the subsequent years. For example, the 16 visas revoked in FY 2019 will be added to FY 2020 numerical cap and available for filing in FY 2020. As a result, approximately 8 petitions will be filed in FY 2020 to request these 16 available visas.[87] Columns E and F in Table 13 show the estimated number of revoked visas that will be added and available for filing and the corresponding number of petitions filed in the subsequent FYs 2020 to 2030.[88]

TABLE 13—TOTAL NUMBER OF FORM I–129CW PETITIONS AMENDED, PETITIONS AND VISAS REVOKED AND SUBSEQUENTLY ADDED VISAS

[FY 2019 to 2030]

Fiscal year	CW–1 visa numerical caps	Estimated number of petitions approved	Estimated number of petitions amended	Estimated number of visas revoked	Estimated number revoked visas filed	Estimated number of revoked petitions filed [a]
	A	B	C = B × 2.20%	D = A × 0.20%	E	F = E ÷ 2
2019	8,001	4,001	88.0	16.0		
2020	10,001	5,001	110.0	20.0	16.0	8.0
2021	12,000	6,000	132.0	24.0	20.0	10.0
2022	11,500	5,750	126.5	23.0	24.0	12.0
2023	11,000	5,500	121.0	22.0	23.0	11.5
2024	10,000	5,000	110.0	20.0	22.0	11.0
2025	9,000	4,500	99.0	18.0	20.0	10.0
2026	8,000	4,000	88.0	16.0	18.0	9.0
2027	7,000	3,500	77.0	14.0	16.0	8.0
2028	6,000	3,000	66.0	12.0	14.0	7.0
2029	5,000	2,500	55.0	10.0	12.0	6.0
2030	1,000	500	11.0	2.0	10.0	5.0
Total	98,502	49,251	1,083.5	197.0	195.0	97.5

Source: USCIS analysis.

[a] To estimate the approximate number of petitions that will be filed, USCIS divides the number of revoked visas by the number of beneficiaries per petition (2). This is because the numerical caps for subsequent years are increased by the number of visas revoked in the preceding years and made available for use by any petitioner.

Qualifying dependents (*i.e.,* eligible spouse or child) of nonimmigrant workers with valid CW–1 status can apply for CW–2 status using Form I–539. DHS assumes that applications requesting a CW–2 status are filed by qualifying dependents of approximately 15 percent of the total number of nonimmigrant workers with approved CW–1 status (see Table 7) during the implementation period. DHS also assumes that 96 percent of these CW–2 applications will be approved in FYs 2019 to 2030, where on average one beneficiary is approved per application (see Table 6). DHS multiplies the estimated number of petitions that will be approved in FYs 2019 to 2030 by 15 percent to obtain the estimated number of CW–2 applications that may be filed in the same period. DHS multiplies the estimated number of CW–2 applications that may be filed in FYs 2019 to 2030 by 96 percent to obtain the estimated number of CW–2 applications that will be approved in the same period. DHS also calculates the estimated number of dependents of the nonimmigrants workers whose request for CW–2 status will be approved each year by multiplying the estimated number of CW–2 applications that will be approved each year by the average

[85] 1,084 petitions amended = 49,251 petitions approved × 2.20 percent of petitions amended annually.

[86] 197 visas revoked = 98,502 visas approved × 0.20 percent visas revoked annually.

[87] 8 petitions filed = 16 visas revoked ÷ 2 beneficiaries per petition.

[88] Note that two visas (in column D), revoked in fiscal year 2030 cannot be filed before the end of the implementation period.

number of dependents approved per application (1). Overall, nonimmigrant workers are expected to file a total of 14,775 applications requesting a CW–2 status for their qualifying dependents from FYs 2019 to 2030, of which 14,184 applications (or dependents) may be approved by USCIS.[89] Table 14 shows the total number of CW–2 applications and dependents whose request for CW–2 status may be approved in FYs 2019 to 2030.

TABLE 14—TOTAL NUMBER OF CW–2 FORM I–539 APPLICATIONS FILED AND APPROVED

[FY 2019 to 2030]

Fiscal year	Estimated number of Form I–539 applications approved A	Estimated number of CW–2 Form I–539 applications B = A × 15%	Estimated number of dependents for whom CW–2 status requested C = B × 1	Estimated number of CW–2 Form I–539 applications approved D = C × 96%	Estimated number of dependents whose CW–2 status approved E = D × 1
2019	8,001	1,200.2	1,200.2	1,152.1	1,152.1
2020	10,001	1,500.2	1,500.2	1,440.1	1,440.1
2021	12,000	1,800.0	1,800.0	1,728.0	1,728.0
2022	11,500	1,725.0	1,725.0	1,656.0	1,656.0
2023	11,000	1,650.0	1,650.0	1,584.0	1,584.0
2024	10,000	1,500.0	1,500.0	1,440.0	1,440.0
2025	9,000	1,350.0	1,350.0	1,296.0	1,296.0
2026	8,000	1,200.0	1,200.0	1,152.0	1,152.0
2027	7,000	1,050.0	1,050.0	1,008.0	1,008.0
2028	6,000	900.0	900.0	864.0	864.0
2029	5,000	750.0	750.0	720.0	720.0
2030	1,000	150.0	150.0	144.0	144.0
Total	98,502	14,775	14,775	14,184	14,184

Source: USCIS analysis.

5. Cost-Benefit Analysis

This section presents the costs and benefits associated with the requirements for hiring CW–1 nonimmigrant workers in the CNMI based on the numerical caps set by the Workforce Act. A total of 1,471 petitioners (see Table 2) in the CNMI will file 52,699 petitions for a total 98,502 visas (see Table 9) available in the implementation period (FYs 2019 to 2030). These constitute the total estimated number of affected population for petitioners, petitions and nonimmigrant workers (beneficiaries), respectively. In this analysis, DHS uses an hourly compensation rate for estimating the opportunity cost of time for human resources (HR) specialists. DHS uses this occupation as a proxy of who might prepare and complete these petitions for an entity. DHS notes that not all entities may have an HR specialist, but rather some equivalent occupation may prepare and complete the petition. DHS also uses an hourly compensation rate to determine the opportunity costs of time for qualifying dependents (*i.e.,* spouse or child) of the CW–1 nonimmigrant workers who file applications for CW–2 status. DHS estimates the hourly compensation rates by adjusting the average hourly wage rates by a benefit-to-wage multiplier to account for the full cost of benefits such as paid leave, insurance, and retirement. Based on the most recent report by the Bureau of Labor Statistics (BLS) on the average employers' costs for employee compensation for all civilian workers in major occupational groups and industries, DHS estimates that the benefits-to-wage multiplier is 1.46.[90]

DHS uses an average hourly compensation rate of $36.30 for HR specialists in Guam[91] as a reasonable proxy for the CNMI in the estimation of the opportunity cost of time for preparing and filing a Form I–129CW petition on behalf of CW–1 nonimmigrant workers.[92] Additionally, DHS uses an average hourly compensation rate of $10.59 in the CNMI[93] as a reasonable proxy for dependents of CW–1 nonimmigrant workers in the CNMI in the estimation of the opportunity cost of time for filing Form I–539 applications requesting a CW–2 status.

i. Baseline Estimate of Current Costs

As mandated by the Consolidated Natural Resources Act of 2008 (CNRA), which created a Commonwealth of the Northern Mariana Islands Transitional Worker Classification to employ adequate numbers of nonimmigrant workers in the CNMI during the 5-year transitional period, DHS published a final rule on September 7, 2011 to implement a temporary CW classification that included CW–1 for principal workers and CW–2 for spouses and minor children. Since then, DHS has been setting the CW–1 numerical

[89] Because nonimmigrant workers with CW–1 status apply on average for one family member in each CW–2 application, the number of applications is equal to the number of dependents.

[90] The benefits-to-wage multiplier is calculated as follows: ($36.63 Total Employee Compensation per hour) ÷ ($25.03 Wages and Salaries per hour) = 1.463 = 1.46 (rounded). *See* Economic News Release, *Employer Cost for Employee Compensation (September 2018),* U.S. Department of Labor, BLS, Table 1. Employer costs per hour worked for employee compensation and costs as a percent of total compensation: Civilian workers, by major occupational and industry group. Released December 14, 2018, available at *https://www.bls.gov/news.release/archives/ecec_12142018.pdf* (last visited February 4, 2019).

[91] Hourly compensation of $36.30 = $24.86 average hourly wage rate for HR specialists × 1.46 benefits-to-wage multiplier. *See* Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2018 National Occupational Employment and Wage Estimates Guam, SOC 13–1071—Human Resources Specialist. Available at *https://www.bls.gov/oes/2018/may/oes_gu.htm* (last visited June 20, 2019).

[92] The Bureau of Labor Statistics does not report hourly wage rates for the CNMI.

[93] Hourly compensation of $10.59 = $7.25 federal minimum hourly wage rate in the CNMI × 1.46 benefits-to-wage multiplier. *See* Employee Rights Under The Fair Labor Standards Act, Federal Minimum Wage In the Commonwealth Of The Northern Mariana Islands, Department of Labor, Wage and Hour Division, September 30, 2018. Available at *https://www.dol.gov/whd/regs/compliance/posters/cnmi.pdf* (last visited June 13, 2019).

caps on the number of nonimmigrant workers employed annually by announcing them, first by amending its existing regulations and later in **Federal Register** notices. The CNRA mandated an annual reduction in the number of permits issued per year and the total elimination of the CW nonimmigrant classification by the end of the transition period. The transition period was initially set to expire on December 31, 2014, but the Secretary of the Department of Labor later extended it to December 31, 2019 as per the provision in the CNRA.

However, before the expiration of the transition period on December 31, 2019, the Workforce Act was signed into law on July 24, 2018. The Workforce Act extends the transition period to December 31, 2029 and makes several changes that affect, among others, existing regulations governing DHS immigration policy and procedures. As a result, DHS issues this IFR to make amendments to its existing regulations and establish procedures to implement the provisions of the Workforce Act.

The provisions of the Workforce Act will be implemented in a period primarily occurring after the previously authorized transition period, because the overlap between that transition period and the transition period established by the Workforce Act is only for about two years, of the 12 transition years.[94] This indicates that the numerical caps set by the Workforce Act on the number of CW–1 nonimmigrant workers employed annually took effect before DHS's previously scheduled reductions in the numerical cap took effect. As a result, to account for the net number of CW–1 permits available during the overlap period, DHS subtracts the numerical caps authorized during the previous transition period from the numerical caps established by the Workforce Act as shown in Table 8. Therefore, the net number of CW–1 permits available during the overlapping period is 8,001 and 10,001 for FYs 2019 and 2020, respectively.[95] This helps shorten the steps required to separately estimate costs, first for the previously authorized transition period, second for the transition period established by the Workforce Act, and then take the difference between these costs to capture the net cost attributable to the IFR in the overlapping period. DHS estimates the costs resulting from the regulatory changes and incurred in the implementation period (*i.e.,* FYs 2019 to 2030) using the affected population estimated based on the net numerical caps in FYs 2019 and 2020 (*i.e.,* 8,001 and 10,001, respectively) and the numerical caps set forth by the Workforce Act for FYs 2021 to 2030.

ii. Costs of Regulatory Changes to Petitioners

The new costs associated with the IFR include costs of preparing and filing Form I–129CW petitions, filing applications for extension of stay, participating in the E-Verify program, submitting semiannual reports and document retention, filing amended petitions and sending notifications, and filing revoked petitions. These costs are presented in detail in the following subsections.

(a) Cost of Filing Form I–129CW Petitions

A petitioner is required to file Form I–129CW to employ nonimmigrant workers who are otherwise ineligible to work in the CNMI under other nonimmigrant worker categories. DHS estimates that the time burden per response, which includes the time for reviewing instructions, gathering the required documentation and information, completing the petition, preparing statements, attaching necessary documentation, and submitting the petition, is 4 hours.[96] The filing fee for an employer to petition on behalf of one or more nonimmigrant workers is $460 per petition.

Additionally, DHS is increasing the supplemental CNMI education funding fee from $150 to $200 per beneficiary issued CW–1 status per year. This updates the regulation, at 8 CFR 103.7(b)(1)(i)(J) to reflect that in 2017 Congress raised the supplemental CNMI education funding fee from $150 to $200[97] per each beneficiary issued CW–1 status, per year. Consistent with the Workforce Act, the IFR also provides the Secretary of Homeland Security the discretion to annually adjust this supplemental fee via notice in the **Federal Register**. This fee is characterized as a transfer payment[98] for the purposes of our analysis.

This IFR also updates existing regulations, at 8 CFR 214.2(w)(5), to include the Workforce Act's requirement that CW–1 employers must pay a mandatory $50 fraud prevention and detection fee with each petition, in addition to other current fees DHS is updating the regulatory provision as the increase is not new and has been in effect since 2017. The additional $50 fraud prevention and detection fee per each petition is intended for a new and permanent site visit program. The fee is for the sole purpose of fraud deterrence and detecting immigration benefit fraud in the Northern Mariana Islands.[99] DHS characterizes this fee as a cost because in general, fee revenues will support new activities that were not previously conducted.

DHS estimates the opportunity cost of time to complete and submit Form I–129CW by multiplying the estimated total number of petitions filed (52,699) in the implementation period by the average time it takes to complete and submit a petition (4 hours) and the average hourly compensation rate for a HR specialist ($36.30). DHS estimates the costs associated with a petition filing fee, supplemental education funding fee and fraud prevention and detection fee by multiplying the estimated total affected population under each case by their respective fee amounts. DHS also applies the average mailing cost per package ($53.50) [100] to the total number of petitions filed

[94] The overlap between the previously authorized transition period (ending on December 31, 2019) and the transition period established by the Workforce Act (ending on December 31, 2029) is only between the last quarter of fiscal year 2018 (which has already elapsed), fiscal year 2019, and the first quarter of fiscal year 2020.

[95] For FY 2019: 8,001 net numerical cap in the IFR = 13,000 numerical cap set by the Workforce Act − 4,999 numerical cap authorized in the previous transition period. For FY 2020: 10,001 net numerical cap in the IFR = 12,500 numerical cap set by the Workforce Act − 2,499 numerical cap authorized in the previous transition period.

[96] USCIS Office of Policy and Strategy, PRA Compliance provided the time burden for Form I–129 CW.

[97] In 2017, Congress enacted the Northern Mariana Islands Economic Expansion Act, Public Law 115–53, 131 Stat. 1091, which increased the supplemental fee paid for each CW permit to $200 and banned issuing new CW–1 permits to construction workers.

[98] Transfer payments are monetary payments from one group to another that do not affect total resources available to society. *See* Office of Management and Budget (OMB). Circular A–4 pages 14 and 38 for further discussion on transfer payments and distributional effects. September 17, 2003. Available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf.*

[99] This fee is for the sole purpose of preventing and detecting immigration benefit fraud in the Northern Mariana Islands. The fraud fee will also assist with any new filings processed for review, site visits, and/or administrative investigation by USCIS Fraud Detection and National Security personnel at the California Service Center.

[100] Although petitioners may choose other means of shipping, for the purposes of this analysis, DHS uses the shipping prices of United States Postal Service (USPS) Domestic Priority Mail Express Flat Rate Envelopes, which is currently priced at $53.50 per package, as a proxy estimate for the postage cost of mailing a package containing completed Form I–129CW. DHS also assumes that the package on average weighs three pounds and ships to zone 8 (from CNMI to Laguna Niguel, California Service Center). *See* U.S. Postal Service, Price List, Notice 123, Effective January 27, 2019 at: *https://pe.usps.com/text/dmm300/Notice123.htm#_c011* (last visited May 29, 2019).

(52,699) in the implementation period to estimate the postage cost associated with mailing the completed petitions to USCIS. Table 15 shows the detailed calculation of the total petition filing cost of the IFR in FYs 2019 to 2030.

TABLE 15—PETITION FILING COST FOR PETITIONERS
[FY 2019 to FY 2030]

Fiscal year	CW–1 numerical caps (or number of beneficiaries) (from Table 9)	Number of CW–1 petitions to be filed (from Table 9)	OCT to complete Form I–129CW	Form I–129CW filing fee cost	Education funding fee cost (per beneficiary)	Fraud prevention & detection fee cost	Postage cost to mail completed Form I–129CW	Total petition filing cost
	A	B	C = B × 4 hours × $36.30/hour	D = B × $460 filing fee	E = A × $200 education fee	F = B × $50 fraud fee	G = B × $53.50 postage cost	H = C + D + E + F + G
2019	8,001	4,281	$621,534	$1,969,046	$1,600,200	$214,027	$229,009	$4,633,815
2020	10,001	5,351	776,898	2,461,246	2,000,200	267,527	286,254	5,792,124
2021	12,000	6,420	932,184	2,953,200	2,400,000	321,000	343,470	6,949,854
2022	11,500	6,153	893,343	2,830,150	2,300,000	307,625	329,159	6,660,277
2023	11,000	5,885	854,502	2,707,100	2,200,000	294,250	314,848	6,370,700
2024	10,000	5,350	776,820	2,461,000	2,000,000	267,500	286,225	5,791,545
2025	9,000	4,815	699,138	2,214,900	1,800,000	240,750	257,603	5,212,391
2026	8,000	4,280	621,456	1,968,800	1,600,000	214,000	228,980	4,633,236
2027	7,000	3,745	543,774	1,722,700	1,400,000	187,250	200,358	4,054,082
2028	6,000	3,210	466,092	1,476,600	1,200,000	160,500	171,735	3,474,927
2029	5,000	2,675	388,410	1,230,500	1,000,000	133,750	143,113	2,895,773
2030	1,000	535	77,682	246,100	200,000	26,750	28,623	579,155
Total	98,502	52,699	7,651,832	24,241,342	19,700,400	2,634,929	2,819,373	57,047,877

Source: USCIS analysis.
Note: Totals may not sum due to rounding.

As discussed in the preamble to this IFR, an employer filing a petition is eligible to apply for a waiver of the petition fee (but not the CNMI education funding fee or the fraud prevention and detection fee) based upon inability to pay.[101] However, it is important to note that due to lack of historical data on fee waiver requests, DHS is unable to estimate the fee waiver cost in this analysis. As a result, the estimated petition filing cost ($57,047,877) represents an upper bound cost in this analysis being that it could be lower by the value of the fee waiver cost because granted fee waivers accrue as cost savings to petitioners.

(b) Cost Savings From Filing Extension of Stay Applications

Petitioners will be required to file a new petition to request an extension of stay for their currently approved CW–1 nonimmigrant employees. However, DHS does not estimate the cost of filing an extension of stay applications to avoid double counting. The cost of filing new petitions requesting an extension of stay for an existing CW–1 nonimmigrant worker is already captured under the cost of filing petitions for CW–1 status discussed in subsection (a). The cost of filing petitions is estimated using the total number of visas (98,502) available for the duration of the IFR's implementation period, based on the numerical caps set for each year in the IFR, and the total estimated number of petitions that can potentially be filed in this period (52,699, see Table 9). Because an employer's request for extending the period of stay for an existing CW–1 worker in a given year counts towards the numerical cap in the same year, estimating the cost for those who petition for an extension of stay for their nonimmigrant workers results in double counting the cost.[102] That means, whether petitioning for a new CW–1 nonimmigrant worker or requesting an extension of stay for an existing CW–1 nonimmigrant worker, it counts towards the same numerical cap that limits the number of visas available in a given year. Any request for an extension of stay is bound by the numerical caps and USCIS does not accept petitions once the number of visas set for a given year are fully used.[103]

The IFR also states that an extension of stay may be granted for a period of up to three years if the employee is a long-term worker. DHS estimates the cost savings for petitioners who will request a three-year extension of stay for their long-term workers using the lower and upper bound estimates for the net number of beneficiaries for whom a three-year extension of stay will be requested (see Tables 11 and 12). That means, instead of filing a new request to extend permits for all nonimmigrant workers every year, petitioners will save time and resources by applying a three-year extension of stay for their long-term employees once every three years. DHS estimates the cost savings in terms of the opportunity cost of time for filing Form I–129CW, paying a filing fee of $460 and a fraud prevention and detection fee of $50 per application, and a postage cost of $53.50 for mailing the completed application.[104] As shown in Tables 16 and 17, the total petitioners' cost savings resulting from filing a three-year extension of stay for long-term nonimmigrant workers, as opposed to filing a one-year extension of stay, ranges from $978,034 to $8,802,309 from FY 2019 to 2030.

[101] *See* 8 CFR 214.2(w)(5).

[102] The 52,699 initial petitions filed for 98,502 permits available for the implementation period (see Table 9) can also be viewed as consisting of the 39,401 extension of stay applications filed for 78,802 nonimmigrant workers of which 75,650 nonimmigrant workers will be granted an extension of stay (see Table 10).

[103] The IFR states that ''USCIS may reject an employer's petition for new or extended CW–1 status if the numerical limitation has been met.'' When such cases arise, USCIS notifies employers ''that numbers are unavailable for the CW nonimmigrant classification.'' 8 CFR 214.7(w)(21).

[104] It should be noted that there will be no cost savings from paying the educational fund fee as the Workforce Act requires this fee to be collected from all beneficiaries for each year of approval. The educational fee is represented in this analysis as a transfer. See Section (VI)(5)(ii)(b) in this economic analysis.

TABLE 16—PETITIONERS' COST SAVINGS FROM APPLYING FOR THREE-YEAR EXTENSION OF STAY (LOWER BOUND)

[FY 2019 to 2030]

Fiscal year	Estimated number of applications for three-year extension of stay (from Table 11)	OCT to complete Form I–129CW [a]	Form I–129CW filing fee cost	Fraud prevention & detection fee cost	Postage cost to mail completed Form I–129CW	Total application filing cost
	A	B = A × 4 hours × $36.30/hour	C = A × $460 filing fee	D = A × $50 fraud fee	E = A × $53.50 postage cost	F = B + C + D + E
2019	.....	.....	.....	.....	.....	.....
2020	320	$46,470	$147,218	$16,002	$17,122	$226,812
2021	80	11,616	36,800	4,000	4,280	56,696
2022	80	11,610	36,782	3,998	4,278	56,668
2023	300	43,566	138,018	15,002	16,052	212,638
2024	60	8,712	27,600	3,000	3,210	42,522
2025	40	5,802	18,382	1,998	2,138	28,320
2026	260	37,758	119,618	13,002	13,912	184,290
2027	20	2,904	9,200	1,000	1,070	14,174
2028	0	0	0	0	0	0
2029	220	31,944	101,200	11,000	11,770	155,914
2030	0	0	0	0	0	0
Total	1,380	200,382	634,818	69,002	73,832	978,034

Source: USCIS analysis.

[a] OCT denotes the opportunity cost of time and estimated by multiplying the time burden to complete Form I–129CW (4 hours) by the average hourly compensation rate of a HR specialist (36.30).

TABLE 17—PETITIONERS' COST SAVINGS FROM APPLYING FOR THREE-YEAR EXTENSION OF STAY (UPPER BOUND)

[FY 2019 to 2030]

Fiscal year	Estimated number of applications for three-year extension of stay (from Table 12)	OCT to complete Form I–129CW [a]	Form I–129CW filing fee cost	Fraud prevention & detection fee cost	Postage cost to mail completed Form I–129CW	Total application filing cost
	A	B = A × 4 hours × $36.30/hour	C = A × $460 filing fee	D = A × $50 fraud fee	E = A × $53.50 postage cost	F = B + C + D + E
2019	.....	.....	.....	.....	.....	.....
2020	2,880	$418,228	$1,324,966	$144,018	$154,099	$2,041,311
2021	720	104,544	331,200	36,000	38,520	510,264
2022	720	104,492	331,034	35,982	38,501	510,009
2023	2,700	392,092	1,242,166	135,018	144,469	1,913,745
2024	540	78,408	248,400	27,000	28,890	382,698
2025	360	52,220	165,434	17,982	19,241	254,877
2026	2,340	339,820	1,076,566	117,018	125,209	1,658,613
2027	180	26,136	82,800	9,000	9,630	127,566
2028	0	0	0	0	0	0
2029	1,980	287,496	910,800	99,000	105,930	1,403,226
2030	0	0	0	0	0	0
Total	12,420	1,803,436	5,713,366	621,018	664,489	8,802,309

Source: USCIS analysis.

[a] OCT denotes the opportunity cost of time and estimated by multiplying the number of extension of stay applications in each year by the time burden to complete Form I–129CW (4 hours) and the average hourly compensation rate of a HR specialist (36.30).

Please note that totals may not sum due to rounding.

(c) Cost of Participating in the E-Verify Program

This IFR requires that any employer petitioning for a CW–1 nonimmigrant worker must be an E-Verify program participant in good standing. The E-Verify program is a DHS USCIS web-based system that allows enrolled employers to confirm the eligibility of their employees to work in the United States.[105] DHS does not charge a fee to E-Verify employers to create cases to confirm the identity and employment eligibility of newly hired employees by electronically matching information provided by employees on the Form I–9, Employment Eligibility Verification,

[105] *See* E-Verify, available at *https://www.e-verify.gov/* (last visited May 29, 2019).

against records available to DHS and the SSA.

The E-Verify requirement will result in a cost burden to employers currently participating in the E-Verify program as well as to newly enrolling employers. While the employers who will be newly enrolling in the E-Verify program incur startup enrollment or program initiation costs, employers who are currently participating in the E-Verify program do not incur these costs as they already have incurred them previously. However, both groups of employers incur additional cost burdens for ongoing training in E-Verify as they continue to comply with E-Verify requirements and for verifying the identity and work authorization of all of their newly hired employees including new CW–1 nonimmigrant workers.

DHS estimates the number of employers in the CNMI currently participating in the E-Verify program using the data obtained from E-Verify Usage Statistics that tracks E-Verify enrollment and usage on a quarterly basis. The Usage Statistics provide information on enrolled memoranda of understanding (MOU), FY 2018 cases, and usage by U.S. states and territories. Accordingly, there are a total of 141 employers in the CNMI enrolled to use E-Verify and agreed to the terms of the MOU.[106] DHS uses historical data on Form I–129CW petitions from FYs 2012 to 2018 to estimate the number of employers operating in the CNMI each year. These data capture the number of approved employees per petitioning business entity in each fiscal year.[107]

DHS estimates that on average 1,471 business entities (or employers) petitioned for CW–1 nonimmigrants workers each year in the CNMI from FY 2012 to 2018 (see Table 2). Instead of assuming that on average the same number of business entities will continue to petition for CW–1 nonimmigrants workers in FYs 2019 to 2030, DHS uses a linear projection of the FYs 2012 to 2018 data to capture the declining trend in the number of business entities participating in E-Verify during the 12-year implementation period (see Table 19). Because 141 of the 1,771 business entities operating in the CNMI in FY 2019 are currently participating in the E-Verify program, the remaining 1,630 business entities[108] need to enroll in the E-Verify program and incur costs associated with enrollment in order to continue employing CW–1 workers. However, all the business entities will incur the additional time burden cost of ongoing training in E-Verify and creating E-Verify cases to confirm the identity and work authorization of newly hired employees.

Participating in the E-Verify program and remaining in good standing requires employers to enroll online in the program,[109] electronically sign the associated MOU with DHS that set the terms and conditions of participation in the program, and use E-Verify for all newly hired employees. The MOU requires employers to agree to abide by lawful hiring procedures and to ensure that no employee will be unfairly discriminated against as a result of the E-Verify program. Violating the terms of this agreement by the employer is grounds for immediate termination of its participation in the program.[110] Additionally, employers are required to designate and register at least one person that serves as an E-Verify administrator on behalf of the company.

For this analysis, DHS assumes that each employer participating in the E-Verify program designates one HR specialist if operating only in the CNMI, and at least one additional HR specialist if the company is also operating in other U.S. states, to manage the E-Verify program on behalf of the company. Based on the most recent Paperwork Reduction Act Information Collection Package for the E-Verify program, DHS estimates the time burden for the HR specialist to undertake the tasks associated with the E-Verify program. DHS estimates that the enrollment process takes the HR specialist on average 2.26 hours to provide basic company information, review and sign the MOU, take a new user training, and review the user guides. Once enrolled in the E-Verify program, the HR specialist takes training on new features and system updates every year, which takes on average one hour.[111]

Once an employer enrolls in E-Verify program, the employer is responsible for ensuring that the hiring process is undertaken as per the requirements of the MOU and verifying all newly hired employees. Hence, after completing Form I–9, Employment Eligibility Verification, the employer must enter the newly hired employee's information in E-Verify, where the information is checked against records available to SSA and DHS. After checking a worker's information against these records, E-Verify returns the case processing results, which could either automatically confirm the worker as employment authorized or return a tentative non-confirmation (TNC). Receiving a TNC does not mean a worker is not authorized to work in the United States; rather it indicates there is an initial system mismatch between the information the employer entered in E-Verify from the worker's Form I–9 and the records available to DHS or SSA. Workers receiving a TNC have the option to contest (take action) or not contest (not take action) to resolve the DHS or SSA TNC case result. E-Verify requires employers to inform the employee about the TNC and provide instructions for contesting it. The E-Verify website also provides detailed information about contesting the TNC.[112]

As the nationwide E-Verify historical data show, while 98.88 percent of workers are automatically confirmed as work authorized, 1.12 percent have received a TNC as of June 2018.[113] The E-Verify performance data also show that, of the 1.12 percent of workers who receive initial system mismatches, 0.16 percent are later confirmed as work authorized after contesting and resolving the mismatches and the remaining 0.96 percent are not found to be work authorized. Again, of the 0.96 percent of workers not found work authorized, 0.43 percent do not contest the mismatch either because they do not choose to do so or are unaware of the opportunity to contest and as a result are not found work authorized; only 0.02 percent contest the mismatch and

[106] The E-Verify data was updated on Oct. 5, 2018. See *https://www.e-verify.gov/about-e-verify/e-verify-data/e-verify-usage-statistics* (last visited May 29, 2019).

[107] Office of Policy and Strategy, Research and Evaluation Division (OP&S RED) provided the data. The data identify each petitioning business entity by name and tax ID.

[108] 1,630 business entities newly enrolling in E-Verify = 1,771 number of businesses petitioning for CW–1 nonimmigrants workers in FY 2019 − 141 businesses already participating in the E-Verify program.

[109] See the enrollment process at *https://www.e-verify.gov/employers/enrolling-in-e-verify/the-enrollment-process* (last visited May 29, 2019).

[110] *See* USCIS, The E-Verify Memorandum of Understanding for Employers, available at *http://www.uscis.gov/sites/default/files/USCIS/Verification/E-Verify/E-Verify_Native_Documents/MOU_for_E-Verify_Employer.pdf (last visited May 29, 2019).*

[111] The USCIS Office of Policy and Strategy, PRA Compliance Branch estimates the average time burdens. See Paperwork Reduction Act (PRA) E-Verify Program (OMB control number 1615–0092), May 24, 2016. The PRA Supporting Statement can be found under Question 12 at *https://www.regulations.gov/document?D=USCIS-2007-0023-0081 (last visited May 29, 2019).*

[112] See the following for more detailed information *https://www.e-verify.gov/employees/tentative-nonconfirmation-overview/how-to-correct-a-tentative-nonconfirmation* (last visited May 29, 2019).

[113] USCIS E-Verify Performance Statistics, Verification Information System (VIS) Transaction Data. See *https://www.e-verify.gov/about-e-verify/e-verify-data/e-verify-performance* (last visited May 29, 2019).

are not found work authorized; and the remaining 0.51 percent are unresolved cases either because the employer closed the case as ''self-terminated'' or the case was awaiting further action by either the employer or worker as of June 2018.

DHS estimates the time burden to submit a query in E-Verify as a weighted average of the time required to enter workers' initial information for verification and the time required to assist workers with the TNC contestation process to resolve the mismatch,[114] using the above E-Verify case processing results as weights. The most recent Paperwork Reduction Act Information Collection Package for the E-Verify program estimates the time burdens to enter workers' initial information in E-Verify and assist workers with the TNC contestation to be 0.12 hours (or 7.2 minutes) and 0.5 hours (or 30 minutes) per worker, respectively.[115] DHS estimates that on average it takes an HR specialist 0.121 hours (or 7.26 minutes) per worker to submit a query in E-Verify. Table 18 shows estimation of this time burden in detail.

TABLE 18—AVERAGE TIME BURDEN ESTIMATION FOR INITIAL EMPLOYEE CASE VERIFICATION USING E-VERIFY

E-Verify performance categories	Case processing results (%)	Time to submit initial verification query (hours)	Time to resolve mismatch (hours)	Total time burden (hours per worker)	Weighted product
	A	B	C	D = B + C	E = A × D
Automatically confirmed as work authorized	98.88	0.12	0	0.12	0.118656
Confirmed after initial mismatch	0.16	0.12	0.5	0.62	0.000992
Not confirmed after initial mismatch is contested	0.02	0.12	0.5	0.62	0.000124
Not found authorized [a]	0.94	0.12	0	0.12	0.001128
Total	100%				0.121
Weighted Average [b]					0.121

Source: USCIS E-Verify Performance Statistics, Verification Information System (VIS) Transaction Data as of June 2018. Time burden data from Paperwork Reduction Act (PRA) E-Verify Program (OMB control number 1615–0092), May 24, 2016.

[a] 0.94 percent not found authorized = 0.43 percent do not contest the mismatch + 0.51 percent unresolved cases.

[b] 0.121 hours weighted average time burden for submitting a verification query = 0.121 hours sum of weighted product in column E ÷ 100% sum of case processing results in column A.

Using the number of affected populations and the time burdens estimated above, and the hourly compensation rates for HR specialists, DHS estimates the opportunity cost of time of employers participating in the E-Verify program in two parts. First, DHS estimates the opportunity cost of time for employers petitioning for CW–1 nonimmigrant workers in the CNMI. Second, DHS estimates the opportunity cost of time for employers who are operating both in the CNMI and other locations in the U.S. and use E-Verify to confirm the identity and work authorization of all their newly hired employees during the IFR implementation period.

Employers Petitioning for CW–1 Nonimmigrant Workers in the CNMI

Table 19 shows in detail estimation of the opportunity cost for the time employers in the CNMI will spend to enroll in E-Verify, take annual training, and submit a query in E-Verify. As discussed above, 1,630 of the 1,771 employers that petition for CW–1 nonimmigrant workers in FY 2019 need to enroll in E-Verify and incur a one-time enrollment cost at the beginning of the implementation period. Hence, for employers petitioning for CW–1 nonimmigrant workers in the CNMI the total opportunity cost of participating in the E-Verify program is $1,097,732 from FY 2019 to 2030.[116]

TABLE 19—EMPLOYERS' OPPORTUNITY COST OF TIME TO PARTICIPATE IN E-VERIFY PROGRAM

[FY 2019 to 2030]

Fiscal year	Estimated number of employers in the CNMI [a]	Newly enrolling employers [b]	CW–1 numerical caps (or number of beneficiaries) (from Table 9)	Enrollment cost for newly enrolling employers	Employers' annual training cost	Case submission and verification cost	Total E-Verify participation cost in CNMI
	A	B = A − 141 currently participating employers	C	D = B × 2.26 hours × $36.30/hour	E = A × 1 hour × $36.30/hour	F = C × 0.121 hour × $36.30/hour	G = D + E + F
2019	1,771	1,630	8,001	$133,722	$64,287	$35,143	$233,152
2020	1,671		10,001		60,657	43,927	104,585
2021	1,571		12,000		57,027	52,708	109,735
2022	1,471		11,500		53,397	50,511	103,909
2023	1,370		11,000		49,731	48,315	98,046

[114] Here, DHS estimates the amount of time the employer spends in the TNC contestation process, not the time burden for the contesting workers.

[115] The USCIS Office of Policy and Strategy, PRA Compliance Branch estimates the average time burdens. See Paperwork Reduction Act (PRA) E-Verify Program (OMB control number 1615–0092), May 24, 2016. The PRA Supporting Statement can be found under Question 12 at *https://www.regulations.gov/document?D=USCIS-2007-0023-0081* (last visited May 29, 2019).

[116] Note that this cost estimate does not include the cost of job search for employees who are legally able to work in the U.S. but choose not to contest a TNC for whatever reason and lose their jobs. DHS does not have data to estimate the job search cost for this group of employees.

TABLE 19—EMPLOYERS' OPPORTUNITY COST OF TIME TO PARTICIPATE IN E-VERIFY PROGRAM—Continued
[FY 2019 to 2030]

Fiscal year	Estimated number of employers in the CNMI [a]	Newly enrolling employers [b]	CW–1 numerical caps (or number of beneficiaries) (from Table 9)	Enrollment cost for newly enrolling employers	Employers' annual training cost	Case submission and verification cost	Total E-Verify participation cost in CNMI
	A	B = A − 141 currently participating employers	C	D = B × 2.26 hours × $36.30/hour	E = A × 1 hour × $36.30/hour	F = C × 0.121 hour × $36.30/hour	G = D + E + F
2024	1,270		10,000		46,101	43,923	90,024
2025	1,170		9,000		42,471	39,531	82,002
2026	1,069		8,000		38,805	35,138	73,943
2027	969		7,000		35,175	30,746	65,921
2028	869		6,000		31,545	26,354	57,899
2029	769		5,000		27,915	21,962	49,876
2030	668		1,000		24,248	4,392	28,641
Total			98,502	133,722	531,359	432,650	1,097,732

Source: USCIS analysis

[a] DHS uses a linear forecasting equation y = −100.29x + 1,871.7 (obtained using the FY 2012 to 2018 data shown in Table 2, Column A) to estimate the number of business entities that will be petitioning for CW–1 nonimmigrant workers in the CNMI each year during the implementation period. In this equation, y denotes the number of business entities estimated for each year, while x denotes each year of the implementation period (where year 1 represents FY 2019, year 2 represents FY 2020, and so on). For example, the number of business entities operation in the CNMI (y) in FY 2019 (or year 1) = −100.29 × (1) + 1,8771.7 = 1,771 (rounded). For each of the remaining years, the number of business entities operating in the CNMI can be estimated in the same way. Averaging over all years, DHS estimates that an average of 1,220 business entities will be operating in the CNMI each year during the implementation period.

[b] Of the number of business entities operating in the CNMI in FY 2019 (1,771), 141 of them are already participating in the E-Verify program and do not need to enroll in the E-Verify program.

Employers Operating in the CNMI and Other Locations in the U.S. and Hiring New U.S. Employees

To estimate the opportunity cost of time to confirm the identity and work authorization of newly hired U.S. employees using E-Verify, DHS first estimates the number of employers (businesses) that petition for CW–1 nonimmigrant workers operating both in the CNMI and other locations in the U.S. DHS identified a total of 2,481 business entities that have operated in the CNMI and petitioned for CW–1 nonimmigrant workers at one time or another from FY 2012 to 2018. DHS provided the names and Tax ID of these 2,481 business entities to the USCIS E-Verify, Verification Information System (VIS) to identify whether the entities are (a) enrolled in E-Verify and (b) operating in other locations in the U.S. (*i.e.,* outside the CNMI).[117] The E-Verify team conducted individual business name and Tax ID searches in the VIS database and reported the data, based on which DHS estimates that of the total business entities that have been operating in the CNMI and petitioned for CW–1 workers (2,481), only 101 (or 4.1 percent) have already been enrolled in E-Verify for at least one hiring site in the CNMI and other locations in the U.S. Of the 101 enrolled in E-Verify, 70 use E-Verify for at least one hiring site in the CNMI, 30 are operating in other locations in the U.S. but are not enrolled in E-Verify for those locations, and 1 is enrolled in E-Verify for hiring sites in the CNMI and other locations in the U.S. For the remaining number of businesses not enrolled in E-Verify in the CNMI (2,380),[118] USCIS did not assess whether they are operating in other locations in the United States.

Overall, DHS concludes that of the 2,481 business entities only 31 (1.2 percent) operate in the CNMI and other locations in the U.S. DHS applies this rate to the estimated number of employers operating in the CNMI who are expected to petition for CW–1 nonimmigrant workers during the IFR implementation period to obtain that on average 15 employers [119] will be operating both in the CNMI and other locations in the U.S. each year during the implementation period. As per the requirement to participate in the E-Verify program in good standing, all employers operating both in the CNMI and other locations in the U.S. are required to use E-Verify to confirm the identity and work authorization of all their newly hired U.S. employees during the implementation period.

DHS estimates the average number of new employees each of the employers operating in the CNMI and other locations in the U.S. will be hiring each year during the implementation period based on the average employment size of businesses operating in the U.S. and their average hiring rate. As the data obtained from the U.S. Census Bureau shows, the average employment size for a business entity operating in the U.S. is 17 employees.[120] Using the Bureau of Labor Statistics (BLS) 2018 data from the Job Openings and Labor Turnover Survey (JOLTS) Database, DHS also estimates the annual hires rate across all industries in the U.S. to be 51 percent.[121] DHS multiplies the average

[117] DHS searches information for the 2,481 petitioning business entities in the E-Verify VIS database because this database provides two important pieces of information relevant to the analysis: (a) Whether the entities are enrolled in E-Verify program and (b) where they are operating in the U.S. In addition, conducting a global name search for the 2,481 petitioning business entities using other external databases is a time-consuming endeavor as it involves conducting searches in multiple databases only to identify their locations of operation. Given the time constraint to complete the rulemaking, DHS opts to use the E-Verify VIS database as the most viable option to extract both the E-Verify enrollment and location information from a single and reliable source.

[118] 2,380 business entities not enrolled in E-Verify = 2,481 total number of business entities − 101 business entities enrolled in E-Verify.

[119] 15 (rounded) average number of employers operating in the CNMI and other locations in the U.S. = 1,220 average number of employers operating in the CNMI each year × 1.2 percent of business entities operating in the CNMI and other locations in the U.S. Alternatively, the same result is obtained by averaging the number of employers operating in CNMI and other U.S. locations each year shown in Table 20, Column B.

[120] This is estimated by dividing the total number of employment to the total number of establishments in each industry using the U.S. 6-digit NAICS data obtained from the U.S. Census Bureau. Taking the average over all industries, DHS obtains that a business entity in the U.S. on average employs 17 employees. *See* U.S. Census Bureau, Statistics of U.S. Businesses (SUBS), 2016 SUSB Annual Data Tables by Establishment Industry, released on Dec. 18, 2018. *https://www.census.gov/data/tables/2016/econ/susb/2016-susb-annual.html* (last visited June 19, 2019).

[121] BLS, News Release, Job Openings and Labor Turnover—January 2019, Table 14. Annual hires rates by industry and region, not seasonally adjusted. Released March 15, 2019. *See https://*

employment size across businesses (17 employees per business entity) by the annual hires rate (51 percent per business entity) to estimate that an employer in the U.S. hires approximately 9 new employees each year.[122] Finally, DHS multiplies the number of employers operating in the CNMI and other locations in the U.S. each year by the average number of new hires per year to estimate an average of approximately 123 newly hired employees each year during the implementation period.[123] Table 20 shows in detail estimation of the total number of new hire U.S. employees for FY 2019 to 2030.

TABLE 20—ESTIMATED NUMBER OF CNMI EMPLOYERS OPERATING IN OTHER STATES IN THE U.S. AND NUMBER OF NEW HIRES

[FY 2019 to 2030]

Fiscal year	Estimated number of employers operating in CNMI A	Number of employers operating in CNMI & other U.S. locations B = A × 1.2 percent	Average number of employees per businesses entity in U.S. C	Average number of new hires per business entity per year D = C × 51 percent	Total number of new hires per year in other U.S. locations E = B × D
2019	1,771	21.3	17	8.7	185
2020	1,671	20.1	17	8.7	175
2021	1,571	18.9	17	8.7	164
2022	1,471	17.7	17	8.7	154
2023	1,370	16.4	17	8.7	143
2024	1,270	15.2	17	8.7	132
2025	1,170	14.0	17	8.7	122
2026	1,069	12.8	17	8.7	111
2027	969	11.6	17	8.7	101
2028	869	10.4	17	8.7	90
2029	769	9.2	17	8.7	80
2030	668	8.0	17	2.2 [a]	18
Average	1,220	15	17	8.2	123

Source: USCIS analysis

[a] The IFR implementation period ends in FY 2030 quarter 1. Accordingly, the average number of new hires per business entity is estimated only for 3 months for FY 2030 (*i.e.*, 17 × (51 percent ÷ 12 months) × 3 months = 2.2).

Employers that will petition for CW–1 nonimmigrant workers and operate only in the CNMI are also required to use E-Verify to confirm the identity and work authorization of all their newly hired employees. For these businesses operating only in the CNMI, DHS assumes the average employment size to be 15 employees per entity[124] and the annual hires rate across all industries to be 25 percent[125] during the implementation period. DHS estimates that a CW–1 nonimmigrant petitioning employer that operates only in the CNMI on average employs nearly 4 new hires each year,[126] of which approximately 2 will be U.S. employees.[127] Finally, DHS multiplies the number of these employers operating only in the CNMI by the average number of new hire U.S. employees per year to estimate an average of approximately 2,092 new hire U.S. employees each year during the implementation period. Table 21 shows the estimation of the total number of new hire U.S. employees for employers operating only in the CNMI.

www.bls.gov/news.release/archives/jolts_03152019.pdf (last visited August 7, 2019). The hires rate is the number of hires during a reference period as a percent of total employment. The number of hires is the total additions to the payroll occurring at any time during the reference month, including (but not limited to) both new and rehired employees, full-time and part-time, permanent, short-term and seasonal employees.

[122] 9 (rounded) number of new hires per business entity per year = 17 number of employees per business entity × 51 percent hires rate per year. Note that the average number of new hires per business entity falls to 8.2 when we include the new hires for FY 2030 quarter 1.

[123] 123 (rounded) average number of newly hired employees each year = 15 average number of employers operating in the CNMI and other states in the U.S. each year × 8.72 average number of new hires per business entity per year. Table 20 shows in detail the estimation for each year.

[124] This is estimated by dividing the total number of employment to the total number of business entities operating in the CNMI in 2016. According to the CNMI 2016 Prevailing Wage and Workforce Assessment Study (PWWAS) released in September 2017, there were 32,061 employees working for 2,146 employers. 15 employees per business entity = 32,061 employees ÷ 2,146 business entities. *See* 2018 Draft Modification to the Workforce Innovation and Opportunities Act (WIOA) State Plan for the CNMI, submitted by the State Workforce Development Board, final publication date March 15, 2018. *https://www.marianaslabor.net/resources/files/CNMIMondifiedUnifiedStatePlanunderWIOA02072018.pdf* (last visited June 24, 2019).

[125] Id. This is estimated based on projected demand for additional employees over and above the total number of employees in the CNMI in 2016. According to PWWAS, the newly approved projects in the CNMI would raise the demand for additional employees by 8,000 in the following year, resulting in annual hires rate of 25 percent (*i.e.,* 25 percent = (8,000 additional employees ÷ 32,061 number of employees in 2016) × 100).

[126] 4 (rounded) number of new hires per entity per year = 15 number of employees per entity × 25 percent hires rate per year.

[127] 2 (rounded) number of new hire U.S. workers per year = 3.6 number of new hires per year × 47 percent. Using the 2011 to 2016 data obtained from the 2018 GAO report, DHS estimates that U.S. workers account on average for 47 percent of the total workforce in the CNMI. *See* United States Government Accountability Office (GAO), Testimony Before the Committee on Energy and Natural Resources, U.S. Senate, Commonwealth of the Northern Mariana Islands, Recent Economic Trends and Preliminary Observations on Workforce Data. GAO–18–373T, Feb. 2018. GAO used the most recent available CNMI tax data.

TABLE 21—ESTIMATED NUMBER OF EMPLOYERS OPERATING ONLY IN THE CNMI AND THEIR NEWLY HIRED U.S. EMPLOYEES

[FY 2019 to 2030]

Fiscal year	Estimated number of employers operating only in CNMI [a] A	Average number of employees per business entity in CNMI B	Average number of new hires per business entity per year C = B × 25%	Number of newly hired U.S. employees in CNMI D = C × 47%	Total number of newly hired U.S. employees per year in CNMI E = A × D
2019	1,750	15	3.8	1.8	3,149.5
2020	1,651	15	3.8	1.8	2,971.6
2021	1,552	15	3.8	1.8	2,793.8
2022	1,453	15	3.8	1.8	2,615.9
2023	1,354	15	3.8	1.8	2,436.5
2024	1,255	15	3.8	1.8	2,258.6
2025	1,156	15	3.8	1.8	2,080.8
2026	1,056	15	3.8	1.8	1,901.2
2027	957	15	3.8	1.8	1,723.3
2028	859	15	3.8	1.8	1,545.5
2029	760	15	3.8	1.8	1,367.6
2030	660	15	[b] 0.9	0.4	264.0
Total	1,205	15	3.6	1.7	2,092.4

Source: USCIS analysis

[a] Calculation: Number of employers operating only in CNMI = Number of employers operating in CNMI (from Table 20, Column A) − Number of employers operating in CNMI & other U.S. locations (Table 20, Column B).

[b] The IFR implementation period ends in FY 2030 quarter 1. Accordingly, the average number of new hires per business entity is estimated only for 3 months for FY 2030 (*i.e.*, 15 × 2.1 percent × 3 = 0.9 (rounded)).

Using the number of newly hired U.S. employees shown in Tables 20 and 21, DHS estimates the opportunity cost of time to participate in the E-Verify program for employers operating in the CNMI and other locations in the U.S. While employers operating in other locations in the U.S. incur costs for taking annual training and submitting a query in E-Verify for their newly hired employees, employers operating only in the CNMI incur the cost for submitting a query in E-Verify for their newly hired employees.[128] As described above, employers operating both in the CNMI and other locations in the U.S. assign at least one additional HR specialist to handle the case submissions for the new employees hired in other locations in the U.S. DHS uses the average hourly compensation rate of $46.88 for an HR specialist located outside the CNMI [129] and $36.30 for an HR specialist located in the CNMI (as discussed before).

Table 22 shows estimation of the opportunity cost of time employers operating in other locations in the U.S. spend to confirm the identity and work authorization of their newly hired U.S. employees in FYs 2019 to 2030. Likewise, Table 23 shows estimation of the opportunity cost of time employers operating only in the CNMI spend to confirm the identity and work authorization of their newly hired U.S. employees in FYs 2019 to 2030.

TABLE 22—EMPLOYERS OPPORTUNITY COST OF TIME TO PARTICIPATE IN E-VERIFY PROGRAM (OPERATING IN OTHER U.S. LOCATIONS)

[FY 2019 to 2030]

Fiscal year	Number of CNMI employers operating in other U.S. locations A	Total number of new hire U.S. employees per year B	Employers' annual training cost C = A × 1 hour × $46.88/hour	Case submission and verification cost D = B × 0.121 hours × $46.88/hour	Total E-Verify participation cost in other U.S. locations E = C + D
2019	21.3	185.3	$999	$1,051	$2,050
2020	20.1	174.9	942	992	1,934
2021	18.9	164.4	886	933	1,819
2022	17.7	154.0	830	874	1,703
2023	16.4	142.7	769	809	1,578
2024	15.2	132.2	713	750	1,463
2025	14.0	121.8	656	691	1,347
2026	12.8	111.4	600	632	1,232

[128] It should be noted that the costs to enroll in E-Verify and annual training have already been accounted for in Table 19.

[129] Hourly compensation of $46.88 = $32.11 average hourly wage rate for HR specialists (national) × 1.46 benefits-to-wage multiplier. *See* Bureau of Labor Statistics, U.S. Department of Labor, Occupational Employment Statistics, May 2018 National Occupational Employment and Wage Estimates National, SOC 13–1071—Human Resources Specialist. *https://www.bls.gov/oes/2018/may/oes_nat.htm* (last visited June 20, 2019).

TABLE 22—EMPLOYERS OPPORTUNITY COST OF TIME TO PARTICIPATE IN E-VERIFY PROGRAM (OPERATING IN OTHER U.S. LOCATIONS)—Continued

[FY 2019 to 2030]

Fiscal year	Number of CNMI employers operating in other U.S. locations A	Total number of new hire U.S. employees per year B	Employers' annual training cost C = A × 1 hour × $46.88/hour	Case submission and verification cost D = B × 0.121 hours × $46.88/hour	Total E-Verify participation cost in other U.S. locations E = C + D
2027	11.6	100.9	544	572	1,116
2028	10.4	90.5	488	513	1,001
2029	9.2	80.0	431	454	885
2030	8.0	17.6	375	100	475
Total	175.6	1475.7	8,232	8,371	16,603

Source: USCIS analysis

TABLE 23—EMPLOYERS OPPORTUNITY COST OF TIME TO PARTICIPATE IN E-VERIFY PROGRAM (OPERATING ONLY IN THE CNMI)

[FY 2019 to 2030]

Fiscal year	Total number of new hire U.S. employees per year in CNMI A	Case submission and verification cost B = A × 0.121 hours × $36.30/hour
2019	3,149.5	$13,833
2020	2,971.6	13,052
2021	2,793.8	12,271
2022	2,615.9	11,490
2023	2,436.5	10,702
2024	2,258.6	9,921
2025	2,080.8	9,139
2026	1,901.2	8,350
2027	1,723.3	7,569
2028	1,545.5	6,788
2029	1,367.6	6,007
2030	264.0	1,160
Total	25,108.3	110,283

Source: USCIS analysis

(d) Cost of Obtaining TLC From DOL

All new petitions and extension of stay petitions are required to include a TLC approved by the DOL if they are requesting an employment start date on or after October 1, 2019. The TLC is used to confirm that there are not sufficient United States workers in the CNMI who are able, willing, qualified and available at the time and place needed to perform the services or labor involved in the petition, and that the employment of the CW–1 nonimmigrant will not adversely affect the wages and working conditions of similarly employed United States workers. Obtaining a TLC results in a cost burden to petitioners. However, this cost is addressed in the DOL rulemaking.[130]

(e) Cost of Semiannual Reporting and Document Retention

An employer whose petition has been approved will be required to submit a semiannual report every six months after the petition validity start date to DHS to verify the continuing employment and payment of the beneficiary under the terms and conditions of the approved petition. The petitioners must retain all documents and records in support of the petition, including information submitted to DHS in the semiannual report, for 3 years from the petition validity end date. Petitioners are also required to provide the documents and records supporting the information in the semiannual report to DHS and DOL upon request.

Petitioners use the newly developed Form I–129CWR, Semiannual Report for CW–1 Employers, to submit their semiannual reports to DHS. DHS estimates that the time burden for completing Form I–129CWR, which includes reviewing instructions, gathering the required documentation and information, attaching necessary documentation, and completing and submitting the form, is 2.5 hours.[131] DHS also estimates that the time burden

[130] *See* Labor Certification Process for Temporary Employment in the Commonwealth of the Northern Mariana Islands (CW–1 Workers), 84 FR 12380 (Apr. 1, 2019).

[131] USCIS Office of Policy and Strategy, PRA Compliance Branch, Instruction on Form I–129CWR.

for gathering and retaining documents and records is at least 1 hour for the duration of the 3-year document retention period.[132] DHS assumes that petitioners retain separate documents and records for each approved petition. As a result, the affected population is the number of petitions approved each year.

DHS applies the time burdens, the frequency of reporting and an HR specialist's hourly compensation rate to the affected population to estimate the total cost of semiannual reporting and document retention. As shown in Table 24, DHS estimates the total semiannual reporting and document retention cost to be $15,996,725 for FYs 2019 to 2030.

TABLE 24—SEMIANNUAL REPORTING AND DOCUMENT RETENTION COST FOR EMPLOYERS

[FY 2019 to 2030]

Fiscal year	Estimated number of CW–1 petitions approved (from Table 9)	OCT to complete form I–129CWR [a]	Postage cost to mail completed Form I–129CWR	OCT to gather and retain documents & records [b]	Total semiannual reporting & document retention cost
	A	B = A × 2 reports per year × 2.5 hours × $36.30/hour	C = A × 2 reports per year × $53.50 postage cost	D = A × 1 hour × $36.30/hour	E = B + C + D
2019	4,001	726,091	428,054	145,218	1,299,362
2020	5,001	907,591	535,054	181,518	1,624,162
2021	6,000	1,089,000	642,000	217,800	1,948,800
2022	5,750	1,043,625	615,250	208,725	1,867,600
2023	5,500	998,250	588,500	199,650	1,786,400
2024	5,000	907,500	535,000	181,500	1,624,000
2025	4,500	816,750	481,500	163,350	1,461,600
2026	4,000	726,000	428,000	145,200	1,299,200
2027	3,500	635,250	374,500	127,050	1,136,800
2028	3,000	544,500	321,000	108,900	974,400
2029	2,500	453,750	267,500	90,750	812,000
2030	500	90,750	53,500	18,150	162,400
Total	49,251	8,939,057	5,269,857	1,787,811	15,996,725

Source: USCIS analysis.

[a] OCT denotes the opportunity cost of time estimated by multiplying the number of CW–1 petitions in each year by the number of reports per year (2), the time burden to complete Form I–129CWR (2.5 hours), and the average hourly compensation rate of a HR specialist ($36.30). It should be noted that there is no filing fee for Form I–129CWR.

[b] OCT denotes the opportunity cost of time estimated by multiplying the number of CW–1 petitions in each year by the time burden to gather and retain documents and records (1 hour) and the average hourly compensation rate of a HR specialist ($36.30).

(f) Cost of Notifications

The IFR requires a petitioner to immediately notify USCIS if there are any changes in the terms and conditions of employment of the CW–1 nonimmigrant worker that may affect eligibility for CW–1 classification. Petitioners can notify USCIS about the changes that affect the eligibility of the nonimmigrant worker in two ways. Petitioners may file an amended or new petition that reflects the changes using Form I–129CW if the nonimmigrant worker is still working for them. The amended or new petition must be submitted with a new TLC approved by DOL that supports the new terms and conditions. The second way of notifying USCIS is by sending a letter to the office at which the CW–1 petition was filed explaining the basis on which the specific CW–1 nonimmigrant is no longer employed. DHS estimates the number of petitions to be amended during the implementation period based on estimates derived from historical data on CNMI-Only Transitional Worker program as shown in Table 13. However, due to lack of similar data on the number of notification letters sent to USCIS or relevant proxy measure, DHS is not able to estimate the number of letters to be sent during the implementation period. DHS assumes that filing an amended petition takes the same amount of time as filing a new petition (4 hours) [133] while sending a letter takes approximately 1 hour,[134] which includes gathering the relevant information, preparing the letter, and sending the letter to USCIS. DHS uses the postage cost of $53.50 for mailing amended petitions [135] and $7.35 for mailing withdrawal letters.[136] DHS estimates the opportunity cost of time (OCT) of completing amended petitions by multiplying the number of petitions amended each year by the time burden to complete Form I–129CW (4 hours) and the average hourly compensation rate of an HR specialist ($36.30). DHS

[132] The joint USCIS and DOL temporary final rule, Exercise of Time-Limited Authority to Increase the Fiscal Year 2018 Numerical Limitation for the H–2B Temporary Nonagricultural Worker Program uses 1 hour for document retention. See 83 FR 24905 (May 31, 2018).

[133] USCIS Office of Policy and Strategy, PRA Compliance Branch provided the time burden for completing Form I–129 CW.

[134] DHS is not able to find data on how much time it would take to prepare a withdrawal letter and send it to USCIS. However, DHS assumes that it would not take more than 1 hour.

[135] Although petitioners may choose other means of shipping, for the purposes of this analysis, DHS uses the shipping prices of United States Postal Service (USPS) Domestic Priority Mail Express Flat Rate Envelopes, which is currently priced at $53.50 per package, as a proxy estimate for the postage cost of mailing a package containing amended Form I–129CW. DHS also assumes that the package on average weighs three pounds and ships to zone 8 (from CNMI to Laguna Niguel, California Service Center). *See* U.S. Postal Service, Price List, Notice 123, Effective January 27, 2019 at: *https://pe.usps.com/text/dmm300/Notice123.htm#_c011* (last visited May 29, 2019).

[136] Although petitioners may choose other means of shipping, for the purposes of this analysis, DHS uses the shipping prices of United States Postal Service (USPS) Domestic Priority Mail Flat Rate Envelopes, which is currently priced at $7.35 per package, as a proxy estimate for the postage cost of mailing an envelope containing a withdrawal letter. DHS also assumes that the mail ships to Laguna Niguel, California Service Center. *See* U.S. Postal Service, Price List, Notice 123, Effective January 27, 2019 at: *https://pe.usps.com/text/dmm300/Notice123.htm#_c011* (last visited May 29).

applies the postage cost of 53.50 per package to the number of petitions amended and sent to USCIS each year to estimate the postage cost of mailing amended petitions. Table 25 shows these calculations in detail for FYs 2019 to 2030.

Although DHS is not able to estimate the cost of submitting notification letters due to lack of data on the number of notification letters sent to USCIS or a relevant proxy measure, DHS provides a unit cost estimates for the opportunity cost of time of preparing and submitting a withdrawal letter and for the postage cost of mailing the letter to USCIS. DHS obtains an opportunity cost of time of $36.30 by multiplying the time burden to prepare and submit a notification letter to USCIS (1 hour) by the average hourly compensation rate of an HR specialist ($36.30). DHS adds the postage cost of mailing the notification letter ($7.35) to the estimated opportunity cost of time to obtain a total unit cost of $43.65 per notification letter. This means, an affected petitioner on average will incur a unit cost of $43.65 to send a letter notifying USCIS that a CW–1 nonimmigrant is no longer working for him or her.

TABLE 25—EMPLOYERS NOTIFICATION COST FOR FILING AMENDED PETITIONS

[FY 2019 to 2030]

Fiscal year	Estimated number of petitions amended (from Table 13) A	OCT to complete amended petitions (Form I–129CW) B = A × 4 hours × $36.30/hour	Postage cost to mail amended petitions C = A × $53.50 postage cost	Total notification cost D = B + C
2019	88	$12,779	$4,709	$17,488
2020	110	15,974	5,886	21,859
2021	132	19,166	7,062	26,228
2022	127	18,368	6,768	25,136
2023	121	17,569	6,474	24,043
2024	110	15,972	5,885	21,857
2025	99	14,375	5,297	19,671
2026	88	12,778	4,708	17,486
2027	77	11,180	4,120	15,300
2028	66	9,583	3,531	13,114
2029	55	7,986	2,943	10,929
2030	11	1,597	589	2,186
Total	1,084	157,327	57,968	215,296

Source: USCIS analysis.

(g) Cost of Filing Revoked Petitions

As discussed in the preamble of this IFR, USCIS has the authority to fully or partially revoke petitions at any time under specified conditions. The approval of any petition may either be immediately and automatically revoked or revoked on notice. An immediate and automatic revocation of an approved petition occurs if the petitioner ceases operations, files a written withdrawal of the petition, or DOL revokes the labor certification upon which the petition is based. For revocation on notice, USCIS has the discretion to send to the petitioner a notice of intent to revoke the petition in relevant part, for good cause, based on grounds for revocation specifically listed in this IFR. The grounds listed in 8 CFR 214.2(w)(27)(iii) provide clear guidelines for the program consistent with the Workforce Act. This IFR also states that for each beneficiary of a petition revoked entirely or in part in a fiscal year, the numerical limitation for the next fiscal year will be increased by the number of nonimmigrant workers of such petitions subject to such revocation.[137] This means all the petitions revoked in a given year will be added to a subsequent year's numerical cap. To estimate an upper bound cost, DHS assumes that the CW–1 petitions revoked in a given year will be filed in the subsequent year given the larger numerical cap available. Table 13 shows the CW–1 revoked visas (or revoked petitions) that will be filed each year using Form I–129CW. As in the case for initial filing of Form I–129CW, a petitioner incurs the opportunity cost of time to complete Form I–129CW ($145.204),[138] the postage cost to mail the form to USCIS ($53.50), and the costs associated with filing fee ($460), education funding fee ($200 per approved beneficiary), and fraud prevention and detection fee ($50). DHS applies these unit costs to the relevant affected population under consideration to estimate the total cost of filing revoked petitions as shown in Table 26. DHS also estimates the cost of confirming the identity and work authorization of beneficiaries whose permits are revoked and subsequently filed using E-Verify.[139] DHS estimates that the total cost of filing Form I–129CW for revoked petitions is $108,957 for FYs 2019 to 2030.

[137] *See* 8 CFR 214.2 (w)(1)(x)(C).

[138] $145.20 unit cost for opportunity cost of time estimation = 4 hours, the time burden to complete Form I–129CW × $56.30 average hourly compensation rate for an HR specialist.

[139] See section V.A.5.ii(c) for the details in the estimation of the case submission and verification cost.

TABLE 26—REVOKED PETITIONS REFILING COST FOR PETITIONERS
[FY 2019 to 2030]

Fiscal year	Estimated number revoked permits to be filed (from Table 13)	Estimated number revoked petitions to be filed (from Table 13)	OCT to complete Form I–129CW for revoked petitions	Form I–129CW filing fee cost	Education funding fee cost (per worker)	Fraud prevention & detection fee cost	Postage cost to mail completed Form I–129CW	Case submission and verification cost (for E-Verify)	Total revoked petition filing cost
	A	B	C = B × 4 hours × $36.30/hour	D = B × $460 filing fee	E = A × $200 education fee	F = B × $50 fraud fee	G = B × $53.50 postage cost	H = B × 0.121 hours × $36.30/hour	I = C+D+E+F+G+H
2019	.....	.....	.....	.....	.....	.....	.....	.....	.....
2020	16	8	1,162	3,680	3,200	400	428	70.29	8,941
2021	20	10	1,452	4,600	4,000	500	535	87.85	11,176
2022	24	12	1,742	5,520	4,800	600	642	105.42	13,410
2023	23	12	1,670	5,290	4,600	575	615	101.02	12,851
2024	22	11	1,597	5,060	4,400	550	589	96.63	12,292
2025	20	10	1,452	4,600	4,000	500	535	87.85	11,175
2026	18	9	1,307	4,140	3,600	450	482	79.06	10,057
2027	16	8	1,162	3,680	3,200	400	428	70.28	8,940
2028	14	7	1,016	3,220	2,800	350	375	61.49	7,822
2029	12	6	871	2,760	2,400	300	321	52.71	6,705
2030	10	5	726	2,300	2,000	250	268	43.92	5,587
Total	195	98	14,157	44,851	39,001	4,875	5,216	857	108,957

(h) Cost of Appealing Revoked Petitions

As discussed above, the IFR sets forth the conditions that lead to an immediate and automatic revocation and the grounds to revoke on notice the approval of any petition. While the IFR provides that only a petition that has been revoked on notice (in whole or in part) may be appealed, it prohibits the appeal of petitions that are automatically revoked.[140] Due to lack of historical data on the appeal process, DHS is unable to estimate the cost employers incur appealing petitions that have been revoked on notice during the implementation period. However, given that the total number of petitions revoked (due to immediate and automatic as well as on notice revocations) are estimated to be only 197 for FYs 2019 to 2030, DHS assumes that the proportion of appeals due to revocation on notice alone is likely to be smaller.

To show the minimum cost employers appealing revoked petitions are likely to incur, DHS uses the cost of filing Form I–290B, Notice of Appeal or Motion, as a unit cost estimate. The filing fee for Form I–290B is $675 and the time burden to complete this form is 1.5 hours. DHS multiplies the time burden by the average hourly compensation rate of a HR specialist ($36.30) to obtain the opportunity cost of time to complete Form I–290B ($54.45).[141] Adding the postage cost of mailing the completed form to USCIS ($53.50) to the above costs, DHS estimates that an affected employer on average incurs a cost of $782.95 appealing a petition revoked on notice.[142]

iii. Cost to Nonimmigrant CW–2 Applicants

Qualifying dependents (*i.e.,* an eligible spouse or child) of nonimmigrant workers with a CW–1 status are eligible to apply for a grant of a CW–2 status. The CW–2 applicants must use Form I–539, Application to Extend/Change Nonimmigrant Status, to apply for an initial grant or extension of stay of a CW–2 status if the qualifying dependent is in the CNMI. Table 14 shows the number of applications that will be filed each year requesting a CW–2 status for qualifying dependents of nonimmigrant workers in the CNMI in FYs 2019 to 2030.

The filing fee for Form I–539 is $370 for each dependent applicant and it takes a nonimmigrant applicant 2 hours to review instructions and complete and submit the form.[143] DHS uses $10.59 as the average hourly compensation rate for dependent applicants in the CNMI. Additionally, each qualifying dependent applicant must submit a biometric services fee of $85 with the application, or must obtain a waiver of the biometric services fee for any biometric services provided, including but not limited to reuse of previously provided biometric information for background checks. However, a biometric services fee is not required for qualifying dependents under the age of 14 or who are at least 79 years of age. As described above, historical data are not available to estimate the number of applicants that request a waiver of the biometric services fee in the implementation period.

DHS applies the opportunity cost of time ($21.18),[144] Form–I–539 filing fee ($370), biometric fee ($85), and the postage cost ($53.50) to the number of applications that will be filed each year for CW–2 status to estimate the total cost of filing applications for CW–2 status as shown in Table 27. DHS estimates that the total cost of filing applications for CW–2 status is $7,826,181 for nonimmigrant applicants in the CNMI from FYs 2019 to 2030.

[140] *See* 8 CFR 214.2 (w)(27)–-(28).

[141] $54.45 opportunity cost of time to complete Form I–290 B = 1.5 hours, time burden to complete Form I–290B × $36.30 hourly compensation rate for a HR specialist.

[142] $782.95 unit cost of appealing a petition revoked on notice = $675 filing fee for Form I–290B + $54.45 opportunity cost of time to compete Form I–290B + $53.50 postage cost of mailing completed form.

[143] USCIS Office of Policy and Strategy, PRA Compliance Branch, Instruction on Form I–539.

[144] $21.18 opportunity cost of time = 2 hours, time burden to complete Form I–539 × $10.59 average hourly compensation rate for CW–2 applicants in the CNMI.

TABLE 27—APPLICATION FILING COST FOR CW–2 STATUS
[FY 2019 to 2030]

Fiscal year	Estimated number of applications for CW–2 status (from Table 14)	OCT to complete Form I–539	Form I–539 filing fee cost	Biometric services fee cost	Postage cost to mail completed Form I–539	Total application cost for CW–2 status
	A	B = A × 2 hours × $10.59/hour	C = A × $370 filing fee	D = A × $85 biometric fee	E = A × $53.50 postage cost	F = B + C + D + E
2019	1,200	$25,419	$444,056	$102,013	$64,208	$635,695
2020	1,500	31,773	555,056	127,513	80,258	794,599
2021	1,800	38,124	666,000	153,000	96,300	953,424
2022	1,725	36,536	638,250	146,625	92,288	913,698
2023	1,650	34,947	610,500	140,250	88,275	873,972
2024	1,500	31,770	555,000	127,500	80,250	794,520
2025	1,350	28,593	499,500	114,750	72,225	715,068
2026	1,200	25,416	444,000	102,000	64,200	635,616
2027	1,050	22,239	388,500	89,250	56,175	556,164
2028	900	19,062	333,000	76,500	48,150	476,712
2029	750	15,885	277,500	63,750	40,125	397,260
2030	150	3,177	55,500	12,750	8,025	79,452
Total	14,775	312,941	5,466,861	1,255,901	790,479	7,826,181

Source: USCIS analysis.

iv. Total Estimated and Discounted Costs of Regulatory Changes to Employers and Nonimmigrant CW–2 Applicants

Table 28 summarizes the total estimated and discounted costs of regulatory changes in this IFR to employers and nonimmigrant CW–2 applicants. DHS estimates the total cost of the rule by summing the total estimated costs in Tables 15, 19, 22 through 27. To compare costs over time, DHS applies 3-percent and 7-percent discount rates to the total estimated costs of the IFR. Over the 12 years of implementation, DHS estimates that the total cost of the IFR to employers and nonimmigrant CW–2 applicants is $82,419,653 undiscounted, $70,327,737 discounted at 3-percent, and $57,952,479 discounted at 7-percent.

TABLE 28—TOTAL ESTIMATED AND DISCOUNTED COSTS TO EMPLOYERS AND NONIMMIGRANT CW–2 APPLICANTS
[FY 2019 to 2030]

Fiscal year	Form I–129CW petition filing cost	Total E-Verify program participation cost	Semiannual reporting & document retention cost	Notification cost	Revoked petitions filing cost	Application cost for CW–2 status	Total IFR cost		
							Undiscounted	Discounted at 3%	Discounted at 7%
2019	$4,633,815	$249,035	$1,299,362	$17,488	$0	$635,695	$6,835,396	$6,636,307	$6,388,221
2020	5,792,124	119,571	1,624,162	21,859	8,941	794,599	8,361,257	7,881,287	7,303,046
2021	6,949,854	123,825	1,948,800	26,228	11,176	953,424	10,013,307	9,163,595	8,173,841
2022	6,660,277	117,102	1,867,600	25,136	13,410	913,698	9,597,222	8,527,008	7,321,675
2023	6,370,700	110,326	1,786,400	24,043	12,851	873,972	9,178,292	7,917,275	6,543,995
2024	5,791,545	101,407	1,624,000	21,857	12,292	794,520	8,345,622	6,989,327	5,561,040
2025	5,212,391	92,488	1,461,600	19,671	11,175	715,068	7,512,393	6,108,263	4,678,341
2026	4,633,236	83,525	1,299,200	17,486	10,057	635,616	6,679,120	5,272,559	3,887,309
2027	4,054,082	74,606	1,136,800	15,300	8,940	556,164	5,845,892	4,480,389	3,179,778
2028	3,474,927	65,688	974,400	13,114	7,822	476,712	5,012,663	3,729,892	2,548,184
2029	2,895,773	56,769	812,000	10,929	6,705	397,260	4,179,435	3,019,312	1,985,619
2030	579,155	30,275	162,400	2,186	5,587	79,452	859,055	602,524	381,431
Total	57,047,877	1,224,618	15,996,725	215,296	108,957	7,826,181	82,419,653	70,327,737	57,952,479
Annualized								7,065,271	7,296,332

DHS estimates the net total cost by subtracting the cost savings to petitioners shown in Tables 16 and 17 from the total estimated cost shown in Table 28. To compare the net total estimated costs over time, DHS applies 3-percent and 7-percent discount rates to the net total estimated costs attributable to the IFR. Tables 29 and 30, respectively, show the summary of lower and upper bound undiscounted and discounted net total estimated costs to employers and nonimmigrant CW–2 applicants.[145] Over the implementation period, DHS estimates the lower bound net total estimated costs of the IFR to employers and nonimmigrant CW–2 applicants to be $73,578,345 undiscounted, $62,851,776 discounted at 3-percent, and $51,858,612 discounted at 7-percent. Likewise, DHS estimates the upper bound net total estimated costs of the IFR to employers and nonimmigrant CW–2 applicants to be $61,741,219 undiscounted, $52,693,918 discounted at 3-percent,

[145] It should be noted that because the upper bound cost savings are much larger than the lower bound cost savings, DHS subtracts the upper bound cost savings from the total estimated cost to provide a lower bound net total cost. Similarly, DHS subtracts the lower bound cost savings from the total estimated cost to provide an upper bound net total cost. Estimated this way, the lower and upper bound net total costs can provide intuitively meaningful net total costs that range from a low to high value.

and $43,433,060 discounted at 7-percent.[146]

TABLE 29—NET TOTAL ESTIMATED AND DISCOUNTED COSTS (LOWER BOUND)

[FY 2019 to 2030]

Fiscal year	Total estimated cost	Transfers	Cost savings (upper bound) [a]	Net total IFR cost (lower bound)		
				Undiscounted	Discounted at 3%	Discounted at 7%
	A	B	C	(= A − B − C)		
2019	$6,835,396	.....	.....	$6,835,396	$6,636,307	$6,388,221
2020	8,361,257	3,200	2,041,311	6,316,746	5,954,139	5,517,291
2021	10,013,307	4,000	510,264	9,499,043	8,692,970	7,754,049
2022	9,597,222	4,800	510,009	9,082,413	8,069,606	6,928,929
2023	9,178,292	4,600	1,913,745	7,259,947	6,262,494	5,176,242
2024	8,345,622	4,400	382,698	7,958,524	6,665,139	5,303,101
2025	7,512,393	4,000	254,877	7,253,516	5,897,772	4,517,125
2026	6,679,120	3,600	1,658,613	5,016,907	3,960,393	2,919,886
2027	5,845,892	3,200	127,566	5,715,126	4,380,168	3,108,650
2028	5,012,663	2,800	0	5,009,863	3,727,809	2,546,760
2029	4,179,435	2,400	1,403,226	2,773,809	2,003,859	1,317,817
2030	859,055	2,000	0	857,055	601,121	380,543
Total	82,419,653	39,000	8,802,309	73,578,345	62,851,776	51,858,612
Annualized					6,310,318	6,528,999

[a] Because the upper bound cost savings are much larger than the lower bound cost savings, DHS subtracts the upper bound cost savings from the total estimated costs to construct a meaningful range for the net total estimated cost.

TABLE 30—NET TOTAL ESTIMATED AND DISCOUNTED COSTS (UPPER BOUND)

[FY 2019 to 2030]

Fiscal year	Total estimated cost	Transfers	Cost savings (Lower bound) [a]	Net total IFR cost (Upper bound)		
				Undiscounted	Discounted at 3%	Discounted at 7%
	A	B	C	(= A − B − C)		
2019	6,835,396	1,600,200	.....	5,235,196	5,082,715	4,892,707
2020	8,361,257	2,000,200	226,812	6,134,245	5,782,114	5,357,887
2021	10,013,307	2,400,000	56,696	7,556,611	6,915,370	6,168,446
2022	9,597,222	2,300,000	56,668	7,240,554	6,433,138	5,523,784
2023	9,178,292	2,200,000	212,638	6,765,654	5,836,113	4,823,818
2024	8,345,622	2,000,000	42,522	6,303,100	5,278,747	4,200,022
2025	7,512,393	1,800,000	28,320	5,684,073	4,621,672	3,539,755
2026	6,679,120	1,600,000	184,290	4,894,830	3,864,024	2,848,836
2027	5,845,892	1,400,000	14,174	4,431,718	3,396,543	2,410,561
2028	5,012,663	1,200,000	0	3,812,663	2,836,979	1,938,165
2029	4,179,435	1,000,000	155,914	3,023,521	2,184,256	1,436,453
2030	859,055	200,000	0	659,055	462,248	292,628
Total	82,419,653	19,700,400	978,034	61,741,219	52,693,918	43,433,060
Annualized					5,290,469	5,468,222

[a] Because the lower bound cost savings are much smaller than the upper bound cost savings, DHS subtracts the lower bound cost savings from the total estimated costs to construct a meaningful upper range for the net total estimated cost.

E.O. 13771 directs agencies to reduce regulation and control regulatory costs. This interim final rule (IFR) is considered a regulatory action for the purposes of E.O. 13771. The total annualized cost over a perpetual time period using a 7 percent discount rate, in 2016 dollars, and discounted back to 2016 is $2,608,771.

v. Costs to DHS

USCIS incurs costs while administering the requirements set forth by this IFR. However, these costs are covered by fees collected from employers and nonimmigrant workers covered by this rule when they apply for the benefits this IFR provides. Therefore, there are no additional costs incurred by USCIS in this IFR.

[146] Note that the upper bound net total estimated cost is smaller than the lower bound net total cost due to the fact that the upper bound cost savings are much larger than the lower bound cost savings.

vi. Benefits of the Regulatory Changes

This IFR specifies the conditions under which DHS intends to implement the statutory changes and provisions in the Workforce Act. This section presents a qualitative description of the benefits of the regulatory changes in the IFR.

The IFR provides an orderly transition from the CNMI permit system to the United States federal immigration system under the Immigration and Nationality Act (INA), which mitigates the potential harm to the CNMI economy as employers adjust their hiring practices and as nonimmigrant workers obtain the United States' nonimmigrant status. In this regard, the purposes of the Workforce Act are (a) to increase the percentage of United States workers in the total workforce of the CNMI, while maintaining the minimum number of non-U.S. workers to meet the changing demands of the CNMI's economy; (b) to encourage the hiring of United States workers into the CNMI workforce; and (c) to ensure that no United States worker is at a competitive disadvantage for employment compared to a non-U.S. worker or is displaced by a non-U.S. worker. The IFR also provides additional benefits to petitioners. The requirement to enroll in the E-Verify program allows employers to ensure that they hire only CW–1 nonimmigrant workers with valid work authorization, serving as an additional layer of the work authorization confirmation process. Recapturing the number of beneficiaries of petitions revoked in a fiscal year by adding it to the CW–1 numerical cap of the next fiscal year can be considered as a benefit to petitioners because it helps preserve the total number of CW–1 visas available each year during the implementation period.

To achieve the stated purposes, the Workforce Act sets numerical caps limiting the total number of permits to be issued to prospective employers each year during the implementation period (FYs 2019 to 2030). To implement the Workforce Act, this IFR establishes terms and conditions to administer and enforce a system for allocating the visas to be issued each year. According to the 2018 GAO report, after nearly a decade of annual decline, the total number of workers employed in the CNMI increased from 2013 through 2016, in which nonimmigrant workers accounted for 53 percent of the total workforce in 2016, compared to 76 percent in 2002.[147] Particularly, during the period when the number of approved CW–1 permits were increasing from 7,127 in FY 2012 to 12,862 in FY 2017, the proportion of nonimmigrant workers in the CNMI workforce declined from 55 percent to 53 percent.[148] Conversely, this means the proportion of United States workers in the CNMI increased from 45 percent to 47 percent between 2012 and 2017, indicating that the increase in the number of United States workers was higher than the increase in the number of nonimmigrant workers. DHS believes that the Workforce Act will further contribute to this declining trend in the proportion of nonimmigrant workers in the CNMI workforce because it limits the number of permits to be issued to CW–1 nonimmigrants workers to 13,000 for FY 2019 and sets it to decline gradually to 1,000 in FY 2030.

To ensure that no United States worker is at a competitive disadvantage compared to a non-U.S. worker or is displaced by a non-U.S. worker, the Workforce Act prohibits employers from paying nonimmigrant workers a wage that is not less than the greater of (a) the statutory minimum wage in the CNMI, (b) the federal minimum wage, or (c) the prevailing wage in the CNMI for the occupation in which the nonimmigrant worker is employed. The fact that the Workforce Act requires employers not to underpay nonimmigrant workers serves as a protection to the United States workers from unfair competition, and ensures that the employment of the nonimmigrant worker will not adversely affect the wages and working conditions of similarly employed U.S. workers. Additionally, under the Workforce Act, employers must prove to DOL, via the TLC that, there are not sufficient U.S. workers in the CNMI who are able, willing, qualified, and available. These requirements help discourage employers from employing CW–1 nonimmigrant workers at an uncompetitive or unfair wage and from resorting to hiring nonimmigrant workers before they exhaustively search for equally qualified locally available workers.

According to GAO's projection in its 2017 report,[149] if all nonimmigrant workers with the CW–1 visas were removed from the CNMI's labor market in 2015, the CNMI's 2015 gross domestic product (GDP) would have declined by 26 percent to 62 percent. This shows the continuing demand for and the substantial contribution of these nonimmigrant workers to the CNMI's economy, and hence highlights the significance of the CNMI-Only Transitional Worker program. The GAO report also indicates that the demand for nonimmigrant workers in the CNMI exceeded the available CW–1 visas in 2016. Accordingly, the GAO report projects that the demand for nonimmigrant workers would continue to grow and, if the CNMI-Only Transitional Worker program ended in 2019 in accordance with the termination date established prior to enactment of the Workforce Act, the domestic workforce would be well below the CNMI's demand for labor. DHS believes that the Workforce Act alleviates the anticipated labor shortage in the CNMI as it extends the CNMI-Only Transitional Worker program and makes additional CW–1 visas available for the period extending from FY 2019 to FY 2030.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 605(b), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires an agency to prepare and make available to the public a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small governmental jurisdictions). A regulatory flexibility analysis is not required when a rule is exempt from notice and comment rulemaking. This rule is exempt from notice and comment rulemaking. Therefore, a regulatory flexibility analysis is not required for this rule.

D. Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (UMRA) is intended, among other things, to curb the practice of imposing unfunded Federal mandates on State, local, and tribal governments. Title II of UMRA requires each Federal agency to prepare a written statement assessing the effects of any Federal mandate in a proposed rule, or final rule for which the agency published a proposed rule, that includes any Federal mandate that may result in a $100 million or more expenditure (adjusted annually for inflation) in any one year by State, local, and tribal governments, in the aggregate, or by the private sector.

[147] United States Government Accountability Office (GAO), Testimony Before the Committee on Energy and Natural Resources, U.S. Senate, COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS, Recent Economic Trends and Preliminary Observations on Workforce Data. GAO–18–373T, Feb. 2018. GAO used the most recent available CNMI tax data.

[148] *Id.* The numerical caps set by DHS on the CNMI-Only Transitional Worker (CW–1) permits available for foreign workers were set to decline from 22,416 in fiscal year 2012 to 13,348 in fiscal year 2017.

[149] United States Government Accountability Office (GAO), Report to Congressional Addressees, COMMONWEALTH OF THE NORTHERN MARIANA ISLANDS, Implementation of Federal Minimum Wage and Immigration Laws. GAO–17–437, May 2017.

This rule is exempt from the written statement requirement, because DHS did not publish a notice of proposed rulemaking for this rule.

In addition, this rule does not exceed the $100 million expenditure in any one year when adjusted for inflation ($165 million in 2018 dollars, per the CPI–U), and this rulemaking does not contain such a mandate.

E. Congressional Review Act

The Office of Information and Regulatory Affairs has determined that this interim final rule is not a major rule, as defined by 5 U.S.C. 804, for purposes of congressional review of agency rulemaking pursuant to the Congressional Review Act, Public Law 104–121, sec. 251, 110 Stat. 868, 873 (codified at 5 U.S.C. 804). This rule will not 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 U.S.-based companies to compete with foreign-based companies in domestic and export markets.

F. Executive Order 13132 (Federalism)

This interim final rule does 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 section 6 of Executive Order No. 13132, 64 FR 43,255 (Aug. 4, 1999), this interim final rule does not have sufficient federalism implications to warrant the preparation of a federalism summary impact statement.

G. Executive Order 12988 (Civil Justice Reform)

This rule meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order No. 12988, 61 FR 4729 (Feb. 5, 1996).

H. National Environmental Policy Act (NEPA)

The DHS Management Directive (Dir.) 023–01 Rev. 01 establishes the procedures that DHS and its components use to comply with the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321–4375, and the Council on Environmental Quality (CEQ) regulations for implementing NEPA, 40 CFR parts 1500–1508.

The CEQ regulations allow federal agencies to establish, with CEQ review and concurrence, categories of actions (''categorical exclusions'') which experience has shown do not individually or cumulatively have a significant effect on the human environment and, therefore, do not require an Environmental Assessment (EA) or Environmental Impact Statement (EIS). 40 CFR 1507.3(b)(1)(iii), 1508.4. Dir. 023–01 Rev. 01 establishes Categorical Exclusions that DHS has found to have no such effect. Dir. 023–01 Rev. 01 Appendix A Table 1. For an action to be categorically excluded, Dir. 023–01 Rev. 01 requires the action to satisfy each of the following three conditions: (1) The entire action clearly fits within one or more of the categorical exclusions; (2) the action is not a piece of a larger action; and (3) no extraordinary circumstances exist that create the potential for a significant environmental effect. Dir. 023–01 Rev. 01 section V.B (1)–(3).

DHS analyzed this action and has determined that because Congress has left DHS with no discretion as to the number of CW–1 permits that may be issued during the transition period, NEPA, which only applies to discretionary actions, does not apply to this IFR. This regulation largely implements amendments to the Workforce Act that dictates both the initial numbers of CW–1 permits that may be issued by DHS on day one as well as the numbers of visas that may be issued in ten years, leaving DHS no discretion.

I. Paperwork Reduction Act

Under the PRA of 1995, 44 U.S.C. 3501 *et seq.,* all Departments are required to submit to the Office of Management and Budget (OMB), for review and approval, any reporting requirements inherent in a rule. DHS is amending application requirements and procedures for aliens to receive nonimmigrant status in the CNMI. DHS has revised Form I–129CW, Petition for CNMI-Only Nonimmigrant Transition Worker, and created a new form, Form I–129CWR, Semiannual Report for CW–1 Employers. These DHS forms are considered information collections and are covered under the PRA. DHS has also updated the estimated number of respondents for the E-Verify information collection. E-Verify is covered under the PRA.

Forms I–129CW and I–129CWR

The revised information collection has been submitted for approval to OMB for review and approval under procedures covered under the PRA. USCIS is requesting comments on this information collection for 30 days until June 15, 2020. When submitting comments on the information collection, your comments should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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 information collection:

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for CNMI-Only Nonimmigrant Transition Worker; Semiannual Report for CW–1 Employers.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–129CW; I–129CWR; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. An employer uses Form I–129CW to petition USCIS for an alien to temporarily enter as a nonimmigrant into the CNMI to perform services or labor as a CNMI-Only Transitional Worker (CW–1). An employer also uses Form I–129CW to request an extension of stay or change of status on behalf of the alien worker. An employer uses Form I–129CWR to comply with reporting requirements. These forms serve the purpose of standardizing requests for these benefits, and ensuring that the basic information required to determine eligibility, is provided by the petitioners.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–129CW is 5,975 and the estimated hour burden per response is 4 hours; the estimated total number of respondents for the information collection I–129CWR is 5,975 and the estimated hour burden per response is 2.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 38,388 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $3,809,063.

E-Verify

The revised information collection has been submitted for approval to OMB for review and approval under procedures covered under the PRA. DHS has revised the estimated number of respondents for this information collection, and noted that E-Verify enrollment will be mandatory for employers petitioning for a CW–1 nonimmigrant worker. USCIS is requesting comments on this information collection for 30 days until June 15, 2020. When submitting comments on the information collection, your comments should address one or more of the following four points:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) 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 information collection:

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* E-Verify Program.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No form number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Business or other for-profit. E-Verify allows employers to electronically confirm the employment eligibility of newly hired employees.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:*

○ 66,330 respondents averaging 2.26 hours (2 hours, 16 minutes) per response (enrollment time includes review and signing of the MOU, registration, new user training, and review of the user guides); plus

○ 425,000, the number of already-enrolled respondents receiving training on new features and system updates averaging 1 hour per response; plus

○ 425,000, the number of respondents submitting E-Verify cases averaging .129 hours (approximately 8 minutes) per case.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 3,590,281 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $1,887,000.

J. Family Assessment

DHS has reviewed this regulation and has determined that it may affect family well-being as that term is defined in section 654 of the Treasury General Appropriations Act, 1999, Public Law 105–277, Div. A, 112 Stat. 2681–528 (Oct. 21, 1998), as amended, 5 U.S.C. 601 note. This action has been assessed in accordance with the criteria specified by section 654(c)(1). This regulation will enhance family well-being by providing immigration benefits that enhance the economic opportunities for those granted CW–1 status and allows certain family members to obtain CW–2 nonimmigrant status once the principal applicant has received status, while also addressing public safety and fraud concerns.

K. Signature

The Acting Secretary of Homeland Security, Chad F. Wolf, having reviewed and approved this document, is delegating the authority to electronically sign this document to Chad R. Mizelle, who is the Senior Official Performing the Duties of the General Counsel, for purposes of publication in the **Federal Register**.

List of Subjects

8 CFR Part 103

Administrative practice and procedure, Authority delegations (Government agencies), Freedom of Information, Privacy, Reporting and recordkeeping requirements, Surety bonds.

8 CFR Part 208

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements.

8 CFR Part 209

Aliens, Immigration, Refugees.

8 CFR Part 212

Administrative practice and procedure, Aliens, Immigration, Passports and visas, Reporting and recordkeeping requirements.

8 CFR Part 214

Administrative practice and procedure, Aliens, Employment, Foreign Officials, Health Professions, Reporting and recordkeeping requirements, Students.

8 CFR Part 235

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements.

8 CFR Part 274a

Administrative practice and procedure, Aliens, Employment, Penalties, Reporting and recordkeeping requirements.

Regulatory Amendments

Accordingly, DHS amends 8 CFR parts 103, 208, 209, 212, 214, 235, and 274a as follows:

PART 103—POWERS AND DUTIES; AVAILABILITY OF RECORDS

■ 1. The authority citation for part 103 is revised to read as follows:

Authority: 5 U.S.C. 301, 552, 552a; 8 U.S.C. 1101, 1103, 1304, 1356; 31 U.S.C. 9701; 48 U.S.C. 1806; Pub. L. 107–296, 116 Stat. 2135 (6 U.S.C. 1 *et seq.*), E.O. 12356, 47 FR 14874, 15557, 3 CFR, 1982 Comp., p. 166; 8 CFR part 2; Pub. L. 112–54, 125 Stat 550. Pub. L. 115–218.

■ 2. Section 103.7 is amended by revising paragraphs (b)(1)(i)(J) to read as follows:

§ 103.7 Fees.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(J) Petition for Nonimmigrant Worker in CNMI, Form I–129CW. For an employer to petition on behalf of one or more beneficiaries: $460 plus the following fees: A supplemental CNMI education funding fee of $200 per beneficiary per year and a $50 fraud prevention and detection fee per employer filing a petition. The CNMI

education and fraud fees cannot be waived. The Secretary may adjust the education fee annually by notice in the **Federal Register** for petitions filed on or after each adjustment's effective date, based on a percentage equal to the annual change in the unadjusted All Items Consumer Price Index for All Urban Consumers (CPI–U) for the U.S. City Average published by the Bureau of Labor Statistics.

* * * * *

PART 208—PROCEDURES FOR ASYLUM AND WITHHOLDING OF REMOVAL

■ 3. The authority citation for part 208 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1158, 1226, 1252, 1282; Title VII of Pub. L. 110–229; 8 CFR part 2; Pub. L. 115–218.

■ 4. Section 208.1 is amended by revising the first two sentences of paragraph (a)(2) to read as follows:

§ 208.1 General.

* * * * *

(a) * * *

(2) * * * The provisions of this subpart A shall not apply prior to January 1, 2030, to an alien physically present in or arriving in the Commonwealth of the Northern Mariana Islands seeking to apply for asylum. No application for asylum may be filed prior to January 1, 2030, pursuant to section 208 of the Act by an alien physically present in or arriving in the Commonwealth of the Northern Mariana Islands. * * *

* * * * *

■ 5. Section 208.2 is amended by revising paragraphs (c)(1)(iii), (iv), (vii), and (viii) to read as follows:

§ 208.2 Jurisdiction.

* * * * *

(c) * * *

(1) * * *

(iii) An alien who is an applicant for admission pursuant to the Visa Waiver Program under section 217 of the Act, except that if such an alien is an applicant for admission to the Commonwealth of the Northern Mariana Islands, then he or she shall not be eligible for asylum prior to January 1, 2030;

(iv) An alien who was admitted to the United States pursuant to the Visa Waiver Program under section 217 of the Act and has remained longer than authorized or has otherwise violated his or her immigration status, except that if such an alien was admitted to the Commonwealth of the Northern Mariana Islands, then he or she shall not be eligible for asylum in the Commonwealth of the Northern Mariana Islands prior to January 1, 2030;

* * * * *

(vii) An alien who is an applicant for admission to Guam or the Commonwealth of the Northern Mariana Islands pursuant to the Guam-CNMI Visa Waiver Program under section 212(l) of the Act, except that if such an alien is an applicant for admission to the Commonwealth of the Northern Mariana Islands, then he or she shall not be eligible for asylum prior to January 1, 2030; or

(viii) An alien who was admitted to Guam or the Commonwealth of the Northern Mariana Islands pursuant to the Guam-CNMI Visa Waiver Program under section 212(l) of the Act and has remained longer than authorized or has otherwise violated his or her immigration status, except that if such an alien was admitted to the Commonwealth of the Northern Mariana Islands, then he or she shall not be eligible for asylum in the Commonwealth of the Northern Mariana Islands prior to January 1, 2030.

* * * * *

■ 6. Section 208.4 is amended by revising the last three sentences of paragraph (a)(2)(ii) to read as follows:

§ 208.4 Filing the application.

* * * * *

(a) * * *

(2) * * *

(ii) * * * For aliens present in or arriving in the Commonwealth of the Northern Mariana Islands, the 1-year period shall be calculated from either January 1, 2030 or the date of the alien's last arrival in the United States (including the Commonwealth of the Northern Mariana Islands), whichever is later. No period of physical presence in the Commonwealth of the Northern Mariana Islands prior to January 1, 2030, shall count toward the 1-year period. After November 28, 2009, any travel to the Commonwealth of the Northern Mariana Islands from any other State shall not re-start the calculation of the 1-year period.

* * * * *

■ 7. Section 208.5 is amended by revising the last sentences of paragraphs (a) and (b)(1)(iii) to read as follows:

§ 208.5 Special duties toward aliens in custody of DHS.

(a) * * * No application for asylum may be filed prior to January 1, 2030, under section 208 of the Act by an alien physically present in or arriving in the Commonwealth of the Northern Mariana Islands.

(b) * * *

(1) * * *

(iii) * * * However, such an alien crewmember is not eligible to request asylum pursuant to section 208 of the Act prior to January 1, 2030.

* * * * *

■ 8. Section 208.30 is amended by revising the last sentences of paragraphs (a) and (e)(2) to read as follows:

§ 208.30 Credible fear determinations involving stowaways and applicants for admission who are found inadmissible pursuant to section 212(a)(6)(C) or 212(a)(7) of the Act or whose entry is limited or suspended under section 212(f) or 215(a)(1) of the Act.

(a) * * * Prior to January 1, 2030, an alien present in or arriving in the Commonwealth of the Northern Mariana Islands is ineligible to apply for asylum and may only establish eligibility for withholding of removal pursuant to section 241(b)(3) of the Act or withholding or deferral of removal under the Convention Against Torture.

* * * * *

(e) * * *

(2) * * * However, prior to January 1, 2030, in the case of an alien physically present in or arriving in the Commonwealth of the Northern Mariana Islands, the officer may only find a credible fear of persecution if there is a significant possibility that the alien can establish eligibility for withholding of removal pursuant to section 241(b)(3) of the Act.

* * * * *

PART 209—ADJUSTMENT OF STATUS OF REFUGEES AND ALIENS GRANTED ASYLUM

■ 9. The authority citation for part 209 is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1157, 1158, 1159, 1228, 1252, 1282; Title VII of Pub. L. 110–229; 8 CFR part 2; Pub. L. 115–218.

■ 10. Section 209.2 is amended by revising paragraph (a)(3) to read as follows:

§ 209.2 Adjustment of status of alien granted asylum.

* * * * *

(a) * * *

(3) No alien arriving in or physically present in the Commonwealth of the Northern Mariana Islands may apply to adjust status under section 209(b) of the Act in the Commonwealth of the Northern Mariana Islands prior to January 1, 2030.

* * * * *

PART 212—DOCUMENTARY REQUIREMENTS; NONIMMIGRANTS; WAIVERS; ADMISSION OF CERTAIN INADMISSIBLE ALIENS; PAROLE

■ 11. The authority citation for part 212 is revised to read as follows:

Authority: 6 U.S.C. 111, 202(4) and 271; 8 U.S.C. 1101 and note, 1102, 1103, 1182 and note, 1184, 1187, 1223, 1225, 1226, 1227, 1255, 1359; section 7209 of Pub. L. 108–458 (8 U.S.C. 1185 note); Title VII of Pub. L. 110–229 (8 U.S.C. 1185 note); 8 CFR part 2; Pub. L. 115–218.

Section 212.1(q) also issued under section 702, Pub. L. 110–229, 122 Stat. 754, 854.

■ 12. Section 212.1 is amended by revising the last two sentences of paragraphs (q)(8)(i)(A) and (q)(8)(ii)(A) to read as follows:

§ 212.1 Documentary requirements for nonimmigrants.

* * * * *

(q) * * *

(8) * * *

(i) * * *

(A) * * * The provisions of 8 CFR subpart 208 subpart A shall not apply to an alien present or arriving in the CNMI seeking to apply for asylum prior to January 1, 2030. No application for asylum may be filed pursuant to section 208 of the Act by an alien present or arriving in the CNMI prior to January 1, 2030; however, aliens physically present in the CNMI during the transition period who express a fear of persecution or torture only may establish eligibility for withholding of removal pursuant to INA 241(b)(3) or pursuant to the regulations implementing Article 3 of the United Nations Convention Against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment.

* * * * *

(ii) * * *

(A) * * * The provisions of 8 CFR part 208 subpart A shall not apply to an alien present or arriving in the CNMI seeking to apply for asylum prior to January 1, 2030. No application for asylum may be filed pursuant to section 208 of the INA by an alien present or arriving in the CNMI prior to January 1, 2030; however, aliens physically present or arriving in the CNMI prior to January 1, 2030, may apply for withholding of removal under section 241(b)(3) of the Act and withholding and deferral of removal under the regulations implementing Article 3 of the United Nations Convention Against Torture, Inhuman or Degrading Treatment or Punishment.

* * * * *

PART 214—NONIMMIGRANT CLASSES

■ 13. The authority citation for part 214 is revised to read as follows:

Authority: 6 U.S.C. 202, 236; 8 U.S.C. 1101, 1102, 1103, 1182, 1184, 1186a, 1187, 1221, 1281, 1282, 1301–1305 and 1372; sec. 643, Pub. L. 104–208, 110 Stat. 3009–708; Pub. L. 106–386, 114 Stat. 1477–1480; section 141 of the Compacts of Free Association with the Federated States of Micronesia and the Republic of the Marshall Islands, and with the Government of Palau, 48 U.S.C. 1901 note and 1931 note, respectively; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 115–218.

■ 14. Section 214.2 is amended by revising paragraphs (e)(23)(ii)(F) and (e)(23)(xiv) to read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(e) * * *

(23) * * *

(ii) * * *

(F) Transition period means the period beginning on the transition program effective date and ending on December 31, 2029.

* * * * *

(xiv) *Expiration of the transition period.* Upon expiration of the transition period, the E–2 CNMI Investor nonimmigrant status will automatically terminate.

* * * * *

■ 16. Section 214.2 is amended by revising paragraph (w) to read as follows:

§ 214.2 Special requirements for admission, extension, and maintenance of status.

* * * * *

(w) *CNMI-Only Transitional Worker (CW–1)*—(1) *Definitions.* The following definitions apply to petitions for and maintenance of CW status in the Commonwealth of the Northern Mariana Islands (the CNMI or the Commonwealth):

(i) *CW–1 Application for Temporary Employment Certification* means the Office of Management and Budget (OMB)-approved Form ETA–9142C (or successor form) and the appropriate appendices, a valid prevailing wage determination (Form ETA–9141C, or successor form), and all supporting documentation submitted by an employer, as set forth in the U.S. Department of Labor's (DOL) regulations at 20 CFR 655.420 through 655.422, to secure a temporary labor certification determination from DOL's Office of Foreign Labor Certification (OFLC) Administrator.

(ii) *Direct Guam transit* means travel from the CNMI to a foreign place by an alien in CW status, or from a foreign place to the CNMI by an alien with a valid CW visa, on a direct itinerary involving a flight stopover or connection in Guam (and no other place).

(iii) *Doing business* means the regular, systematic, and continuous provision of goods or services by an employer as defined in this paragraph and does not include the mere presence of an agent or office of the employer in the CNMI.

(iv) *Employer* means a person, firm, corporation, contractor, or other association, or organization which:

(A) Engages a person to work within the CNMI; and

(B) Has or will have an employer-employee relationship with the CW–1 nonimmigrant being petitioned for.

(v) *Employer-employee relationship* means that the employer will hire, pay, fire, supervise, and control the work of the employee.

(vi) *Lawfully present in the CNMI* means that the alien was lawfully admitted or paroled into the CNMI under the immigration laws on or after the transition program effective date, other than an alien admitted or paroled as a visitor for business or pleasure (B–1 or B–2, under any visa-free travel provision or parole of certain visitors from Russia and the People's Republic of China), and remains in a lawful immigration status or if paroled into the CNMI, the authorized parole period has not expired.

(vii) *Legitimate business,* as determined by DHS, means a real, active, and operating commercial or entrepreneurial undertaking that:

(A) Produces services or goods for profit, or is a governmental, charitable or other validly recognized nonprofit entity;

(B) Meets applicable legal requirements for doing business in the CNMI;

(C) Has substantially complied with wage and hour laws, occupational safety and health requirements, nondiscrimination, and all other Federal, CNMI, and local requirements relating to employment during the five-year period immediately preceding the date of filing the petition, and continues to be in substantial compliance with such requirements;

(D) Does not directly or indirectly engage in, or knowingly benefit from, prostitution, human trafficking, or any other activity that is illegal under Federal, CNMI, or local law;

(E) Is a participant in good standing in the E-Verify program;

(F) Does not have, as an owner, investor, manager, operator, or person meaningfully involved with the undertaking, any individual who has been an owner, investor, manager, operator, or person otherwise meaningfully involved with an undertaking that was not in compliance with paragraph (w)(1)(vii)(C) of this section at the time of the individual's involvement and within the five years immediately preceding the date of filing the petition; or that was not in compliance with clause paragraph (w)(1)(vii)(D) of this section at any time during which the individual was involved with the undertaking, or is an agent of such individual; and

(G) Is not a successor in interest to an undertaking that has not complied with paragraphs (C) or (D).

(viii) *Long-term worker* means an alien who was admitted to the CNMI, or otherwise granted status, as a CW–1 nonimmigrant during fiscal year 2015, and during each of fiscal years 2016 through 2018.

(ix) *Minor child* means a child as defined in section 101(b)(1) of the Act who is under 18 years of age.

(x) *Numerical limitation* means the maximum number of persons who may be granted CW–1 status in a given fiscal year, as follows:

(A) For fiscal years 2018 through the first quarter of fiscal year 2030, the numerical limitations are:

(*1*) 9,998 for fiscal year 2018;
(*2*) 13,000 for fiscal year 2019;
(*3*) 12,500 for fiscal year 2020;
(*4*) 12,000 for fiscal year 2021;
(*5*) 11,500 for fiscal year 2022;
(*6*) 11,000 for fiscal year 2023;
(*7*) 10,000 for fiscal year 2024;
(*8*) 9,000 for fiscal year 2025;
(*9*) 8,000 for fiscal year 2026;
(*10*) 7,000 for fiscal year 2027;
(*11*) 6,000 for fiscal year 2028;
(*12*) 5,000 for fiscal year 2029; and
(*13*) 1,000 for the first quarter of fiscal year 2030.

(B) A long-term worker granted CW–1 nonimmigrant status for a period exceeding one year shall be counted toward the numerical limitation, and toward any reservation of CW–1 numbers, as described in paragraph (w)(1)(x)(D)(*1*) of this section, if applicable, for each fiscal year within the period of petition validity.

(C) For each petition revoked entirely or in part in a fiscal year, the numerical limitation for the next fiscal year shall be increased by the number of beneficiaries of such petitions subject to such revocation before the end of the validity period of the petition.

(D)(*1*) Within the numerical limitations described in paragraph (w)(1)(x)(A) of this section, the following reservations of CW–1 numbers for specified occupational categories shall apply:

(*i*) 200 for occupational categories 29–0000 (Healthcare Practitioners and Technical Occupations) and 31–0000 (Healthcare Support Occupations); and

(*ii*) 60 for occupational categories related to the operations of the CNMI public utilities services, including, but not limited to, 17–2081 (Water/Waste Water Engineers), 17–2071 (Electrical Engineers), 17–2141 (Mechanical Engineers), and Trades Technicians.

(*2*) Reserved CW–1 numbers described in paragraph (w)(1)(x)(D)(*1*) of this section will be made available to eligible petitioners requesting such numbers for a fiscal year in order of filing, separately under either paragraph (w)(1)(x)(D)(*1*)(*i*) or (*ii*) of this section, until exhausted. Unused reserved numbers under either paragraph (w)(1)(x)(D)(*1*)(*i*) or (*ii*) of this section will not be available to other petitioners.

(*3*) DHS may adjust the reservation of numbers for specified occupational categories for a fiscal year or other period via publication of a notice in the **Federal Register**, as long as such adjustment is consistent with paragraph (w)(1)(x)(A) of this section. DHS will base any such adjustment on factors including: The level of past demand for reserved numbers compared to supply; whether a reservation of numbers has resulted in unused numbers; reservation of numbers compared to overall numerical limitation in a fiscal year; and any recommendation received from the Governor of the CNMI regarding the adjustment of the reservation of numbers.

(E) If the numerical limitation is not reached for a specified fiscal year, unused numbers do not carry over to the next fiscal year.

(F) If USCIS receives a sufficient number of petitions to meet the numerical limitation in paragraph (w)(1)(x)(A) of this section in a fiscal year, USCIS will cease processing further cap-subject petitions in that fiscal year, and DOL may cease processing cap-subject applications for temporary labor certification for that fiscal year.

(xi) *Occupational category* means those employment activities that DHS has determined require alien workers to supplement the resident workforce and includes:

(A) Professional, technical, or management occupations;
(B) Clerical and sales occupations;
(C) Service occupations;
(D) Agricultural, fisheries, forestry, and related occupations;
(E) Processing occupations;
(F) Machine trade occupations;
(G) Benchwork occupations;
(H) Structural work occupations; and
(I) Miscellaneous occupations.

(xii) *Participant in good standing in the E-Verify program* means an employer, as defined in paragraph (w)(1)(iv) of this section, that has enrolled in E-Verify with respect to all hiring sites in the United States as of the time of filing a petition; is in compliance with all requirements of the E-Verify program, including but not limited to verifying the employment eligibility of newly hired employees in the United States; and continues to be a participant in good standing in E-Verify at any time during which the employer employs any CW–1 nonimmigrant.

(xiii) *Petition* means USCIS Form I–129CW, Petition for a CNMI–Only Nonimmigrant Transitional Worker, a successor form, other form, or electronic equivalent, any supplemental information requested by USCIS, and additional evidence as may be prescribed or requested by USCIS.

(xiv) *Successor in interest* means an employer that is controlling and carrying on the business of a previous employer. The following factors may be considered in determining whether an employer is a successor in interest; no one factor is dispositive, but all of the circumstances will be considered as a whole:

(A) Substantial continuity of the same business operations;
(B) Use of the same facilities;
(C) Continuity of the work force;
(D) Similarity of jobs and working conditions;
(E) Similarity of supervisory personnel;
(F) Whether the former management or owner retains a direct or indirect interest in the new enterprise;
(G) Similarity in machinery, equipment, and production methods;
(H) Similarity of products and services; and
(I) The ability of the predecessor to provide relief.

(xv) *Temporary Labor Certification* or *TLC* means the certification made by the DOL OFLC Administrator, based on the *CW–1 Application for Temporary Employment Certification,* and all supporting documentation, with respect to an employer seeking to file with a CW–1 petition.

(xvi) *Transition period* means the period beginning on the transition program effective date and ending on December 31, 2029.

(xvii) *United States worker* means a citizen or national of the United States,

an alien lawfully admitted for permanent residence, or a citizen of the Federated States of Micronesia, the Republic of the Marshall Islands, or the Republic of Palau who is eligible for nonimmigrant admission and is employment-authorized under the Compacts of Free Association between the United States and those nations.

(2) *Eligible aliens.* Subject to the numerical limitation, an alien may be classified as a CW–1 nonimmigrant if, during the transition period, the alien:

(i) Will enter or remain in the CNMI for the purpose of employment within the transition period in an occupational category that DHS has designated as requiring alien workers to supplement the resident workforce;

(ii) Is petitioned for by an employer;

(iii) Is not present in the United States, other than the CNMI;

(iv) If present in the CNMI, is lawfully present in the CNMI;

(v) Is not inadmissible to the United States as a nonimmigrant or has been granted a waiver of each applicable ground of inadmissibility;

(vi) Is ineligible for status in a nonimmigrant worker classification under section 101(a)(15) of the Act; and

(vii) Will not be employed in a Construction and Extraction Occupation (as defined by the U.S. Department of Labor as Standard Occupational Classification Group 47–0000 or successor provision) unless the alien is a long-term worker.

(3) *Derivative beneficiaries—CW–2 nonimmigrant classification.* The spouse or minor child of a CW–1 nonimmigrant may accompany or follow the alien as a CW–2 nonimmigrant if the alien:

(i) Is not present in the United States, other than the CNMI;

(ii) If present in the CNMI, is lawfully present in the CNMI; and

(iii) Is not inadmissible to the United States as a nonimmigrant or has been granted a waiver of each applicable ground of inadmissibility.

(4) *Eligible employers.* To be eligible to petition for a CW–1 nonimmigrant worker, an employer must:

(i) Be engaged in legitimate business;

(ii) Obtain a TLC from DOL and consider all available United States workers for the position being filled by the CW–1 worker;

(iii) Offer terms and conditions of employment which are consistent with the nature of the petitioner's business and the nature of the occupation, activity, and industry in the CNMI; and

(iv) Comply with all Federal and Commonwealth requirements relating to employment, including but not limited to nondiscrimination, occupational safety, and minimum wage requirements.

(5) *Petition requirements.* An employer who seeks to classify an alien as a CW–1 worker must file a petition with USCIS and pay the requisite petition fees as provided in 8 CFR 103.7(b)(1)(i)(J), along with any required documents and in accordance with form instructions. An employer filing a petition is eligible to apply for a waiver of the petition fee (but not the CNMI education fee or the fraud prevention and detection fee) based upon inability to pay as provided by 8 CFR 103.7(c). If the beneficiary will perform services for more than one employer, each employer must file a separate petition with fees with USCIS.

(6) *Appropriate documents.* Documentary evidence establishing eligibility for CW status is required. A petition must be accompanied by:

(i) Evidence demonstrating the petitioner meets the definition of eligible employer in this section;

(ii) An attestation by the petitioner certified as true and accurate by an appropriate official of the petitioner, of the following:

(A) The employer has not displaced and will not displace a United States worker in order to employ the beneficiary as agreed to in the *CW–1 Application for Temporary Employment Certification;*

(B) The employer is doing business as defined in paragraph (w)(1)(iii) of this section;

(C) The employer is a legitimate business as defined in paragraph (w)(1)(vii) of this section;

(D) The employer is an eligible employer as described in paragraph (w)(4) of this section and will continue to comply with the requirements for an eligible employer until such time as the employer no longer employs the CW–1 nonimmigrant worker;

(E) The beneficiary meets the qualifications for the position;

(F) The beneficiary, if present in the CNMI, is lawfully present in the CNMI;

(G) The position is not temporary or seasonal employment, and the petitioner does not reasonably believe it to qualify as eligible for any other nonimmigrant worker classification, including H–2A or H–2B;

(H) The position falls within the list of occupational categories designated by DHS;

(I) The petitioner will pay the beneficiary a wage that is not less than the greater of—

(*1*) The CNMI minimum wage;

(*2*) The Federal minimum wage; or

(*3*) The prevailing wage in the CNMI for the occupation in which the beneficiary will be employed as established by the U.S. Department of Labor; and

(J) The petitioner will comply with the reporting and retention requirements in paragraph 26.

(iii) Evidence of licensure if an occupation requires a Commonwealth or local license for an individual to fully perform the duties of the occupation. Categories of valid licensure for CW–1 classification are:

(A) *Licensure.* An alien seeking CW–1 classification in that occupation must have that license prior to approval of the petition to be found qualified to enter the CNMI and immediately engage in employment in the occupation.

(B) *Temporary licensure.* If a temporary license is available and allowed for the occupation with a temporary license, USCIS may grant the petition at its discretion after considering the duties performed, the degree of supervision received, and any limitations placed on the alien by the employer and/or pursuant to the temporary license.

(C) *Duties without licensure.* If the CNMI allows an individual to fully practice the occupation that usually requires a license without a license under the supervision of licensed senior or supervisory personnel in that occupation, USCIS may grant CW–1 status at its discretion after considering the duties performed, the degree of supervision received, and any limitations placed on the alien if the facts demonstrate that the alien under supervision could fully perform the duties of the occupation.

(iv) For any petition requesting an employment start date on or after October 1, 2019, including both new petitions and petitions for renewal of an existing permit, a TLC approved by DOL, confirming that there are not sufficient United States workers in the CNMI who are able, willing, qualified, and available at the time and place needed to perform the services or labor involved in the petition, and that the employment of the CW–1 nonimmigrant will not adversely affect the wages and working conditions of similarly employed United States workers. If the TLC accepts certain education, training, experience, or special requirements of the beneficiary, the petition must also be accompanied by documentation that the CW–1 nonimmigrant worker qualifies for the job offer as specified in the TLC.

(7) *Change of employers.* A change of employment to a new employer inconsistent with paragraphs (w)(7)(i) and (ii) of this section will constitute a failure to maintain status within the

meaning of section 237(a)(1)(C)(i) of the Act. A CW–1 nonimmigrant may change employers if:

(i) The prospective new employer files a petition to classify the alien as a CW–1 worker in accordance with paragraph (w)(5) of this section, and

(ii) An extension of the alien's stay is requested if necessary for the validity period of the petition.

(iii) A CW–1 worker may work for a prospective new employer after the prospective new employer files a Form I–129CW petition on the employee's behalf if:

(A) The prospective employer has filed a nonfrivolous petition for new employment before the date of expiration of the CW–1 worker's authorized period of stay; and

(B) Subsequent to his or her lawful admission, the CW–1 worker has not been employed without authorization in the United States.

(iv) Employment authorization shall continue for such alien until the new petition is adjudicated. If the new petition is denied, such authorization shall cease.

(v) If a CW–1 worker's employment has been terminated prior to the filing of a petition by a prospective new employer consistent with paragraphs (w)(7)(i) and (ii), or if the CW–1's current petition has been revoked (other than for the reason described in paragraph (w)(27)(iii)(A)(*7*) of this section) the CW–1 worker will not be considered to be in violation of his or her CW–1 status during the 30-day period immediately following the date on which the CW–1 worker's employment terminated if a nonfrivolous petition for new employment is filed consistent with this paragraph within that 30-day period and the CW–1 worker does not otherwise violate the terms and conditions of his or her status during that 30-day period.

(8) *Amended or new petition.* If there are any material changes in the terms and conditions of employment, the petitioner must file an amended or new petition to reflect the changes. An amended or new petition must be submitted with a new TLC approved by DOL.

(9) *Multiple beneficiaries.* A petitioning employer may include more than one beneficiary in a CW–1 petition if the beneficiaries will be working in the same occupational category, under the same terms and conditions, for the same period of time, and in the same location.

(10) *Named beneficiaries.* The petition must include the name of the beneficiary and other required information, as indicated in the form instructions, at the time of filing. Unnamed beneficiaries are not permitted.

(11) *Early termination.* The petitioning employer must pay the reasonable cost of return transportation of the alien to the alien's last place of foreign residence if the alien is dismissed from employment for any reason by the employer before the end of the period of authorized admission.

(12) *Approval.* USCIS will consider all the evidence submitted and such other evidence required in the form instructions to adjudicate the petition. USCIS will notify the petitioner of the approval of the petition on Form I–797, Notice of Action, or in another form as USCIS may prescribe.

(i) The approval notice will include the CW–1 classification and name of the beneficiary or beneficiaries and the petition's period of validity. A petition for more than one beneficiary may be approved in whole or in part.

(ii) The application for a TLC may not be filed with DOL earlier than 120 days before the date of actual need for the beneficiary's services for an initial petition for CW–1 status, or 180 days before the date of expiration of CW–1 status in the case of an extension petition described in paragraph (w)(18) of this section. The petition may then be filed with USCIS after the TLC is approved. If DOL debars an employer from obtaining a CW–1 TLC, USCIS may not approve future petitions during the debarment period.

(13) *Petition validity.* An approved petition will be valid for a period of up to one year, unless the beneficiary is a long-term worker in which case an approved petition will be valid for a period of up to three years.

(14) *Validity of the labor certification.* A TLC is valid only for the period of employment as approved on the *CW–1 Application for Temporary Employment Certification.* The TLC expires on the last day of authorized employment.

(15) *How to apply for CW–1 or CW–2 status.* (i) Upon approval of the petition, a beneficiary, his or her eligible spouse, and his or her minor child(ren) outside the CNMI will be informed in the approval notice of where they may apply for a visa authorizing admission in CW–1 or CW–2 status.

(ii) If the beneficiary is present in the CNMI, the petition also serves as the application for a grant of status as a CW–1.

(iii) If the eligible spouse and/or minor child(ren) are present in the CNMI, the spouse or child(ren) may apply for CW–2 dependent status on Form I–539 (or such alternative form as USCIS may designate) in accordance with the form instructions. The CW–2 status may not be approved until approval of the CW–1 petition. A spouse or child applying for CW–2 status on Form I–539 is eligible to apply for a waiver of the fee based upon inability to pay as provided by 8 CFR 103.7(c).

(16) *Biometrics and other information.* The beneficiary of a CW–1 petition or the spouse or child applying for a grant or, extension of CW–2 status, or a change of status to CW–2 status, must submit biometric information as requested by USCIS. For a petition where the beneficiary is present in the CNMI, the employer must submit the biometric service fee described in 8 CFR 103.7(b)(1) with the petition for each beneficiary for which CW–1 status is being requested or request a fee waiver for any biometric services provided, including but not limited to reuse of previously provided biometric information for background checks. For a Form I–539 application where the applicant is present in the CNMI, the applicant must submit a biometric service fee for each CW–2 nonimmigrant on the application with the application or obtain a waiver of the biometric service fee described in 8 CFR 103.7(b)(1) for any biometric services provided, including but not limited to reuse of previously provided biometric information for background checks. A biometric service fee is not required for beneficiaries under the age of 14, or who are at least 79 years of age.

(17) *Period of admission.* (i) A CW–1 nonimmigrant will be admitted for the period of petition validity, plus up to 10 days before the validity period begins and 10 days after the validity period ends. The CW–1 nonimmigrant may not work except during the validity period of the petition. A CW–2 spouse will be admitted for the same period as the principal alien. A CW–2 minor child will be admitted for the same period as the principal alien, but such admission will not extend beyond the child's 18th birthday.

(ii) The temporary departure from the CNMI of the CW–1 nonimmigrant will not affect the derivative status of the CW–2 spouse and minor children, provided the familial relationship continues to exist and the principal remains eligible for admission as a CW–1 nonimmigrant.

(18) *Extension of petition validity and extension of stay.* (i) The petitioner may request an extension of an employee's CW–1 nonimmigrant status by filing a new petition.

(ii) A request for a petition extension may be filed only if the validity of the original petition has not expired.

(iii) Extensions of CW–1 status may be granted for a period of up to 1 year (or a period of up to 3 years if the beneficiary is a long-term worker) until the end of the transition period, subject to any numerical limitation.

(iv) To qualify for an extension of stay, the petitioner must demonstrate that the beneficiary or beneficiaries:

(A) Continuously maintained the terms and conditions of CW–1 status;

(B) Remains admissible to the United States; and

(C) Remains eligible for CW–1 classification.

(v) A beneficiary (other than a long-term worker) may not be granted CW–1 status beyond three consecutive petition validity periods unless the beneficiary has departed and remained outside of the United States for a continuous period of at least 30 days after the expiration of the third petition validity period and before the filing of any new petition on behalf of the beneficiary.

(vi) The derivative CW–2 nonimmigrant may file an application for extension of nonimmigrant stay on Form I–539 (or such alternative form as USCIS may designate) in accordance with the form instructions. The CW–2 status extension may not be approved until approval of the CW–1 extension petition.

(19) *Change or adjustment of status.* A CW–1 or CW–2 nonimmigrant can apply to change nonimmigrant status under section 248 of the Act or apply for adjustment of status under section 245 of the Act, if otherwise eligible. During the transition period, CW–1 or CW–2 nonimmigrants may be the beneficiary of a petition for or may apply for any nonimmigrant or immigrant visa classification for which they may qualify.

(20) *Effect of filing an application for or approval of a permanent labor certification, preference petition, or filing of an application for adjustment of status on CW–1 or CW–2 classification.* An alien may be granted, be admitted in and maintain lawful CW–1 or CW–2 nonimmigrant status while, at the same time, lawfully seeking to become a lawful permanent resident of the United States, provided he or she intends to depart the CNMI voluntarily at the end of the period of authorized stay. The filing of an application for or approval of a permanent labor certification or an immigrant visa preference petition, the filing of an application for adjustment of status, or the lack of residence abroad will not be the basis for denying:

(i) A CW–1 petition filed on behalf of the alien;

(ii) A request to extend a CW–1 status pursuant to a petition previously filed on behalf of the alien;

(iii) An application for CW–2 classification filed by an alien;

(iv) A request to extend CW–2 status pursuant to the extension of a related CW–1 alien's extension; or

(v) An application for admission as a CW–1 or CW–2 nonimmigrant.

(21) *Rejection.* USCIS may reject an employer's petition for new or extended CW–1 status if any numerical limitation has been met. In that case, the petition and accompanying fee will be rejected and returned with the notice that numbers are unavailable for the CW nonimmigrant classification. The beneficiary's application for admission based upon an approved petition will not be rejected based upon the numerical limitation.

(22) *Denial.* The ultimate decision to grant or deny CW–1 or CW–2 classification or status is a discretionary determination, and the petition or the application may be denied for failure of the petitioner or the applicant to demonstrate eligibility or for other good cause. The denial of a petition to classify an alien as a CW–1 may be appealed to the USCIS Administrative Appeals Office or any successor body. The denial of CW–1 or CW–2 status within the CNMI, or of an application for change or extension of status filed under this section, may not be appealed.

(23) *Terms and conditions of CW Nonimmigrant status*—(i) *Geographical limitations.* CW–1 and CW–2 statuses are only applicable in the CNMI. Entry, employment and residence in the rest of the United States (including Guam) require the appropriate visa or visa waiver and nonimmigrant classification. Except as provided in paragraph (w)(23)(iii) of this section, an alien with CW–1 or CW–2 status who enters or attempts to enter, or travels or attempts to travel to any other part of the United States without an appropriate visa or visa waiver, or who violates conditions of nonimmigrant stay applicable to any such authorized status in any other part of the United States, will be deemed to have violated CW–1 or CW–2 status.

(ii) *Re-entry.* An alien with CW–1 or CW–2 status who travels abroad from the CNMI will require a CW–1 or CW–2 or other appropriate visa to be re-admitted to the CNMI.

(iii) *Travel outside the CNMI*—(A) *Direct Guam transit from the CNMI.* An alien with CW–1 or CW–2 status may travel to a foreign place via a direct Guam transit without being deemed to violate that status.

(B) *Travel from a foreign place to the CNMI.* An alien with a valid CW–1 or CW–2 visa, who is admissible to the CNMI in such status, may be admitted to the United States in CW–1 or CW–2 status in Guam for the purpose of a direct Guam transit to the CNMI. An alien who violates the terms of direct Guam transit violates his or her CW–1 or CW–2 status.

(iv) *Employment authorization.* An alien with CW–1 nonimmigrant status is only authorized employment in the CNMI for the petitioning employer. An alien with CW–2 status is not authorized to be employed.

(24) *Expiration of status.* CW–1 status expires when the alien violates his or her CW–1 status (or in the case of a CW–1 status violation caused solely by termination of the alien's employment, at the end of the 30 day period described in paragraph (w)(7)(v) of this section), 10 days after the end of the petition's validity period, when the petition is revoked, or at the end of the transitional worker program, whichever is earlier. CW–2 nonimmigrant status expires when the status of the related CW–1 alien expires, on a CW–2 minor child's 18th birthday, when the alien violates his or her status, or at the end of the transitional worker program, whichever is earlier. No alien will be eligible for admission to the CNMI in CW–1 or CW–2 status, and no CW–1 or CW–2 visa will be valid for travel to the CNMI, after the transitional worker program ends.

(25) *Waivers of inadmissibility for applicants lawfully present in the CNMI.* An applicant for CW–1 or CW–2 nonimmigrant status, who is otherwise eligible for such status and otherwise admissible to the United States, and who possesses appropriate documents demonstrating that the applicant is lawfully present in the CNMI, may be granted a waiver of inadmissibility under section 212(d)(3)(A)(ii) of the Act, including the grounds of inadmissibility described in sections 212(a)(6)(A)(i) and 212(a)(7)(B)(i)(II) of the Act, as a matter of discretion for the purpose of granting the CW–1 or CW–2 nonimmigrant status. Such waiver may be granted without additional form or fee. Appropriate documents required for such a waiver include a valid unexpired passport and other documentary evidence demonstrating that the applicant is lawfully present in the CNMI, such as a DHS-issued Form I–94. Evidence that the applicant possesses appropriate documents may be provided by an employer to accompany a petition, by an eligible spouse or minor child to accompany the Form I–539 (or such alternative form as USCIS may designate), or in such other manner as USCIS may designate.

(26) *Semiannual report*—(i) *Filing.* During the validity period of the petition, an employer whose petition has been approved for an employment start date on or after October 1, 2019 and for a validity period of six months or more, shall file a semiannual report, every six months after the petition validity start date up to and including the sixth month preceding the petition's validity end date. The semiannual report must be filed within a 60 day window surrounding the six month anniversary of the petition validity start date, with the filing window opening 30 days before and closing 30 days after the six month anniversary of the petition validity start date. The semiannual report must be filed with USCIS in the form and containing such evidence as USCIS may direct, to verify the continuing employment and payment of the beneficiary under the terms and conditions of the approved petition.

(ii) *Use.* DHS may provide such semiannual reports to other federal partners, including DOL for investigative or other use as the DOL may deem appropriate. Failure to comply with the requirements of paragraph (w)(26) of this section may be a basis for revocation of an approved petition as provided in paragraph (w)(27) of this section, or for denial of subsequent petitions filed by the employer.

(iii) *Document retention.* (A) An employer must retain all documents and records in support of an approved petition, and any semiannual report. An employer must retain evidence that supports the semiannual report including, but not limited to:

(*1*) Personnel records for each CW–1 worker including the name, address of current residence in the Commonwealth, age, domicile, citizenship, point of hire, and approved employment contract termination date;

(*2*) Payroll records for each CW–1 worker including the O*NET job classification; wage rate or salary, number of hours worked each week, gross compensation, itemized deductions, and evidence of net payments made and received biweekly; and

(*3*) Direct evidence of payment of wages and overtime, such as receipts for cash payments, cancelled checks or deposit records. Petitioners must provide such documents and records to DHS and DOL at any time, during the retention period specified in paragraph (w)(26)(iii)(B) of this section.

(B) An employer must retain documents and records until the date that is three years after the ending date of the petition validity period.

(27) *Revocation of approval of petition*—(i) *General.* (A) The petitioner shall immediately notify USCIS of any changes in the terms and conditions of employment of a beneficiary which may affect eligibility under this paragraph (w). To notify USCIS of such changes, an amended petition shall be filed when the petitioner continues to employ the beneficiary. If the petitioner no longer employs the beneficiary, the petitioner shall send a letter to the office at which the CW–1 petition was filed explaining the basis on which the specific CW–1 nonimmigrant is no longer employed.

(B) USCIS may revoke a petition at any time, even after the expiration of the petition.

(ii) *Immediate and automatic revocation.* The approval of any petition is immediately and automatically revoked if the petitioner ceases operations, files a written withdrawal of the petition, or the U.S. Department of Labor revokes the temporary labor certification upon which the petition is based.

(iii) *Revocation on notice*—(A) *Grounds for revocation.* USCIS may in its discretion send to the petitioner a notice of intent to revoke the petition in relevant part, for good cause, including, if it finds that:

(*1*) The beneficiary is no longer employed by the petitioner in the capacity specified in the petition;

(*2*) The facts contained in the petition or on the application for a temporary labor certification was not true and correct, inaccurate, fraudulent, or misrepresented a material fact;

(*3*) The petitioner violated terms and conditions of the approved petition;

(*4*) The petitioner violated a requirement of paragraph (w) of this section;

(*5*) The approval of the petition violated paragraph (w) this section or involved gross error;

(*6*) The petitioner failed to maintain the continuous employment of the CW–1 nonimmigrant, failed to pay the nonimmigrant, failed to timely file a semiannual report described in paragraph (w)(26) of this section, committed any other violation of the terms and conditions of employment, or otherwise ceased to operate as a legitimate business;

(*7*) The beneficiary did not apply for admission to the CNMI within 10 days after the beginning of the petition validity period if the petition has been approved for consular processing; or

(*8*) The employer failed to provide a former, current, or prospective CW–1 nonimmigrant, not later than 21 business days after a written request from such individual, with the original (or a certified copy of the original) of all petitions, notices, and other written communication related to the worker (other than sensitive financial or proprietary information of the employer which may be redacted) that has been exchanged between the employer and the Department of Labor, the Department of Homeland Security, or any other Federal agency or department.

(B) *Notice and decision.* The notice of intent to revoke shall state the grounds for the revocation. The petitioner may submit evidence in rebuttal within 30 days of receipt of the notice. USCIS shall consider all relevant evidence presented in deciding whether to revoke the petition in whole or in part. If the petition is revoked in part, the remainder of the petition shall remain approved and a revised approval notice shall be sent to the petitioner with the revocation notice.

(28) *Appeal of a revocation of a petition.* A petition that has been revoked on notice in whole or in part may be appealed under part 103 of this chapter. Automatic revocations may not be appealed.

(29) *Notice to DOL.* USCIS will provide notice to DOL of CW–1 petition revocations.

PART 235—INSPECTION OF PERSONS APPLYING FOR ADMISSION

■ 17. The authority citation for part 235 is revised to read as follows:

Authority: 8 U.S.C. 1101 and note, 1103, 1183, 1185 (pursuant to E.O. 13323, 69 FR 241, 3 CFR, 2004 Comp., p. 278), 1201, 1224, 1225, 1226, 1228, 1365a note, 1365b, 1379, 1731–32; Title VII of Pub. L. 110–229; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458); Pub. L. 112–54; Pub. L. 115–218.

■ 18. Section 235.6 is amended by revising paragraphs (a)(1)(ii) and (iii) to read as follows:

§ 235.6 Referral.

(a) * * *

(1) * * *

(ii) If an asylum officer determines that an alien in expedited removal proceedings has a credible fear of persecution or torture and refers the case to the immigration judge for consideration of the application for asylum, except that, prior to January 1, 2030, an alien arriving in the Commonwealth of the Northern Mariana Islands is not eligible to apply for asylum but the immigration judge may consider eligibility for withholding of removal pursuant to section 241(b)(3) of the Act or withholding or deferral of removal under the Convention Against Torture.

(iii) If the immigration judge determines that an alien in expedited

removal proceedings has a credible fear of persecution or torture and vacates the expedited removal order issued by the asylum officer, except that, prior to January 1, 2030, an alien physically present in or arriving in the Commonwealth of the Northern Mariana Islands is not eligible to apply for asylum but an immigration judge may consider eligibility for withholding of removal pursuant to section 241(b)(3) of the Act or withholding or deferral of removal under the Convention Against Torture.

* * * * *

PART 274a—CONTROL OF EMPLOYMENT OF ALIENS

■ 19. The authority citation for part 274a is revised to read as follows:

Authority: 8 U.S.C. 1101, 1103, 1324a; Title VII of Pub. L. 110–229; 48 U.S.C. 1806; 8 CFR part 2; Pub. L. 101–410, 104 Stat. 890, as amended by Pub. L. 114–74, 129 Stat. 599; Pub. L. 115–218.

■ 20. Amend § 274a.2 by revising paragraph (a)(2) to read as follows:

* * * * *

§ 274a.2 Verification of identity and employment authorization.

(a) * * *

(2) *Verification form.* Form I–9, Employment Eligibility Verification Form, is used in complying with the requirements of this 8 CFR 274a.1–274a.11. Form I–9 can be in paper or electronic format. A fillable electronic Form I–9 as well as a paper format Form I–9 may be obtained and downloaded from *http://www.uscis.gov.* Paper forms may also be ordered at *https://www.uscis.gov/forms/forms-by-mail* or by contacting the USCIS Contact Center at 1–800–375–5283 or 1–800–767–1833 (TTY). Alternatively, Form I–9 can be electronically generated or retained, provided that the resulting form is legible; there is no change to the name, content, or sequence of the data elements and instructions; no additional data elements or language are inserted; and the standards specified under 8 CFR 274a.2(e), (f), (g), (h), and (i), as applicable, are met. When copying or printing the paper Form I–9, the text of the two-sided form may be reproduced by making either double-sided or single-sided copies.

* * * * *

■ 21. Section 274a.12 is amended by revising paragraph (b)(23) and removing and reserving paragraph (b)(24).

The revision reads as follows:

§ 274a.12 Classes of aliens authorized to accept employment.

* * * * *

(b) * * *

(23) *A Commonwealth of the Northern Mariana Islands transitional worker (CW–1) pursuant to 8 CFR 214.2(w).* An alien in this status may be employed only in the CNMI during the transition period, and only by the petitioner through whom the status was obtained, or as otherwise authorized by 8 CFR 214.2(w).

* * * * *

Chad R. Mizelle,

Senior Official Performing the Duties of the General Counsel, U.S. Department of Homeland Security.

[FR Doc. 2020–08524 Filed 5–13–20; 8:45 am]

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FEDERAL REGISTER

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Part V

The President

Notice of May 13, 2020—Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain

Federal Register
Vol. 85, No. 94
Thursday, May 14, 2020

Presidential Documents

Title 3—

The President

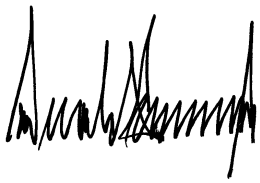
Notice of May 13, 2020

Continuation of the National Emergency With Respect to Securing the Information and Communications Technology and Services Supply Chain

On May 15, 2019, by Executive Order 13873, I declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by the unrestricted acquisition and use of certain information and communications technology and services transactions.

The unrestricted acquisition or use in the United States of information and communications technology or services designed, developed, manufactured, or supplied by persons owned by, controlled by, or subject to the jurisdiction or direction of foreign adversaries augments the ability of these foreign adversaries to create and exploit vulnerabilities in information and communications technology or services, with potentially catastrophic effects. This threat continues 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 on May 15, 2019, must continue in effect beyond May 15, 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 declared in Executive Order 13873 with respect to securing the information and communications technology and services supply chain.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
May 13, 2020.

[FR Doc. 2020–10594
Filed 5–13–20; 11:15 am]
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Thursday, May 14, 2020

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